



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/Mar/202425/19

DATED: 27/03/2025

Minutes of the Norms Committee-3 Meeting No. NC/3/MEET/Mar/202425/19 dated 17/03/2025 (actual held on 28/03/2025) under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

2. Following members were present in the Meeting:-

Sl. No.	Name & Designation	Department
1	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand Lal, Technical Expert	Consultant (Chemical)
In attendance:		
1	Shri Raman Kumar, Deputy DGFT	DGFT (HQ)
2	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

3. The Norms Committee has taken decision only with respect to technical aspect/ wastage norms. While redeeming the application, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in notifications, public notices and policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularization of the case.
4. RAs shall ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
5. 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.

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	KLJ PLASTICIZERS LIMITED.																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM REVIW00006341AM25																
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 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">Di-Ethyl Phthalate (DEP)</td><td rowspan="2">1 kg.</td><td>1</td><td>Phthalic Anhydride</td><td>0.700 kg.</td></tr><tr><td>2</td><td>Denatured Ethyl Alcohol</td><td>0.435 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Di-Ethyl Phthalate (DEP)	1 kg.	1	Phthalic Anhydride	0.700 kg.	2	Denatured Ethyl Alcohol	0.435 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Di-Ethyl Phthalate (DEP)	1 kg.	1	Phthalic Anhydride	0.700 kg.													
		2	Denatured Ethyl Alcohol	0.435 kg.													
Note: NC also recommended to amend the import item No.2 in SION A-1294 based on the comments of TE. RA concerned may take further necessary action as per above decision of NC.																	

Case No.	2 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002300AM25
RA File Number	092404000413 AM12
Licence No and Date	0910050238/15/12/2011
Norms Committee Decision:	
The firm was called for Personal Hearing through Video Conference, but the firm could not appear before	

Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.

Case No.	3 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002734AM25
RA File Number	092404000091 AM16
Licence No and Date	0910062478/11/08/2015

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.6/82-ALC4/2020 dated 13/11/2020 against advance authorization No.0910067834 dated 25/07/2019, 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.
GURONSAN C EFFERVESCENT TABLETS ((Each tablet contains Glucuronolactone Ph..Eur -50 Mg, Ascorbic Acid Ph,Eur-300 Mg and Caffeine Ph.Eur-50 Mg))	1 Number	1	Glucuronolactone OR D-Glucuronolactone (Synonym)	51.00 mg/Tablet
		2	Ascorbic Acid (Crystalline)	306.0 mg /Tablet
		3	Caffeine Anhydrous	51.00 mg/Tablet
		4	Sodium Polyphosphate	50.00 mg/Tablet
		5	Sodium Hydrogen Carbonate OR Sodium Bicarbonate (Synonym)	950.00 mg/Tablet
		6	Gin Fizz Micron Flavour	30.00 mg/Tablet

		7	Macrogol 6000	135.00 mg/Tablet
		8	Monosodium Fumarate	2000.00 mg/Tablet
		9	Printed Tube for Guronsan C Eff Tabs	As per packing policy and General Notes.
		10	Cap with Drier - Tamper Evident	As per packing policy and General Notes.

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

Case No.	4 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002446AM25
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 item in meeting No.NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No.5210043424 dated 08/06/2020, it was decided to revise 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.
4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg.	1	Acetyl Salicylic Acid (For Industrial Use)	1.85 kg.
		2	Ethyl Aceto Acetate	1.60 kg.

Note: The above ad-hoc norms fixed for one time basis.

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

Case No.	5 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002314AM25
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 it was decided to revise 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.
DNOVO BP818 (Tetra Methyl Bisphenol F)	1 kg.	1	OCP 50	1.100 kg.
		2	Methanol	1.00 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.	6 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002361AM25

RA File Number	092404000540 AM20													
Licence No and Date	0910068421/28/01/2020													
Norms Committee Decision:														
The Committee considered the case as per the agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No.0910068991 dated 22/07/2020, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride</td><td>1 kg.</td><td>1</td><td>CDX-034 LYOPHILIZED ENZYME POWDER</td><td>0.0154 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	7 / NC/3/MEET/Mar/202425/19
Case Status	Case Rejected
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002322AM25
RA File Number	522404000007 AM21
Licence No and Date	5210043401/22/05/2020
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 <u>reject</u> the case maintaining the status quo.	

Case No.	8 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002780AM25

RA File Number	092404000047 AM21			
Licence No and Date	0910069097/25/08/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202425/7 dated 06/08/2024 against DGFT HQ File No.HQRNORMAPPLY00000350AM25, 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.
FAVIPIRAVIR	1 kg.	1	6-fluoro-3-hydroxypyrazine-2-carbonitrile dicyclohexylamine salt	1.282 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	9 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM REVIW00002781AM25			
RA File Number	092404000042 AM21			
Licence No and Date	0910069098/25/08/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202425/7 dated 06/08/2024 against DGFT HQ File No.HQRNORMAPPLY00000350AM25, 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.
FAVIPIRAVIR	1 kg.	1	6-fluoro-3-hydroxypyrazine-2-carbonitrile dicyclohexylamine salt	1.282 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	10 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	SYNTHO CHIRALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM REVIW00002351AM25										
RA File Number	09AA04003656 AM21										
Licence No and Date	0911000173/11/01/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No.0910068991 dated 22/07/2020, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride</td><td>1 kg.</td><td>1</td><td>CDX-034 LYOPHILIZED ENZYME POWDER</td><td>0.0154 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	11 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002558AM25
RA File Number	03AA04019330 AM22
Licence No and Date	0311004745/19/06/2021
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.
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	MEROPENEM NONSTERILE MEROPENEM TRIHYDRATE NONSTERILE	0.8968 kg.
		2	PACKING MATERIAL	Relevant, as per Packing Policy and General Notes.

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

Case No.	12 / NC/3/MEET/Mar/202425/19
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002563AM25
RA File Number	03AA04019330 AM22
Licence No and Date	0311004745/19/06/2021
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 <u>reject</u> the case maintaining the status quo.	

Case No.	13 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002556AM25
RA File Number	03AX04000308 AM22
Licence No and Date	0311009920/30/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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 (MEROPENEM BUFFERED STERILE) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	MEROPENEM NONSTERILE MEROPENEM TRIHYDRATE NONSTERILE	0.8968 kg.
		2	PACKING MATERIAL	Relevant, as per Packing Policy and General Notes.

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

Case No.	14 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002448AM25
RA File Number	52AX04000101 AM22
Licence No and Date	5211002273/30/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No.5210043424 dated 08/06/2020, 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.
4-HYDROXY COUMARIN	1 kg.	1	Acetyl Salicylic Acid	1.85 kg.

(by Acetyl Salicylic Acid route)			(For Industrial Use)	
		2	Ethyl Aceto Acetate	1.60 kg.

Note: The above ad-hoc norms fixed for one time basis.

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

Case No.	15 / NC/3/MEET/Mar/202425/19
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002559AM25
RA File Number	03AX04002208 AM23
Licence No and Date	0311016558/25/07/2022
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 <u>reject</u> the case maintaining the status quo.	

Case No.	16 / NC/3/MEET/Mar/202425/19
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002557AM25
RA File Number	03AX04003060 AM23
Licence No and Date	0311018071/22/09/2022
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 <u>reject</u> the case maintaining the status quo.	

Case No.	17 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006507AM25
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	Lithium Metal	0.137 kg.
		3	n-Heptane	1.808 kg.
		4	Ethyl Isobutyrate	0.686 kg.
		5	1 Bromo-5-chloropentane	1.10 kg.
		6	Methyl-ethyl-ketone	1.038 kg.
		7	N, N Dimethylacetamide	1.678 kg.
		8	Sodium t-pentoxide	0.567 kg.
		9	Iodine	0.823 kg.
		10	Tosmic	0.512 kg.

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

Case No.	18 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00006284AM25																
RA File Number	NA																
Licence No and Date	0311018393/06/10/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202425/5 dated 14/06/2024 against advance authorization No.0311009117 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:-																	
<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">N-Butylacetoacetate Ester</td><td rowspan="2">1 kg.</td><td>1</td><td>Acetic Acid</td><td>0.95 kg.</td></tr><tr><td>2</td><td>N-Butanol</td><td>0.50 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N-Butylacetoacetate Ester	1 kg.	1	Acetic Acid	0.95 kg.	2	N-Butanol	0.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
N-Butylacetoacetate Ester	1 kg.	1	Acetic Acid	0.95 kg.													
		2	N-Butanol	0.50 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	19 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00000289AM25			
RA File Number	NA			
Licence No and Date	0511017371/17/02/2023			

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.
Terpenyl Acetate (Mixture of alpha, beta, gamma isomers)	1 kg.	1	Gum Turpentine Oil containing Alpha Pinene 82.5%	1.64 kg.

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

Case No.	20 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006508AM25
RA File Number	03AX04005861 AM23
Licence No and Date	0311021934/06/03/2023

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	N-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.
		5	N, N Dimethylacetamide	1.678 kg.

		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.

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

Case No.	21 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	ALKALOIDS PVT LTD.										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00000398AM24										
RA File Number	02AX04000047 AM24										
Licence No and Date	0211004284/25/04/2023										
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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Reserpine BP/USP(Powder)</td><td>1 kg.</td><td>1</td><td>Rauwolfia Vomitoria Root Bark Dried</td><td>138.42 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Reserpine BP/USP(Powder)	1 kg.	1	Rauwolfia Vomitoria Root Bark Dried	138.42 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Reserpine BP/USP(Powder)	1 kg.	1	Rauwolfia Vomitoria Root Bark Dried	138.42 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	22 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00003641AM25
RA File Number	09AX04000226 AM24
Licence No and Date	0911005228/19/06/2023
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.
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 IbrexafungerpCitrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

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

Case No.	23 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00003643AM25
RA File Number	09AX04000257 AM24
Licence No and Date	0911005276/27/06/2023

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.
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	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

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

Case No.	24 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00003644AM25
RA File Number	09AX04000270 AM24
Licence No and Date	0911005295/28/06/2023

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.
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 IbrexafungerpCitrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

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

Case No.	25 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006509AM25

RA File Number	03AX04004237 AM24			
Licence No and Date	0311029470/19/12/2023			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate (CION-4)	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	Lithium Metal	0.137 kg.
		3	n-Heptane	1.808 kg.
		4	Ethyl Isobutyrate	0.686 kg.
		5	1 Bromo-5-chloropentane	1.10 kg.
		6	Methyl-ethyl-ketone	1.038 kg.
		7	N, N Dimethylacetamide	1.678 kg.
		8	Sodium t-pentoxide	0.567 kg.
		9	Iodine	0.823 kg.
		10	Tosmic	0.512 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007772AM24

RA File Number	09AX04000883 AM24			
Licence No and Date	0911006495/05/01/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No.0911005327 dated 06/07/2023, 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.
MARBOFLOXACIN (PHARMACEUTICAL PRODUCT)	1 kg.	1	2,3,4,5-Tetra fluoro benzoyl Chloride	2.60 kg.
		2	Ethyl 3-(N,N-dimethyl amino) acrylate	2.11 kg.
		3	Toluene	9.21 kg.
		4	N-Methyl Piperazine	1.03 kg.
		5	Dimethyl Sulfoxide	1.33 kg.

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

Case No.	27 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007813AM24
RA File Number	03AX04004498 AM24
Licence No and Date	0311029998/08/01/2024
Norms Committee Decision: The committee considered the firm's request for the fixation of ad-hoc norms and observed that the firm has not furnished the specific reply of DL. Therefore, it was decided to call for following information/documents from the firm:- 1. Commercial value of 30% Isomerized Bromo Compounds obtained during manufacturing.	

Case No.	28 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007828AM24
RA File Number	08AX04001867 AM24
Licence No and Date	0811010468/09/01/2024

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024, against advance authorization No. 0811011943 dated 26/06/2024, 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.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 60 MG(EACH FILM COATED EXTENDEDRELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USPEQUIVALENT TO ISOSORBIDE MONONITRATE 60MG	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate) USP	122.40 mg.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 120 MG(EACH FILM COATED EXTENDEDRELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USPEQUIVALENT TO ISOSORBIDE MONONITRATE 120MG	1 Number	2	Isosorbide Mononitrate 50 percent Assay.Diluted ISMN (50% diluted with lactose monohydrate) USP	244.80 mg

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

Case No.	29 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007862AM24
RA File Number	07AX04001619 AM24
Licence No and Date	0711010173/10/01/2024
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms, and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Firm has given two steps reaction whereas the yields claimed for three step. II. Provide complete chemistry as the chemistry given is incomplete. III. Firm may be advised to furnish balanced chemical reactions for the entire process with molecular weight and percentage yield on molar basis.	

Case No.	30 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007864AM24
RA File Number	07AX04001614 AM24
Licence No and Date	0711010175/10/01/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Firm has not giving chemistry of 3rd stage for preparation of export item. 2. Recovering of solvents.	

Case No.	31 / NC/3/MEET/Mar/202425/19																									
Case Status	Case Approved																									
Party Name	R.L.FINE CHEM PRIVATE LIMITED																									
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																									
HQ File Number	HQRNORM APPLY 00007865AM24																									
RA File Number	07AX04001617 AM24																									
Licence No and Date	0711010176/10/01/2024																									
Norms Committee Decision:																										
The Committee considered the case as per the 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 rowspan="5">DOXEPIN HYDROCHLORIDE (BP/EP/USP)</td><td rowspan="5">1 kg.</td><td>1</td><td>1 BROMO 3 CHLORO PROPANE</td><td>1.12 kg.</td></tr><tr><td>2</td><td>TETRA HYDRO FURAN</td><td>0.68 kg.</td></tr><tr><td>3</td><td>METHANOL</td><td>Not required.</td></tr><tr><td>4</td><td>TOLUENE</td><td>Not required</td></tr><tr><td>5</td><td>ACETONE</td><td>Not required.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DOXEPIN HYDROCHLORIDE (BP/EP/USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	1.12 kg.	2	TETRA HYDRO FURAN	0.68 kg.	3	METHANOL	Not required.	4	TOLUENE	Not required	5	ACETONE	Not required.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																						
DOXEPIN HYDROCHLORIDE (BP/EP/USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	1.12 kg.																						
		2	TETRA HYDRO FURAN	0.68 kg.																						
		3	METHANOL	Not required.																						
		4	TOLUENE	Not required																						
		5	ACETONE	Not required.																						
RA concerned may take further necessary action as per above decision of NC.																										

Case No.	32 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00007866AM24			
RA File Number	07AX04001599 AM24			
Licence No and Date	0711010178/10/01/2024			

Norms Committee Decision:

The Committee considered the case as per the 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.
DOXYCYCLINE 100MG DISPERSIBLE TABLETS (Eq to anhydrous Doxycycline 100mg) (400.00kgs)	1 Number	1	DOXYCYCLINE MONOHYDRATE U.S.P/B.P	106.13 mg/100 mg. Tablet

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

The Committee also recommended to make a new SION for the above item.

Case No.	33 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00007890AM24
RA File Number	03AX04004630 AM24
Licence No and Date	0311030104/11/01/2024

Norms Committee Decision:

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.
CHLORAMPHENICOL EYE DROPS 10 ML (CLORAH EYE DROPS 10 ML AND OPTIPHEN OPHTHALMIC SOLUTIONS 5 mg/ml 10ML)(EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET	590000 Vials	1	CHLORAMPHENICOL MICRONIZED	30.086 kg.

WT OF BULK DRUG IS 29.500 KGS))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	34 / NC/3/MEET/Mar/202425/19													
Case Status	Case Approved													
Party Name	UNIMAX LABORATORIES													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025													
HQ File Number	HQRNORM APPLY 00007901AM24													
RA File Number	05AX04003229 AM24													
Licence No and Date	0511023203/11/01/2024													
Norms Committee Decision:														
The Committee considered the case as per the 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>Spiramycin Tablets 3.0 MIU (Each tablet contains Spiramycin EP 3.0 MIU)</td><td>1 Number</td><td>1</td><td>Spiramycin EP</td><td>670.00 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Spiramycin Tablets 3.0 MIU (Each tablet contains Spiramycin EP 3.0 MIU)	1 Number	1	Spiramycin EP	670.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Spiramycin Tablets 3.0 MIU (Each tablet contains Spiramycin EP 3.0 MIU)	1 Number	1	Spiramycin EP	670.00 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	35 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	AVIK PHARMACEUTICAL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00007926AM24			
RA File Number	52AX04000307 AM24			
Licence No and Date	5211007035/12/01/2024			

Norms Committee Decision:

The Committee considered the case as per the agenda and it was decided to fix ad-hoc norms as per newly fixed SION A3682 or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CLOBETASOL PROPIONATE	1 kg.	1	BETAMETHASONE	0.95 kg.

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

Case No.	36 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008014AM24
RA File Number	08AX04001772 AM24
Licence No and Date	0811010513/17/01/2024

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.
Diosmin and Hesperidin Tablets 500 mg (305.14 KGS)	1 Number	1	DIOSMIN	459.00 mg.
		2	HESPERIDIN	51.00 mg.

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

Case No.	37 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	SANPRAS HEALTHCARE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008015AM24
RA File Number	31AX04000283 AM24
Licence No and Date	3111003005/17/01/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. The firm has to indicate export quantity in number of Bottles. The committee also recommended to make a new SION for above items after receipt of information from the firm.	

Case No.	38 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00008039AM24			
RA File Number	03AX04004687 AM24			
Licence No and Date	0311030266/18/01/2024			
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.
Fenofibrate 145mg tablets)(146415000 NOS)(Net Content:1)21442.184 KGS 2)21313.632 KGS 3) (Indi):4325.099 KGS 4) (Indi):423.139KGS 5) (Indi):1471.471KGS 6) (Indi):19126.191KGS 7) (Indi):12467.237KGS 8) (Indi):10934.272KGS 9)(Indi):131.774KGS 10)(Indi): 4348.526KGS)	1Number	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.
		2	Sucrose PH.Eur (exepient)	146.45 mg.

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

Case No.	39 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008068AM24
RA File Number	09AX04000846 AM24
Licence No and Date	0911006469/19/01/2024

Norms Committee Decision:

The Committee considered the case as per the 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.
Gabapentin Oral Solution 250 mg / 5 ML 470 ML ((Each 5 mL of Oral Solution Contains, Gabapentin USP 250 mg))	1 Number	1	GABAPENTIN USP	23.97 gm/Bottle

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

Case No.	40 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006510AM25
RA File Number	03AX04004728 AM24
Licence No and Date	0311030291/19/01/2024

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information

provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	Lithium Metal	0.137 kg.
		3	n-Heptane	1.808 kg.
		4	Ethyl Isobutyrate	0.686 kg.
		5	1 Bromo-5-chloropentane	1.10 kg.
		6	Methyl-ethyl-ketone	1.038 kg.
		7	N, N Dimethylacetamide	1.678 kg.
		8	Sodium t-pentoxide	0.567 kg.
		9	Iodine	0.823 kg.
		10	Tosmic	0.512 kg.

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

Case No.	41 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008094AM24
RA File Number	08AX04001922 AM24
Licence No and Date	0811010550/22/01/2024
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.
Pazopanib Tablet 200 MG(Each film coated tablet contains: Pazopanib Hydrochloride 216.70 mg equivalent to Pazopanib 200mg. Net content of active ingredient Pazopanib Hydrochloride should not be less than 43.340 kgs in export product.)	200000 Numbers	1	Pazopanib Hydrochloride	44.207 kg.

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

Case No.	42 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008141AM24
RA File Number	09AX04000959 AM24
Licence No and Date	0911006629/24/01/2024

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.
Fendizoic acid(Drug Intermediate)	1 kg.	1	2-Phenyl phenol	0.83 kg.
		2	Ethylene dichloride	2.80 kg.

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

Case No.	43 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008188AM24
RA File Number	34AX04000814 AM24
Licence No and Date	3411004545/29/01/2024

Norms Committee Decision:

The Committee considered the case as per the 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.
CIPROFLOXACIN AND DEXAMETHASONE OTIC SUSPENSION USP 0.3% /0.1% -7.5 ML	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE USP	25.475 mg.
		2	DEXAMETHASONE USP	7.65 mg.
TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC SUSPENSION USP 0.3% /0.1% - 2.5 ML	1 Number	3	TOBRAMYCIN USP	7.65 mg.
		4	DEXAMETHASONE USP	2.55 mg.
TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC SUSPENSION USP 0.3% /0.1% - 5 ML	1 Number	5	TOBRAMYCIN USP	15.30 mg.
		6	DEXAMETHASONE USP	5.10 mg.
TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC SUSPENSION USP 0.3% /0.1% - 10 ML	1 Number	7	TOBRAMYCIN USP	30.60 mg.
		8	DEXAMETHASONE USP	10.20 mg.

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

Case No.	44 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00008190AM24
RA File Number	08AX04001949 AM24
Licence No and Date	0811010589/29/01/2024

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.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg/50 mL (4 mcg/mL)	1 Number	1	DEXMEDETOMIDINE	210.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg/100 mL (4 mcg/mL)	1 Number	2	DEXMEDETOMIDINE	420.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg per 50 mL (4 mcg/mL)	1 Number	3	DEXMEDETOMIDINE	210.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg per 100 mL (4 mcg/mL)	1 Number	4	DEXMEDETOMIDINE	420.00 mcg.

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

Case No.	45 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00002816AM25
RA File Number	03AX04005187 AM24

Licence No and Date	0311031241/15/02/2024			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	Vitamin B2 Or Riboflavin	1.269 kg.
		2	Pyridine	1.20 kg.
		3	Acetonitrile	1.538 kg.
		4	Phosphorus Oxychloride	2.00 kg.

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

Case No.	46 / NC/3/MEET/Mar/202425/19																	
Case Status	Case Approved																	
Party Name	BLUE JET HEALTHCARE LIMITED																	
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																	
HQ File Number	HQRNORM REVIW00006511AM25																	
RA File Number	03AX04000076 AM25																	
Licence No and Date	0311033249/22/04/2024																	
Norms Committee Decision:																		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-																		
<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">1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate</td><td rowspan="2">1 kg.</td><td>1</td><td>Tetrahydrofuran</td><td>1.137 kg.</td></tr><tr><td>2</td><td>N-Heptane</td><td>1.808 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.	2	N-Heptane	1.808 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.														
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.														
		2	N-Heptane	1.808 kg.														

		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.
		5	N, N Dimethylacetamide	1.678 kg.
		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.

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

Case No.	47 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006512AM25
RA File Number	03AX04000120 AM25
Licence No and Date	0311033250/22/04/2024

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	N-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.
		5	N, N Dimethylacetamide	1.678 kg.

		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.

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

Case No.	48 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000410AM25
RA File Number	52AX04000014 AM25
Licence No and Date	5211007960/24/04/2024

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/8 dated 17/03/2025 against advance authorization No. 5211003710 dated 07/12/2022, 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.
4-{1-[(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	2-chloro-4-(1H-pyrazol-3-yl)benzonitrile	0.963 kg.
		2	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate	0.826 kg.
		3	Diisopropyl azodicarboxylate	1.034 kg.
		4	TRIPHENYLPHOSPHINE	1.237 kg.

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

Case No.	49 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	CONNEX PHARMA PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00000436AM25																
RA File Number	26AX04000084 AM24																
Licence No and Date	2611001430/25/04/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance authorization No. 2611000980 dated16/06/2023, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">CHLOROMETHYL ISOPROPYL CARBONATE</td><td rowspan="2">1 kg.</td><td>1</td><td>METHYL CHLOROFORMATE</td><td>0.885 kg.</td></tr><tr><td>2</td><td>ISOPROPYL ALCOHOL</td><td>0.492 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CHLOROMETHYL ISOPROPYL CARBONATE	1 kg.	1	METHYL CHLOROFORMATE	0.885 kg.	2	ISOPROPYL ALCOHOL	0.492 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
CHLOROMETHYL ISOPROPYL CARBONATE	1 kg.	1	METHYL CHLOROFORMATE	0.885 kg.													
		2	ISOPROPYL ALCOHOL	0.492 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	50 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000484AM25
RA File Number	09AX04001160 AM24
Licence No and Date	0911007159/30/04/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the application of the firm was sent to Deptt. of Bio-Technology (DBT) for comments on 15/10/2024. DBT vide e-mail dated 21/10/2024 has informed that the export item mentioned in the application is comes under chemical item and requested	

to seek the comments from Deptt. of Chemical & Petrochemicals. The application of the firm was sent to Deptt. of C&PC on 06/11/2024 and comments is still awaited. A reminder was also issued.

Case No.	51 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000517AM25
RA File Number	08AX04000152 AM25
Licence No and Date	0811011425/02/05/2024

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vasopressin Injection, USP 20 Units per MI	572105 Vials.	1	Vasopressin USP	20.981 gm.

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

Case No.	52 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DEEPAK CHEM TECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000594AM25
RA File Number	34AX04000083 AM25
Licence No and Date	3411004899/08/05/2024

Norms Committee Decision:

The Committee considered the case as per the 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.
Benzo Trifluoride	1 kg.	1	BENZO TRICHLORIDE	1.402 kg.

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

Case No.	53 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	DEEPAK CHEM TECH LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00000595AM25										
RA File Number	34AX04000021 AM25										
Licence No and Date	3411004900/08/05/2024										
Norms Committee Decision:											
The Committee considered the case as per the 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Benzo Trifluoride</td><td>1 kg.</td><td>1</td><td>BENZO TRICHLORIDE</td><td>1.402 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benzo Trifluoride	1 kg.	1	BENZO TRICHLORIDE	1.402 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Benzo Trifluoride	1 kg.	1	BENZO TRICHLORIDE	1.402 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	54 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000608AM25
RA File Number	03AX04000430 AM25
Licence No and Date	0311033683/08/05/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/18dated 17/03/2024 against advance authorization No. 0311025742 dated 25/07/2023, 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.
TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG)	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATEEQ. TO TYLOSIN BASE 50MG)	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	3	TYLOSIN TARTRATE	6.111 gm.
TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH MLCONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH MLCONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% -500GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	7	TYLOSIN TARTRATE	505 gm.
TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM	1 Number	8	TYLOSIN TARTRATE	1010 gm.

CONTAINS TYLOSIN TARTRATE 100%)				
TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINSTYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.
TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	10	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	11	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% -100GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% -500GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	14	TYLOSIN TARTRATE	500 gm.
TYLOSIN TARTRATE POWDER 99% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	15	TYLOSIN TARTRATE	1000 gm.
TYLOSIN TARTRATE BOLUS 600MG(EACH BOLUS CONTAINSTYLOSIN TARTRATE 600MG)	1 Number	16	TYLOSIN TARTRATE	612.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	K.P.MANISH GLOBAL INGREDIENTS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00000654AM25										
RA File Number	04AX04000110 AM25										
Licence No and Date	0411007398/10/05/2024										
Norms Committee Decision:											
The Committee considered the case as per the 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>MUPIROCIN USP/EP (Assay (by HPLC) (Not less than 990 µg/mg)</td><td>1 kg.</td><td>1</td><td>CARBOXYLIC ACID-S-ACPE 9-[(E) -4-[(2S,3R,5S)-3,4-dihydroxy-5-[[[(2S,3S)-3-[(2S,3S)-3-hydroxybutan-2-yl]oxiran-2-yl]methyl]oxan-2-yl]-3-methylbut-2-enoyl] (Crude) (Assy not more than 92.1%</td><td>1.07 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MUPIROCIN USP/EP (Assay (by HPLC) (Not less than 990 µg/mg)	1 kg.	1	CARBOXYLIC ACID-S-ACPE 9-[(E) -4-[(2S,3R,5S)-3,4-dihydroxy-5-[[[(2S,3S)-3-[(2S,3S)-3-hydroxybutan-2-yl]oxiran-2-yl]methyl]oxan-2-yl]-3-methylbut-2-enoyl] (Crude) (Assy not more than 92.1%	1.07 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
MUPIROCIN USP/EP (Assay (by HPLC) (Not less than 990 µg/mg)	1 kg.	1	CARBOXYLIC ACID-S-ACPE 9-[(E) -4-[(2S,3R,5S)-3,4-dihydroxy-5-[[[(2S,3S)-3-[(2S,3S)-3-hydroxybutan-2-yl]oxiran-2-yl]methyl]oxan-2-yl]-3-methylbut-2-enoyl] (Crude) (Assy not more than 92.1%	1.07 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	56 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000693AM25
RA File Number	30AX04000069 AM25
Licence No and Date	3011005168/13/05/2024
Norms Committee Decision:	

The Committee considered the case as per the 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.
Ceftibuten Hydrate (62/0-Ceftibuten Hydrate)	1 kg.	1	GHYH	2.977 kg.
		2	Ethyl-4-chloroacetoacetate	1.82 kg.
		3	Methylene Chloride	85.60 kg.
		4	Triethylamine	3.214 kg
		5	Isopropyl acetate	7.99 kg.
		6	DL Malic acid	7.18 kg.
		7	Methanol	52.50 kg.
		8	Prenol (Prenyl alcohol)	3.114 kg.
		9	Methyl 3-methoxyacrylate	1.62 kg.
		10	Dimethylformamide (DMF)	4.82 kg.
		11	Toluene	0.38 kg.
		12	Acetone	2.13 kg.

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

Case No.	57 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025

and Date	
HQ File Number	HQRNORM APPLY 00000698AM25
RA File Number	03AX04000618 AM25
Licence No and Date	0311033818/14/05/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- As per details furnished by firm 0.21 kg of white oil is added per kg of export product, hence, the percentatage of purity of export is required.	

Case No.	58 / NC/3/MEET/Mar/202425/19																			
Case Status	Case Approved																			
Party Name	KLJ PLASTICIZERS LIMITED.																			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																			
HQ File Number	HQRNORM APPLY 00000703AM25																			
RA File Number	05AX04000448 AM25																			
Licence No and Date	0511025482/14/05/2024																			
Norms Committee Decision:																				
The Committee considered the case as per the 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 rowspan="3">DIMETHYL ADIPATE (DMA) (PACKED IN 426 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (3,621.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))</td><td rowspan="3">1 kg.</td><td>1</td><td>ADIPIC ACID</td><td>0.925 kg.</td></tr><tr><td>2</td><td>METHANOL</td><td>0.423 kg.</td></tr><tr><td>3</td><td>HDPE GRANULES (TOTAL WEIGHT = 3,802.050 KGS.)</td><td>Relevant, as per Packing Policy and General Notes.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DIMETHYL ADIPATE (DMA) (PACKED IN 426 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (3,621.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))	1 kg.	1	ADIPIC ACID	0.925 kg.	2	METHANOL	0.423 kg.	3	HDPE GRANULES (TOTAL WEIGHT = 3,802.050 KGS.)	Relevant, as per Packing Policy and General Notes.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
DIMETHYL ADIPATE (DMA) (PACKED IN 426 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (3,621.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))	1 kg.	1	ADIPIC ACID	0.925 kg.																
		2	METHANOL	0.423 kg.																
		3	HDPE GRANULES (TOTAL WEIGHT = 3,802.050 KGS.)	Relevant, as per Packing Policy and General Notes.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	59 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000712AM25
RA File Number	03AX04000705 AM25
Licence No and Date	0311033849/14/05/2024

Norms Committee Decision:

The Committee considered the case as per the 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 Item	Qty	S.No.	Import item	Qty. allowed
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG DISPERSIBLE TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 40 MG & LUMEFANTRINE 240 MG TABLETS	1 Number Tablet	1	ARTEMETHER	40.8 mg/Tablet
		2	LUMEFANTRINE	244.8 mg/Tablet
ARTEMETHER 80 MG & LUMEFANTRINE 480 MG TABLETS	1 Number Tablet	1	ARTEMETHER	81.6 mg./Tablet
		2	LUMEFANTRINE	489.60 mg./Tablet

Norms Proposed for 1 kg of ARTEMETHER

Export Item	Qty	S.No.	Import item	Qty. allowed
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ARTEMETHER	1Kg	1	Artemisinin	1.04 Kg
		2	Sodium Borohydride	0.188 Kg
		3	Trimethyl Ortho Acetate 99% MIN	0.50 Kg.

Norms Proposed for 1 kg of LUMEFANTRINE				
Export Item	Qty	S.No.	Import item	Qty. allowed
LUMEFANTRINE	1Kg	1	2, 7 DICHLORO A DIBUTYLAMINO METHYL 9 HFLUORENE-4- METHANOL DBA 99 PERCENT MIN	0.86896 kg
		2	4-chlorobenzaldehyde	0.3476 Kg

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

Case No.	60 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000731AM25
RA File Number	03AX04000559 AM25
Licence No and Date	0311033874/15/05/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/18dated 17/03/2024 against advance	

authorization No. 0311025665dated24/07/2023, 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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eqOxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial

Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial				
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml viaL	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 50ml vial	1 Number	22	PROPYLENE GLYCOL	10.40 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial

Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 250ml vial	1 Number	24	PROPYLENE GLYCOL	52.00 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	61 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000736AM25
RA File Number	03AX04000697 AM25
Licence No and Date	0311033882/15/05/2024

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 Item	Qty	S.No.	Import item	Qty. allowed
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG DISPERSIBLE TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 40 MG & LUMEFANTRINE 240 MG TABLETS	1 Number Tablet	1	ARTEMETHER	40.8 mg/Tablet
		2	LUMEFANTRINE	244.8 mg/Tablet

ARTEMETHER 80 MG & LUMEFANTRINE 480 MG TABLETS	1 Number Tablet	1	ARTEMETHER	81.6 mg./Tablet
		2	LUMEFANTRINE	489.60 mg./Tablet

Norms Proposed for 1 kg of ARTEMETHER

Export Item	Qty	S.No.	Import item	Qty. allowed
ARTEMETHER	1Kg	1	Artemisinin	1.04 Kg
		2	Sodium Borohydride	0.188 Kg
		3	Trimethyl Ortho Acetate 99% MIN.	0.50 Kg.

Norms Proposed for 1 kg of LUMEFANTRINE

Export Item	Qty	S.No.	Import item	Qty. allowed
LUMEFANTRINE	1Kg	1	2, 7 DICHLORO A DIBUTYLAMINO METHYL 9 HFLUORENE-4- METHANOL DBA 99 PERCENT MIN	0.86896 kg
		2	4-chlorobenzaldehyde	0.3476 Kg

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

Case No.	62 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	VINS BIOPRODUCTS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00000776AM25										
RA File Number	09AX04000030 AM25										
Licence No and Date	0911007243/17/05/2024										
Norms Committee Decision:											
The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to ffix ad-hoc norms as under:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Tetanus Antitoxin I.H.S B.P 1500 IU, Plus [overage of 150 IU in addition] in PFS/Vials/Ampoule</td><td>100000 Vials</td><td>1</td><td>Tetanus Antitoxin 2500 I.U/ml</td><td>69.3 Liter</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tetanus Antitoxin I.H.S B.P 1500 IU, Plus [overage of 150 IU in addition] in PFS/Vials/Ampoule	100000 Vials	1	Tetanus Antitoxin 2500 I.U/ml	69.3 Liter
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Tetanus Antitoxin I.H.S B.P 1500 IU, Plus [overage of 150 IU in addition] in PFS/Vials/Ampoule	100000 Vials	1	Tetanus Antitoxin 2500 I.U/ml	69.3 Liter							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	63 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	KLJ PLASTICIZERS LIMITED.										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00000784AM25										
RA File Number	05AX04000474 AM25										
Licence No and Date	0511025589/17/05/2024										
Norms Committee Decision:											
The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>DI-ETHYL MALEATE (DEM)</td><td>1 kg.</td><td>1</td><td>MALEIC ANHYDRIDE</td><td>0.67 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DI-ETHYL MALEATE (DEM)	1 kg.	1	MALEIC ANHYDRIDE	0.67 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
DI-ETHYL MALEATE (DEM)	1 kg.	1	MALEIC ANHYDRIDE	0.67 kg.							

(PACKED IN 852 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (7,242.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))	2	DENATURED ETHYL ALCOHOL	0.65 kg.
	3	HDPE GRANULES (TOTAL WEIGHT = 7,604.100 KGS.)	Relevant, as per Packing Policy & General Notes.
RA concerned may take further necessary action as per above decision of NC.			

Case No.	64 / NC/3/MEET/Mar/202425/19																													
Case Status	Case Approved																													
Party Name	MOREPEN LABORATORIES LIMITED																													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																													
HQ File Number	HQRNORM APPLY 00000787AM25																													
RA File Number	05AX04000479 AM25																													
Licence No and Date	0511025590/17/05/2024																													
Norms Committee Decision:																														
The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-																														
<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="6">8-CHLORO-6, 11-DIHYDRO -11(1-METHYL-4-PIPERIDINYLLIDENE)-5HBENZO(5,6)CYCLOHEPTA (1,2-B) PYRIDINE (LH09)</td><td rowspan="6">1 kg.</td><td>1</td><td>3-Chloro Benzyl Cyanide</td><td>1.37 kg.</td></tr><tr><td>2</td><td>Sodium Methoxide</td><td>0.54 kg.</td></tr><tr><td>3</td><td>Toluene</td><td>3.74 kg.</td></tr><tr><td>4</td><td>N,N-Dimethyl Carbamoyl Chloride</td><td>0.68 kg.</td></tr><tr><td>5</td><td>Methanol</td><td>0.47 kg.</td></tr><tr><td>6</td><td>Tetrahydrofuran</td><td>2.41 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	8-CHLORO-6, 11-DIHYDRO -11(1-METHYL-4-PIPERIDINYLLIDENE)-5HBENZO(5,6)CYCLOHEPTA (1,2-B) PYRIDINE (LH09)	1 kg.	1	3-Chloro Benzyl Cyanide	1.37 kg.	2	Sodium Methoxide	0.54 kg.	3	Toluene	3.74 kg.	4	N,N-Dimethyl Carbamoyl Chloride	0.68 kg.	5	Methanol	0.47 kg.	6	Tetrahydrofuran	2.41 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																										
8-CHLORO-6, 11-DIHYDRO -11(1-METHYL-4-PIPERIDINYLLIDENE)-5HBENZO(5,6)CYCLOHEPTA (1,2-B) PYRIDINE (LH09)	1 kg.	1	3-Chloro Benzyl Cyanide	1.37 kg.																										
		2	Sodium Methoxide	0.54 kg.																										
		3	Toluene	3.74 kg.																										
		4	N,N-Dimethyl Carbamoyl Chloride	0.68 kg.																										
		5	Methanol	0.47 kg.																										
		6	Tetrahydrofuran	2.41 kg.																										

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

Case No.	65 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000797AM25
RA File Number	03AX04000605 AM25
Licence No and Date	0311033967/17/05/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Certificate of Analysis with percentage of purity of export product. 2. Justification of low yield which is around 80%. 3. Quantity of value of By-product 'Methanol'.	

Case No.	66 / NC/3/MEET/Mar/202425/19								
Case Status	Case Approved								
Party Name	NEOGEN CHEMICALS LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025								
HQ File Number	HQRNORM APPLY 00000901AM25								
RA File Number	03AX04000936 AM25								
Licence No and Date	0311034124/27/05/2024								
Norms Committee Decision:									
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202425/6 dated 01/07/2024 against advance authorization No. 0311026825 dated01/09/2023, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	67 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	MELOG SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000920AM25
RA File Number	03AX04000829 AM25
Licence No and Date	0311034133/27/05/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Value of by-product not given. 2. Recovery of Methanol in kg.	

Case No.	68 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00000952AM25
RA File Number	26AX04000006 AM25
Licence No and Date	2611001464/28/05/2024
Norms Committee Decision: The firm was called for Personal Hearing on through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information.	

Case No.	69 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006513AM25
RA File Number	03AX04001124 AM25
Licence No and Date	0311034554/12/06/2024

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.132 kg.
		2	N-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.
		5	N, N Dimethylacetamide	1.678 kg.
		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.

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

Case No.	70 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00001490AM25
RA File Number	03AX04001450 AM25
Licence No and Date	0311034819/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information.	

Case No.	71 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00001493AM25
RA File Number	03AX04001447 AM25
Licence No and Date	0311034821/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information.	

Case No.	72 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00001494AM25
RA File Number	03AX04001441 AM25
Licence No and Date	0311034822/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u>	

with relevant documents/information.

Case No.	73 / NC/3/MEET/Mar/202425/19																			
Case Status	Case Approved																			
Party Name	AMI ORGANICS LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																			
HQ File Number	HQRNORM APPLY 00001818AM25																			
RA File Number	52AX04000090 AM25																			
Licence No and Date	5211008811/08/07/2024																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/8 dated 17/03/2025 against advance authorization No. 5211003710 dated 07/12/2022, 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="3">4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)</td><td rowspan="3">1 kg.</td><td>1</td><td>Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate</td><td>0.826 kg.</td></tr><tr><td>2</td><td>Diisopropyl azodicarboxylate</td><td>1.034 kg.</td></tr><tr><td>3</td><td>TRIPHENYLPHOSPHINE</td><td>1.237 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate	0.826 kg.	2	Diisopropyl azodicarboxylate	1.034 kg.	3	TRIPHENYLPHOSPHINE	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate	0.826 kg.																
		2	Diisopropyl azodicarboxylate	1.034 kg.																
		3	TRIPHENYLPHOSPHINE	1.237 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	74 / NC/3/MEET/Mar/202425/19			
Case Status	Case Deferred			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00001820AM25			
RA File Number	52AX04000089 AM25			
Licence No and	5211008812/08/07/2024			

Date	
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	75 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002263AM25
RA File Number	03AX04002117 AM25
Licence No and Date	0311036002/01/08/2024
Norms Committee Decision:	
The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that input Galaxmusk Pure (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feeding ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP and the RA concerned is directed to provide its comments.	

Case No.	76 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002279AM25
RA File Number	05AX04001164 AM25
Licence No and Date	0511026980/02/08/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To give a balanced chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of the reaction. 2. To indicate where Alumino Silicate catalyst, Denatured Ethyl alcohol and kmethanol are used in the chemical reaction, giving their application/use.	

3. Calculation of the requirement of all the chemicals with justification of low yield, if any.
4. In chemical reaction Ethyl acetate has been shown as one of the reactants whereas the same has neither been shown in import nor in indigenous inputs.

Case No.	77 / NC/3/MEET/Mar/202425/19															
Case Status	Case Approved															
Party Name	TORRENT PHARMACEUTICALS LTD															
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025															
HQ File Number	HQRNORM APPLY 00002282AM25															
RA File Number	08AX04000713 AM25															
Licence No and Date	0811012276/02/08/2024															
Norms Committee Decision:																
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No.0811008360 dated 09/06/2023, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)</td><td>1 Number</td><td>1</td><td>CLOZAPINE BP</td><td>25.50 mg/Tablet</td></tr><tr><td>CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)</td><td>1 Number</td><td>2</td><td>CLOZAPINE BP</td><td>102.00 mg/Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)	1 Number	1	CLOZAPINE BP	25.50 mg/Tablet	CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)	1 Number	2	CLOZAPINE BP	102.00 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)	1 Number	1	CLOZAPINE BP	25.50 mg/Tablet												
CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)	1 Number	2	CLOZAPINE BP	102.00 mg/Tablet												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	78 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	TORRENT PHARMACEUTICALS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002284AM25			
RA File Number	08AX04000714 AM25			

Licence No and Date	0811012277/02/08/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/012/2024 against advance authorization No.0811011729 dated 03/06/2024, 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.
CAPTOPRIL TABLETS USP -25 MG (ANGIOPRIL 25 MG TABLET)((each uncoated tablet contains USP 25mg))	1 Number	1	CAPTOPRIL USP	25.50 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	TORRENT PHARMACEUTICALS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002285AM25			
RA File Number	08AX04000715 AM25			
Licence No and Date	0811012278/02/08/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No.0811011729 dated 03/06/2024, 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.
CAPTOPRIL TABLETS USP -25 MG (ANGIOPRIL 25 MG TABLET)((each uncoated tablet contains USP 25mg))	1 Number	1	CAPTOPRIL USP	25.50 mg.

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

Case No.	80 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002286AM25
RA File Number	08AX04000716 AM25
Licence No and Date	0811012279/02/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No.0811008938 dated 30/07/2023, 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.
CLOZAPINE TABLETS 100MG (CLOZAPYL 100MG TABLET)(EACH UNCOATED TABLET CONTAINS : CLOZAPINE B.P 100 MG	1 Number	1	CLOZAPINE BP	102.00 mg/tablet

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

Case No.	81 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002287AM25
RA File Number	30AX04000217 AM25
Licence No and Date	3011005556/02/08/2024

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.
Ceftazidime Powder for Solution for Injection or Infusion 1.0 g(Each Vial Contains: Ceftazidime (as pentahydrate) 1 g with sodium carbonate (118 mg per gram of ceftazidime CONTAINING 50.005 KG OF CEFTAZIDIME PENTAHYDRATE WITH SODIUMCARBONATE STERILE)	1 Number	1	CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE STERILE	1.258 gm.
Ceftazidime Powder for Solution for Injection or Infusion 2.0 g(Each Vial Contains: Ceftazidime (as pentahydrate) 2 g with sodium carbonate (118 mg per gram of ceftazidime CONTAINING 50.003 KG OF CEFTAZIDIME PENTAHYDRATE WITH SODIUMCARBONATE STERILE)	1 Number	2	CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE STERILE	2.516 gm.

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

Case No.	82 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002293AM25
RA File Number	03AX04002152 AM25
Licence No and Date	0311036037/03/08/2024

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.
MOXILEB KID TABLET (AMOXICILLIN TABLET 125MG)((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 125MG OF AMOXICILLIN) NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORTPRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) - 71.751KGS (EXCL 2% WASTAGE))	1 Number	1	AMOXICILLIN TRIHYDRATE BP COMPACTED	146.32 mg.
MOXILEB- 250DT . AMOXICILLIN TABLET 250MG.((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATEEQUIVALENT TO 250MG OF AMOXICILLIN) . NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1)AMOXICILLIN TRIHYDRATE BP (COMPACTED) -157.850KGS (EXCL 2% WASTAGE))	1 Number	2	AMOXICILLIN TRIHYDRATE BP COMPACTED	292.639 mg.
MOXILEB -250 CAPSULE. (AMOXICILLIN CAPSULE 250MG)((EACH CAPSULE CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 250MGOF AMOXICILLIN) . NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN BP (COMPACTED) -1205.400KGS (EXCL 2% WASTAGE))	1 Number	3	AMOXICILLIN TRIHYDRATE BP COMPACTED	292.639 mg.
MOXILEB -500 CAPSULE . (AMOXICILLIN CAPSULE 500MG) .((EACH CAPSULE CONTAINING AMOXICILLINTRIHYDRATE EQUIVALENT TO 500MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORTPRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) -3286.150KGS (EXCL 2% WASTAGE))	1 Number	4	AMOXICILLIN TRIHYDRATE BP COMPACTED	585.28 mg.
MOXILEB ORAL SUSPENSION AMOXICILLIN ORAL SUSPENSION (AMOXICILLIN SYRUP) 125MG/100MLBOTTLE.((EACH 5ML	1 Number	5	AMOXICILLIN TRIHYDRATE BP COMPACTED	2625.00 mg.

CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 125MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) - 60.270KGS (EXCL2% WASTAGE))				
AMOXICILLIN ORAL SUSPENSION. AMOXICILLIN ORAL SUSPENSION (AMOXICILLIN SYRUP) 250MG/100ML BOTTLE. ((EACH 5ML CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 250MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) - 120.54KGS (EXCL2% WASTAGE).)	1 Number	6	AMOXICILLIN TRIHYDRATE BP COMPACTED	5250.00 mg.

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

Case No.	83 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	LEBEN LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002308AM25			
RA File Number	03AX04002153 AM25			
Licence No and Date	0311036028/05/08/2024			
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.
ALCLOX-250 CAPSULE. CLOXACILLIN SODIUM CAPSULES USP-250MG.((EACH CAPSULE CONTAININGCLOXACILLIN SODIUM BP EQUIVALENT TO 250MG OF CLOXACILLIN).	1376235 Numbers	1	CLOXACILLIN SODIUM BP COMPACTED	382.52 kg.

ALCLOX-500 CAPSULE. CLOXACILLIN SODIUM CAPSULES USP-500MG.(EACH CAPSULE CONTAININGCLOXACILLIN SODIUM BP EQUIVALENT TO 500MG OF CLOXACILLIN).	9000000 Numbers	2	CLOXACILLIN SODIUM BP COMPACTED	5003.1 kg.
LAMPYKLOX CAPSULE. CLOXACILLIN CAP (250+250MG)((EACH CAP CONTAINING CLOXACILLIN SODIUMEQUT TO 250MG OF CLOXACILLIN)	2000000 Numbers	3	CLOXACILLIN SODIUM BP COMPACTED	555.9 kg.
ALCLOX - 125 SYRUP. CLOXACILLIN SODIUM FOR ORAL SOLUTION USP.((EACH 5ML CONTAINSCLOXACILLIN SODIUM BP EQUIVALENT TO 125MG OF CLOXACILLIN) (100 ml Bottle).	21000 Numbers	4	CLOXACILLIN SODIUM BP COMPACTED	58.48 kg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	84 / NC/3/MEET/Mar/202425/19													
Case Status	Case Approved													
Party Name	JODAS EXPOIM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025													
HQ File Number	HQRNORM APPLY 00002321AM25													
RA File Number	09AX04000342 AM25													
Licence No and Date	0911007698/06/08/2024													
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>Aztreonam for Injection USP 1 Gram</td><td>1 Number</td><td>1</td><td>Aztreonam and Arginine</td><td>1.10 gm.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Aztreonam for Injection USP 1 Gram	1 Number	1	Aztreonam and Arginine	1.10 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Aztreonam for Injection USP 1 Gram	1 Number	1	Aztreonam and Arginine	1.10 gm.										

Aztreonam for Injection USP 500 mg	1 Number	2	Aztreonam and Arginine	0.55 gm.
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RA concerned may take further necessary action as per above decision of NC

Case No.	85 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002334AM25			
RA File Number	07AX04000751 AM25			
Licence No and Date	0711012019/06/08/2024			
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.
DOXYCYCLINE 100MG DISPERSIBLE TABLETS(DOXYCYCLINE 100MG DISPERSIBLE TABLETS (Eq to ANHYDROUS DOXYCYCLINE 100MG) (400KGS))	1 Number	1	DOXYCYCLINE MONOHYDRATE USP/BP	106.13 mg.

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

Case No.	86 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002335AM25			
RA File Number	07AX04000750 AM25			
Licence No and	0711012020/06/08/2024			

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.
INDORAMIN 20MG TABLETS (INDORAMIN 20MG TABLETS (10KGS))	1 Number	1	INDORAMIN HYDROCHLORIDE	22.54 mg.

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

Case No.	87 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00002346AM25																
RA File Number	03AX04002200 AM25																
Licence No and Date	0311036131/06/08/2024																
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 rowspan="2">MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) (Containing NLT 84% Sterile Meropenem)</td><td rowspan="2">1 kg.</td><td>1</td><td>MEROPENEM NONSTERILE MEROPENEM TRIHYDRATE NONSTERILE</td><td>0.8968 kg.</td></tr><tr><td>2</td><td>PACKING MATERIAL</td><td>Relevant, as per Packing Policy and General Notes.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	MEROPENEM NONSTERILE MEROPENEM TRIHYDRATE NONSTERILE	0.8968 kg.	2	PACKING MATERIAL	Relevant, as per Packing Policy and General Notes.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	MEROPENEM NONSTERILE MEROPENEM TRIHYDRATE NONSTERILE	0.8968 kg.													
		2	PACKING MATERIAL	Relevant, as per Packing Policy and General Notes.													

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

Case No.	88 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002366AM25
RA File Number	34AX04000972 AM24
Licence No and Date	3411005275/07/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.3411002884 dated 11/10/2022, 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.
Guanfacine Extended-Release Tablets USP 1 mg (Net content of active ingredients 3.900 kgs)	1 Number	1	Guanfacine Hydrochloride	1.171 mg.
		2	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		3	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		4	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		5	Lactose Monohydrate (Flowlac100)	46.35 mg.
		6	Magnesium stearate	1.00 mg.
Guanfacine Extended-Release Tablets USP 2 mg (Net content of active ingredients 7.800 kgs)	1 Number	7	Guanfacine Hydrochloride	2.342 mg.
		8	Methacrylic Acid and Ethyl	55.00 mg.

			Acrylate Copolymer (Eudragit L 100-55)	
		9	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		10	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		11	Lactose Monohydrate (Flowlac100)	45.20 mg.
		12	Magnesium stearate	1.00 mg.
	Guanfacine Extended-Release Tablets 1 Number USP 3 mg (Net content of active ingredients 7.50 kgs)	13	Guanfacine Hydrochloride	3.513 mg.
		14	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		15	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		16	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		17	Lactose Monohydrate (Flowlac100)	43.56 mg.
		18	Magnesium stearate	1.00 mg.
	Guanfacine Extended-Release Tablets 1 Number USP 4 mg (Net content of active ingredients 9.60 kgs)	19	Guanfacine Hydrochloride	4.684 mg.
		20	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		21	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		22	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.

		23	Lactose Monohydrate (Flowlac100)	42.40 mg.
		24	Magnesium stearate	1.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002396AM25
RA File Number	03AX04002271 AM25
Licence No and Date	0311036187/08/08/2024

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.
Clobetasol Propionate Foam 0.05percent 50gm((Net. wt. of Net. wt. of Clobetasol Propionate USP (Micronized) is1.00 Kgs.))	40000 Numbers	1	CLOBETASOL PROPIONATE USP (MICRONIZED)	19.93 kg.
Clobetasol Propionate Foam 0.05percent 100gm((Net. wt. of Clobetasol Propionate USP (Micronized) is 2.00 Kgs.))	40000 Numbers	2		
Clobetasol Propionate Cream USP 0.05percent (Pack Size 15gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.300 Kgs))	40000 Numbers	3		
Clobetasol Propionate Cream USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.600 Kgs))	40000 Numbers	4		
Clobetasol Propionate Cream USP 0.05percent	40000	5		

(Pack size 45 gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.900 Kgs))	Numbers			
Clobetasol Propionate Cream USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP(Micronized) 1.200 Kgs))	40000 Numbers	6		
Clobetasol Propionate Ointment USP 0.05percent (Pack size 15gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.300 Kgs))	40000 Numbers	7		
Clobetasol Propionate Ointment USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.600 Kgs))	40000 Numbers	8		
Clobetasol Propionate Ointment USP 0.05percent (Pack size 45gm)((Net Weight of Clobetasol Propionate USP(Micronized) 0.900 Kgs))	40000 Numbers	9		
Clobetasol Propionate Ointment USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP(Micronized) 1.200 Kgs))	40000 Numbers	10		
Clobetasol Propionate Spray 0.05percent (Pack size 59ml)((Net Weight of Clobetasol Propionate USP (Micronized)1.180 Kgs))	40000 Numbers	11		
Clobetasol Propionate Spray 0.05percent (Pack size 125ml)((Net Weight of Clobetasol Propionate USP (Micronized)2.500 Kgs))	40000 Numbers	12		
Clobetasol Prop. Top Sol USP, 0.05percent 25ml((Net Weight of Clobetasol Propionate USP (Micronized) 0.500Kgs))	40000 Numbers	13		
Clobetasol Prop. Top Sol USP, 0.05percent 50ml((Net Weight of Clobetasol Propionate USP (Micronized) 1.000Kgs))	40000 Numbers	14		

Clobetasol Pro Shampoo, 0.05 percent 118ml((Net Weight of Clobetasol Propionate USP (Micronized) 2.360 Kgs))	40000 Numbers	15		
Clobetasol Propionate Foam 0.05percent 100gm (Emulsion Formulation)((Net. wt. of Clobetasol Propionate USP(Micronized) is 2.000 Kgs.))	40000 Numbers	16		
Clobetasol Propionate Foam 0.05percent 50gm (Emulsion Formulation)((Net. wt. of Clobetasol Propionate USP(Micronized) is 1.000 Kgs.))	40000 Numbers	17		

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

Case No.	90 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	MEDREICH LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00002405AM25																
RA File Number	07AX04000768 AM25																
Licence No and Date	0711012041/08/08/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0711010859 dated 21/03/2024, 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 rowspan="2">REBAMIPIDE 100MG TABLETS</td><td rowspan="2">1 Number Tablet</td><td>1</td><td>REBAMIPIDE JP</td><td>102.00 mg.</td></tr><tr><td>2</td><td>Ethyl Alcohol 200 Proof</td><td>0.19 ml.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	REBAMIPIDE 100MG TABLETS	1 Number Tablet	1	REBAMIPIDE JP	102.00 mg.	2	Ethyl Alcohol 200 Proof	0.19 ml.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
REBAMIPIDE 100MG TABLETS	1 Number Tablet	1	REBAMIPIDE JP	102.00 mg.													
		2	Ethyl Alcohol 200 Proof	0.19 ml.													

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

Case No.	91 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DIVI'S LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002430AM25
RA File Number	09AX04000389 AM25
Licence No and Date	0911007722/09/08/2024

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.
IOPAMIDOL (POWDER)	1 kg.	1	ATIPA DI CHLORIDE	1.27 kg.
		2	DIMETHYL FORMAMIDE	0.68 kg.
		3	N N DIMETHYL ACETAMIDE	1.46 kg.
		4	NITRO METHANE	0.48 kg.
		5	L LACTIC ACID	0.67 kg.

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

Case No.	92 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002458AM25
RA File Number	08AX04000712 AM25
Licence No and Date	0811012363/12/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0811011943 dated 26/06/2024, 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.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 60 MG(EACH FILM COATED EXTENDEDRELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 60MG, NET CONTENT OF ACTIVE INGREDIENT ISMN SHOULD NOT BE LESS THAN1815.264 KGS.)	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate) USP	122.40 mg.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 120 MG(EACH FILM COATED EXTENDEDRELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 120MG, NET	1 Number	2	Isosorbide Mononitrate 50 percent Assay.Diluted ISMN (50% diluted with lactose monohydrate) USP	244.80 mg.

CONTENT OF ACTIVE INGREDIENT ISMN SHOULD NOT BE LESSTHAN 113.454 KGS)				
RA concerned may take further necessary action as per above decision of NC				

Case No.	93 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002468AM25
RA File Number	03AX04002293 AM25
Licence No and Date	0311036279/12/08/2024

Norms Committee Decision:

The Committee considered the case as per the 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.
Doxycycline Tablets, USP 50 MG 100 S((21,600 Bottles X 100 Per Bottles = 21,60,000 Tablets) (Total Weight of ExportProduct = 108.000 Kgs) (Net Content weight of Import Product = 116.327 kgs))	1 Number	1	Doxycycline USP (Monohydrate)	53.066 mg./50 mg. Tablet
Doxycycline Tablets, USP 100 MG 500 S((2,800 Bottles X 500 Per Bottles = 14,00,000 Tablets) (Total Weight of ExportProduct = 140.000 Kgs) (Net Content weight of Import Product = 150.794 kgs))	1 Number	2	Doxycycline USP (Monohydrate)	106.13 mg./100 mg. Tablet

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

Case No.	94 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002482AM25
RA File Number	03AX04002360 AM25
Licence No and Date	0311036306/13/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No. 0311026225 dated 10/08/2023, 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.
N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 15%	1 kg.	1	LITHIUM METAL	0.0406 kg.
		2	BUTYL CHLORIDE	0.270 kg.
		3	HEXANE	1.760 kg.
N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 24%	1 kg.	1	LITHIUM METAL	0.0650 kg.
		2	BUTYL CHLORIDE	0.432 kg.
		3	HEXANE	1.574 kg.
N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 30%	1 kg.	1	LITHIUM METAL	0.0812 kg.
		2	BUTYL CHLORIDE	0.540 kg.
		3	HEXANE	1.450 kg.

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

Case No.	95 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	COVALENT LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002508AM25
RA File Number	09AX04000392 AM25
Licence No and Date	0911007730/13/08/2024

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.
7-AMINO-3-VINYL-3- CEPHEM-4-CARBOXYLIC ACID (7-AVCA)(API)	1 kg.	1	7-Phenylacetamideo-3-Chloromethyl Cephalosporonic Acid Para Methoxybenzyl Ester (GCLE)	2.672 kg.
		2	Acetone	8.85 kg.
		3	Methylene Chloride	5.70 kg.
		4	Methanol	5.70 kg.
		5	Activated Carbon	0.100 kg.
		6	Triphenyl Phosphine	1.26 kg.

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

Case No.	96 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	AMI ORGANICS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00002521AM25																
RA File Number	52AX04000126 AM25																
Licence No and Date	5211009387/14/08/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/8 dated 17/03/2025 against advance authorization No. 5211003710 dated 07/12/2022, 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="3">4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)</td><td rowspan="3">1 kg.</td><td>1</td><td>Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate</td><td>0.826 kg.</td></tr><tr><td>2</td><td>Diisopropyl azodicarboxylate</td><td>1.034 kg.</td></tr><tr><td>3</td><td>TRIPHENYLPHOSPHINE</td><td>1.237 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate	0.826 kg.	2	Diisopropyl azodicarboxylate	1.034 kg.	3	TRIPHENYLPHOSPHINE	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
4-{1- [(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate	0.826 kg.													
		2	Diisopropyl azodicarboxylate	1.034 kg.													
		3	TRIPHENYLPHOSPHINE	1.237 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	97 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002528AM25
RA File Number	07AX04000784 AM25
Licence No and Date	0711012089/14/08/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance	

authorization No.0711006347 dated 02/02/2023, 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.
RAMELTEON 8MG TABLETS	1 NumberTablet	1	RAMELTEON	8.16 mg/Tablet

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

Case No.	98 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	CHROMO LABORATORIES INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002535AM25
RA File Number	09AX04000325 AM25
Licence No and Date	0911007740/14/08/2024

Norms Committee Decision:

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

1. A balanced chemical reaction indicating molecular weight of both reactants and products with yield of the reaction.
2. Current production/consumption data, duly certified by Chartered Accountant.
3. To indicate the item of inputs, act as reactant, catalyst, consumable etc., as the case may be.
4. End use of export item.

Case No.	99 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002541AM25
RA File Number	09AX04000362 AM25
Licence No and Date	0911007744/16/08/2024

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.
Aspirin and Extended-Release Dipyridamole Capsules 25 mg/200 mg Pack Size : 60s (Consist of 960 Kgs of Dipyridamole USP)	1 Number	1	Dipyridamole USP	204.0 mg/Capsule

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

Case No.	100 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002542AM25
RA File Number	09AX04000364 AM25
Licence No and Date	0911007745/16/08/2024

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.
Dipyridamole modified release and Acetyl Salicylic Acid Capsules 200mg+25mg - Brand Name : (Orisantin 200mg/25mg depotkapseli, kova/kapsel med modifieradfrisattning, hard) Pack Size : 100s (Consist of 960.00 Kgs of Dipyridamole - Ph Eur)	1 Number	1	Dipyridamole	204 mg/Capsule
Dipyridamole modified release and Acetyl Salicylic Acid Capsules 200mg+25mg - Brand Name : (Diprasorin 200mg/25 mg	1 Number	2	Dipyridamole	204 mg/Capsule

hardkapsel med modifieradfrisattning/ hardkapsel med modifieradfrisattning) Pack Size : 100s (Consist of 800.00 Kgs of Dipyridamole - Ph Eur)				
Dipyridamole Modified Release capsules 200 mg Pack Size : 60s Consist of 319.97 Kgs of Dipyridamole - Ph Eur)	1 Number	3	Dipyridamole	204 mg/Capsule
RA concerned may take further necessary action as per above decision of NC				

Case No.	101 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002543AM25
RA File Number	09AX04000378 AM25
Licence No and Date	0911007746/16/08/2024

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.
Amlodipine and Benazepril Hydrochloride Capsules USP 2.5 mg/ 10 mg (Pack size:100s) (Consists of 08 Kgs of Benazepril Hydrochloride USP)	1 Number	1	Benazepril Hydrochloride USP	10.2 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 5 mg/ 10 mg (Pack size:100s) (Consists of 63 Kgs of Benazepril Hydrochloride USP)	1 Number	2	Benazepril Hydrochloride USP	10.2 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 5 mg/ 10 mg (Pack size:500s) (Consists of 21 Kgs	1 Number	3	Benazepril Hydrochloride USP	10.2 mg

of Benazepril Hydrochloride USP)				
Amlodipine and Benazepril Hydrochloride Capsules USP 5 mg/ 20 mg (Pack size:100s) (Consists of 140 Kgs of Benazepril Hydrochloride USP)	1 Number	4	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 5 mg/ 20 mg (Pack size:500s) (Consists of 84 Kgs of Benazepril Hydrochloride USP)	1 Number	5	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg/ 20 mg (Pack size:100s) (Consists of 140 Kgs of Benazepril Hydrochloride USP)	1 Number	6	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg/ 20 mg (Pack size:500s) (Consists of 56 Kgs of Benazepril Hydrochloride USP)	1 Number	7	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 5 mg/ 40 mg (Pack size:100s) (Consists of 252 Kgs of Benazepril Hydrochloride USP))	1 Number	8	Benazepril Hydrochloride USP	40.8 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg/ 40 mg (Pack size:100s) (Consists of 336 Kgs of Benazepril Hydrochloride USP)	1 Number	9	Benazepril Hydrochloride USP	40.8 mg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	102 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	GLAND PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025

HQ File Number	HQRNORM APPLY 00002566AM25
RA File Number	09AX04000345 AM25
Licence No and Date	0911007758/19/08/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	103 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002569AM25
RA File Number	09AX04000367 AM25
Licence No and Date	0911007762/19/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Drug Manufacturing Licence (DML) showing approved composition for each export item.	

Case No.	104 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002574AM25
RA File Number	03AX04002287 AM25
Licence No and Date	0311036455/19/08/2024
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.
TENOFOVIR DISOPROXILE OROTATE(TDO)	1 kg.	1	PMPA [(R)-9-(2-Phosphonyl Methoxy Propyl) Adenine]	0.689 kg.

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

Case No.	105 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	MELOG SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002583AM25
RA File Number	03AX04002187 AM25
Licence No and Date	0311036462/20/08/2024

Norms Committee Decision:

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

1. Quantity and value of products (Iso Butylene, PTBP, High Polymer Butylated Hydrocarbon) not given.
2. Recovery of Methanol in kg.

Case No.	106 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002587AM25
RA File Number	03AX04002398 AM25
Licence No and Date	0311036465/20/08/2024

Norms Committee Decision:

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

product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0311034440 dated 07/06/2024, 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.
ROSUVASTATIN TABLET BP / USP 10 MG.((Each Tablet contains Rosuvastatin Calcium 10.400 mg) Eq. toRosuvastatin 10 mg.	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	13.79 mg/10 mg Tablet

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

Case No.	107 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002591AM25
RA File Number	08AX04000799 AM25
Licence No and Date	0811012437/20/08/2024

Norms Committee Decision:

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

Copy of Certificate of Analysis (CoA) of import item from Foreign Supplier.

Case No.	108 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved

Party Name	MANKIND PHARMA LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																		
HQ File Number	HQRNORM APPLY 00002603AM25																		
RA File Number	05AX04001571 AM25																		
Licence No and Date	0511027226/20/08/2024																		
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202425/4 dated 06/06/2024 against advance authorization No.0511019054 dated 29/05/2023, 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:- <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>Cynacobalamin Injection USP, 1000mcg/ml,</td> <td>1325000 Numbers</td> <td>1</td> <td>CYANOCOBALAMIN USP</td> <td>1457.5 gm.</td> </tr> <tr> <td>Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),</td> <td>35000 Numbers</td> <td>2</td> <td>CYANOCOBALAMIN USP</td> <td>378.77 gm.</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.	Cynacobalamin Injection USP, 1000mcg/ml,	1325000 Numbers	1	CYANOCOBALAMIN USP	1457.5 gm.	Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),	35000 Numbers	2	CYANOCOBALAMIN USP	378.77 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Cynacobalamin Injection USP, 1000mcg/ml,	1325000 Numbers	1	CYANOCOBALAMIN USP	1457.5 gm.															
Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),	35000 Numbers	2	CYANOCOBALAMIN USP	378.77 gm.															

Case No.	109 / NC/3/MEET/Mar/202425/19								
Case Status	Case Approved								
Party Name	BLUE JET HEALTHCARE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025								
HQ File Number	HQRNORM REVIW00006514AM25								
RA File Number	03AX04002439 AM25								
Licence No and Date	0311036466/20/08/2024								
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	N-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.
		5	N, N Dimethylacetamide	1.678 kg.
		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.

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

Case No.	110 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002605AM25			
RA File Number	03AX04002286 AM25			
Licence No and Date	0311036494/21/08/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0311024147 dated 02/06/2023, 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:-				

Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.
		2	Imidazole	0.310 kg.

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

Case No.	111 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002606AM25
RA File Number	03AX04002289 AM25
Licence No and Date	0311036495/21/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0311024147 dated 02/06/2023, 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.
Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.
		2	Imidazole	0.310 kg.

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

Case No.	112 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved

Party Name	UNIMAX LABORATORIES																									
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																									
HQ File Number	HQRNORM APPLY 00002613AM25																									
RA File Number	05AX04001529 AM25																									
Licence No and Date	0511027267/21/08/2024																									
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0511019298 dated 12/06/2023, 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 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>Spiramycin Tablets 1.5 MIU(Each tablet contains Spiramycin EP)</td><td>1 Number</td><td>1</td><td>Spiramycin EP</td><td>373.02 mg.</td></tr> <tr> <td>Spiramycin Tablets 3.0 MIU(Each tablet contains Spiramycin EP)</td><td>1 Number</td><td>2</td><td>Spiramycin EP</td><td>Does not match with DML</td></tr> <tr> <td>Azithromycin Tablets 250 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)</td><td>1 Number</td><td>3</td><td>Azithromycin Dihydrate USP</td><td>267.27 mg.</td></tr> <tr> <td>Azithromycin Tablets 500 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to AnhydrousAzithromycin)</td><td>1 Number</td><td>4</td><td>Azithromycin Dihydrate USP</td><td>534.54 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.	Spiramycin Tablets 1.5 MIU(Each tablet contains Spiramycin EP)	1 Number	1	Spiramycin EP	373.02 mg.	Spiramycin Tablets 3.0 MIU(Each tablet contains Spiramycin EP)	1 Number	2	Spiramycin EP	Does not match with DML	Azithromycin Tablets 250 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	3	Azithromycin Dihydrate USP	267.27 mg.	Azithromycin Tablets 500 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to AnhydrousAzithromycin)	1 Number	4	Azithromycin Dihydrate USP	534.54 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																						
Spiramycin Tablets 1.5 MIU(Each tablet contains Spiramycin EP)	1 Number	1	Spiramycin EP	373.02 mg.																						
Spiramycin Tablets 3.0 MIU(Each tablet contains Spiramycin EP)	1 Number	2	Spiramycin EP	Does not match with DML																						
Azithromycin Tablets 250 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	3	Azithromycin Dihydrate USP	267.27 mg.																						
Azithromycin Tablets 500 mg USP(Each tablet contains Azithromycin USP (As Dihydrate) Eq. to AnhydrousAzithromycin)	1 Number	4	Azithromycin Dihydrate USP	534.54 mg.																						

Case No.	113 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred

Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002617AM25
RA File Number	03AX04002498 AM25
Licence No and Date	0311036513/21/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. The function of Tetrahydrofuraninin the reaction and yield of the reaction. 2. The Stoichiometric material balance on a molar basis. 3. The current production/consumption data duly certified by Chartered Accountant.	

Case No.	114 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002619AM25
RA File Number	31AX04000169 AM25
Licence No and Date	3111003807/21/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical Name of DNOVO CP388. 2. Calculation for the requirement of Raw materials for the manufacture of Export item, giving justification for the yield of the reaction. 3. Production/Consumption data for the current year duly certified by Chartered Accountant.	

Case No.	115 / NC/3/MEET/Mar/202425/19
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Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002625AM25
RA File Number	05AX04001393 AM25
Licence No and Date	0511027293/21/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete technical details as per Annexure to Appendix-4E. 2. Wastage applied for Tablets from API.	

Case No.	116 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002626AM25
RA File Number	05AX04001408 AM25
Licence No and Date	0511027294/21/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete technical details as per Annexure to Appendix-4E.	

Case No.	117 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025

HQ File Number	HQRNORM APPLY 00002628AM25																							
RA File Number	05AX04001578 AM25																							
Licence No and Date	0511027297/22/08/2024																							
Norms Committee Decision:																								
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No.0511019178 dated 05/06/2023, 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>Budesonide Suspension For Inhalation , 0.125 mg / ml (2 ml Ampoule)</td><td>12195000 Numbers</td><td>1</td><td>Budesonide</td><td>3.201 kg.</td></tr><tr><td>Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule)</td><td>11700000 Numbers</td><td>2</td><td>Budesonide</td><td>6.1425 kg.</td></tr><tr><td>Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule)</td><td>3600000 Numbers</td><td>3</td><td>Budesonide</td><td>3.78 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Budesonide Suspension For Inhalation , 0.125 mg / ml (2 ml Ampoule)	12195000 Numbers	1	Budesonide	3.201 kg.	Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule)	11700000 Numbers	2	Budesonide	6.1425 kg.	Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule)	3600000 Numbers	3	Budesonide	3.78 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Budesonide Suspension For Inhalation , 0.125 mg / ml (2 ml Ampoule)	12195000 Numbers	1	Budesonide	3.201 kg.																				
Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule)	11700000 Numbers	2	Budesonide	6.1425 kg.																				
Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule)	3600000 Numbers	3	Budesonide	3.78 kg.																				
RA concerned may take further necessary action as per above decision of NC.																								

Case No.	118 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002629AM25
RA File Number	03AX04002320 AM25
Licence No and Date	0311036536/22/08/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0311024147 dated 02/06/2023, 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.
Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.
		2	Imidazole	0.310 kg.

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

Case No.	119 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002632AM25
RA File Number	30AX04000255 AM25
Licence No and Date	3011005627/22/08/2024

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.
METHOTREXATE INJECTION USP (15 MG/ML)(EACH ML CONTAINS: METHOTREXATE USP...15 MG, WATER FOR INJECTION USP...Q.S CONTAINING 0.103 KG OF METHOTREXATE)	1 Number	1	METHOTREXATE	16.50 mg.

METHOTREXATE INJECTION USP (50 MG/2ML)(EACH ML CONTAINS: METHOTREXATE USP...25 MG, WATER FOR INJECTION USP...Q.S CONTAINING 13.447 KG OF METHOTREXATE)	1 Number	2	METHOTREXATE	55.00 mg.
METHOTREXATE INJECTION USP (500 MG/5 ML)(EACH ML CONTAINS METHOTREXATE USP...100 MG, WATER FOR INJECTION USP...Q.SCONTAINING 10.000 KG OF METHOTREXATE)	1 Number	3	METHOTREXATE	550.00 mg.
METHOTREXATE INJECTION USP (1000mg/10ml)(EACH ML CONTAINS: METHOTREXATE USP...100 MG,WATER FOR INJECTION USP...Q.S CONTAINING 6.456 KG OF METHOTREXATE)	1 Number	4	METHOTREXATE	1100.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	120 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002640AM25
RA File Number	03AX04002521 AM25
Licence No and Date	0311036548/22/08/2024
Norms Committee Decision:	
The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-	

Sl. No	Export Product	Quantity
(i)	Medical Cream and Ointments(Glycerine Vaseline and Paraffin Cream 250gm [Total Wt. 800000Kgs(NetCont:Gly120000Kgs,Vase64000Kgs,ParaLiq 16000Kgs,Ste50% 16800Kgs,Ste95% 7200 Kgs,Cyclo20000Kgs,Sili4000 Kgs,Mac40000Kgs,Trie4000 Kgs)])	1 Number

Sl. No.	Import Items	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy and General Notes.

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	121 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002648AM25
RA File Number	03AX04002485 AM25
Licence No and Date	0311036574/22/08/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance	

authorization No.0311033608 dated 06/05/2024, 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.
ROSUVASTATIN TABLET BP / USP 40 MG.((Each Tablet contains Rosuvastatin Calcium 41.600mg) Eq. to Rosuvastatin 40 mg.	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	55.16 mg./40 mg. Tablet

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

Case No.	122 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002649AM25
RA File Number	03AX04002403 AM25
Licence No and Date	0311036576/22/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202425/6 dated 01/07/2024 against advance authorization No. 0311026825 dated 01/09/2023, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg

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

Case No.	123 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002674AM25
RA File Number	08AX04000823 AM25
Licence No and Date	0811012470/23/08/2024

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.
Paricalcitol Injection USP, 2 mcg/mL (1 mL)	1 Number	1	Paricalcitol	2.20 mcg.
Paricalcitol Injection USP, 5 mcg/mL (1 mL)	1 Number	2	Paricalcitol	5.50 mcg.
Paricalcitol Injection USP, 5 mcg/mL (2 mL)	1 Number	3	Paricalcitol	5.50 mcg.

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

Case No.	124 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025

HQ File Number	HQRNORM APPLY 00002694AM25
RA File Number	03AX04002297 AM25
Licence No and Date	0311036650/26/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Stepwise complete and balanced chemical reaction from MMA and DEO stage; with molecular weight and percentage yield on molar basis.	

Case No.	125 / NC/3/MEET/Mar/202425/19																				
Case Status	Case Approved																				
Party Name	APOTHECARY PHARMACEUTICALS PRIVATE LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																				
HQ File Number	HQRNORM APPLY 00002723AM25																				
RA File Number	31AX04000130 AM25																				
Licence No and Date	3111003822/27/08/2024																				
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>FLORFENICOL Veterinary Oral Liquid 5% w/v</td><td>4000 Liters</td><td>1</td><td>FLORFENICOL (MIN. 98%)</td><td>204.00 kg.</td></tr><tr><td>FLORFENICOL Veterinary Oral Liquid 10% w/v</td><td>3000 Liters</td><td>2</td><td>FLORFENICOL (MIN. 98%)</td><td>306.00 kg.</td></tr><tr><td>FLORFENICOL Veterinary Oral Liquid 20% w/v</td><td>2000 Liters</td><td>3</td><td>FLORFENICOL (MIN. 98%)</td><td>408.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	FLORFENICOL Veterinary Oral Liquid 5% w/v	4000 Liters	1	FLORFENICOL (MIN. 98%)	204.00 kg.	FLORFENICOL Veterinary Oral Liquid 10% w/v	3000 Liters	2	FLORFENICOL (MIN. 98%)	306.00 kg.	FLORFENICOL Veterinary Oral Liquid 20% w/v	2000 Liters	3	FLORFENICOL (MIN. 98%)	408.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
FLORFENICOL Veterinary Oral Liquid 5% w/v	4000 Liters	1	FLORFENICOL (MIN. 98%)	204.00 kg.																	
FLORFENICOL Veterinary Oral Liquid 10% w/v	3000 Liters	2	FLORFENICOL (MIN. 98%)	306.00 kg.																	
FLORFENICOL Veterinary Oral Liquid 20% w/v	2000 Liters	3	FLORFENICOL (MIN. 98%)	408.00 kg.																	

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

Case No.	126 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002725AM25
RA File Number	03AX04002299 AM25
Licence No and Date	0311036686/27/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28.08.2024 against Advance Authorisation No.0311032677 dated 31/03/2024,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.
SULFADOXINE	1 kg	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.
		2	SULFANILAMIDE	0.90 kg.
		3	DIMETHYL FORMAMIDE (DMF)	1.00 kg.

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

Case No.	127 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred

Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002727AM25
RA File Number	03AX04002597 AM25
Licence No and Date	0311036698/28/08/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	128 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00002729AM25										
RA File Number	03AX04002415 AM25										
Licence No and Date	0311036715/28/08/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance authorization No.0311033608 dated 06/05/2024, 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>ROSUVASTATIN TABLET BP / USP 20 MG.((Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.</td><td>1 Number</td><td>1</td><td>Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate</td><td>27.58 mg./20 mg. Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ROSUVASTATIN TABLET BP / USP 20 MG.((Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	27.58 mg./20 mg. Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ROSUVASTATIN TABLET BP / USP 20 MG.((Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	27.58 mg./20 mg. Tablet							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	129 / NC/3/MEET/Mar/202425/19																
Case Status	Case Approved																
Party Name	ANNORA PHARMA PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025																
HQ File Number	HQRNORM APPLY 00002738AM25																
RA File Number	09AX04000337 AM25																
Licence No and Date	0911007832/29/08/2024																
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 rowspan="3">Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5g/3.13g/ 1.6g per 6 Ounce,((Each 6-ouncebottle contains,SodiumSulfate USP 17.5 g Potassium Sulfate 3.13 g Magnesium Sulfate USP 1.6g))</td><td rowspan="3">1 Number Bottle</td><td>1</td><td>Sodium Sulfate USP</td><td>17.85 gm.</td></tr><tr><td>2</td><td>Potassium Sulfate</td><td>3.193 gm</td></tr><tr><td>3</td><td>Magnesium Sulfate USP</td><td>1.632 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5g/3.13g/ 1.6g per 6 Ounce,((Each 6-ouncebottle contains,SodiumSulfate USP 17.5 g Potassium Sulfate 3.13 g Magnesium Sulfate USP 1.6g))	1 Number Bottle	1	Sodium Sulfate USP	17.85 gm.	2	Potassium Sulfate	3.193 gm	3	Magnesium Sulfate USP	1.632 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5g/3.13g/ 1.6g per 6 Ounce,((Each 6-ouncebottle contains,SodiumSulfate USP 17.5 g Potassium Sulfate 3.13 g Magnesium Sulfate USP 1.6g))	1 Number Bottle	1	Sodium Sulfate USP	17.85 gm.													
		2	Potassium Sulfate	3.193 gm													
		3	Magnesium Sulfate USP	1.632 gm.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	130 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	USV PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002752AM25			
RA File Number	03AX04002550 AM25			
Licence No and Date	0311036761/29/08/2024			

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.
Desipramine Hydrochloride Tablets, USP 50 Mg 100 S((6,300 Bottles X 100 Per Bottles = 6,30,000 Tablets) (Total Weight of Export Product = 31.500 Kgs) (Net Content weight of Import Product = 33.355 kgs))	1 Number	1	Desipramine HCL USP	51 mg/50 mg Tablet
Desipramine Hydrochloride Tablets, USP 100 Mg 100 S((3,150 Bottles X 100 Per Bottles = 3,15,000 Tablets) (Total Weight of Export Product = 31.500 Kgs) (Net Content weight of Import Product = 33.355 kgs))	1 Number	2	Desipramine HCL USP	102 mg/100 mg Tablet
Desipramine Hydrochloride Tablets, USP 150 Mg 50 S((5,100 Bottles X 50 Per Bottles = 2,55,000 Tablets) (Total Weight of Export Product = 38.250 Kgs) (Net Content weight of Import Product = 40.503 kgs))	1 Number	3	Desipramine HCL USP	153 mg/150 mg Tablet

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

Case No.	131 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002762AM25
RA File Number	08AX04000876 AM25
Licence No and	0811012520/30/08/2024

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.
Calcium Gluconate in Sodium Chloride Injection 1,000 mg per 50 mL (20 mg per mL)	100502 Numbers	1	CALCIUM GLUCONATE MONOHYDRATE USP	103.416 kg.
Calcium Gluconate in Sodium Chloride Injection 2,000 mg per 100 mL (20 mg per mL)	150882 Numbers	2	CALCIUM GLUCONATE MONOHYDRATE USP	310.515 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	132 / NC/3/MEET/Mar/202425/19			
Case Status	Case Approved			
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025			
HQ File Number	HQRNORM APPLY 00002763AM25			
RA File Number	08AX04000877 AM25			
Licence No and Date	0811012521/30/08/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No.0811012112 dated 15/07/2024, 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.

Calcium Gluconate Injection, USP 1,000 mg per 10 mL (100 mg per mL)	1 Number	1	CALCIUM GLUCONATE MONOHYDRATE USP	1081.0 mg.
Calcium Gluconate Injection, USP 5,000 mg per 50 mL (100 mg per mL)	1 Number	2	CALCIUM GLUCONATE MONOHYDRATE USP	5145.0 mg.
Calcium Gluconate Injection, USP 10,000 mg per 100 mL (100 mg per mL)	1 Number	3	CALCIUM GLUCONATE MONOHYDRATE USP	10290.0 mg.

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

Case No.	133 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002764AM25
RA File Number	03AX04002545 AM25
Licence No and Date	0311036773/30/08/2024

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.
REMURES ULTRA (Diosmin 450 mg + Hesperidine 50 mg) coated tablets Pack 2 x 15 tablets = 30 Tablets in one Pack.(NET CONTENT = 225.00 KGS),TOTAL GROSS CONTENT (MFG OVERAGES 5% + 2% MFG	1 Number	1	DIOSMIN+HESPERIDINE	510 mg/Tablet

LOSS)=240.750 KGS				
REMURES ULTRA (Diosmin 450 mg + Hesperidine 50 mg) coated tablets Pack 4 x 15 tablets = 60 Tablets in one Pack.(NET CONTENT = 255.00KGS) , TOTAL GROSS CONTENT (MFG OVERAGES 5% + 2% MFG LOSS)= 272.85 KGS)	1 Number	2	DIOSMIN+HESPERIDINE	510 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	134 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	CLARIANT INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002789AM25
RA File Number	03AX04002663 AM25
Licence No and Date	0311036805/02/09/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. The norms approved in the past for the export of the same item dated 17.11023 wherein the 4th item Mono Ethanol Amine was not asked for, therefore, reason for asking the item this time. 2. Stoichiometric material balance of the reaction on a molar basis. 3. Calculation of the requirement of raw material Mono Ethanol Amine in the process indicating yield of the reaction. 4. Current production/consumption data duly certified by Chartered Accountant.	

Case No.	135 / NC/3/MEET/Mar/202425/19										
Case Status	Case Approved										
Party Name	MAKCUR LABORATORIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025										
HQ File Number	HQRNORM APPLY 00002790AM25										
RA File Number	08AX04000888 AM25										
Licence No and Date	0811012525/02/09/2024										
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>Ceftriaxone and Sulbactam for Injection 1.5 gm</td><td>1 Number</td><td>1</td><td>Ceftriaxone Sodium (Sterile IP USP)</td><td>1.16 gm.</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.	Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	1	Ceftriaxone Sodium (Sterile IP USP)	1.16 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	1	Ceftriaxone Sodium (Sterile IP USP)	1.16 gm.							

Case No.	136 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002795AM25
RA File Number	08AX04000872 AM25
Licence No and Date	0811012527/02/09/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No. 0811012198 dated 24/07/2024, 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.
CANDESARTAN CILEXETIL 2 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 0.180 KG IN EXPORT ITEM)	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.
CANDESARTAN CILEXETIL 4 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 1.440 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg.
CANDESARTAN CILEXETIL 8 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 5.760 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL 16 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 399.226 KG IN EXPORT ITEM)	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL 32 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 14.400 KG IN EXPORT ITEM)	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 8 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 2.520 KG IN EXPORT ITEM)	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 46.800 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +25 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 25 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

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

Case No.	137 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002810AM25
RA File Number	03AX04002721 AM25
Licence No and Date	0311036834/03/09/2024

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.
Acetazolamide ER capsules 500 MG 100 S, US((15,100 Bottles X 100 Capsules Per Bottles = 15,10,000 Capsules) (Total Weight of Export Product = 755.000 Kgs) (Net Content weight of Import Product = 853.150 kgs))	1 Number	1	Acetazolamide USP	510 mg/Capsule

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

Case No.	138 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025

HQ File Number	HQRNORM APPLY 00002813AM25			
RA File Number	05AX04001720 AM25			
Licence No and Date	0511027509/03/09/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0511026356 dated 27/06/2024, 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.
Atropine Sulfate Ophthalmic Solution USP, 1% 2 ml(Having net content of 3.27 kg of Bulk drug (filling volume 2.32 ml in each number))	1 Number	1	ATROPINE SULPHATE	20.40 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 5 ml(Having net content of 5.61 kg of Bulk drug (filling volume 5.61 ml in each number))	1 Number	2	ATROPINE SULPHATE	51.00 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 15 ml(Having net content of 4.77 kg of Bulk drug (filling volume 15.91 ml in each number))	1 Number	3	ATROPINE SULPHATE	153.0 mg.

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

Case No.	139 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002815AM25
RA File Number	03AX04002677 AM25

Licence No and Date	0311036840/03/09/2024
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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 Item	Qty	S.No.	Import item	Qty. allowed
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 20 MG & LUMEFANTRINE 120 MG DISPERSIBLE TABLETS	1 Number Tablet	1	ARTEMETHER	20.4 mg/Tablet
		2	LUMEFANTRINE	122.4 mg/Tablet
ARTEMETHER 40 MG & LUMEFANTRINE 240 MG TABLETS	1 Number Tablet	1	ARTEMETHER	40.8 mg/Tablet
		2	LUMEFANTRINE	244.8 mg/Tablet
ARTEMETHER 80 MG & LUMEFANTRINE 480 MG TABLETS	1 Number Tablet	1	ARTEMETHER	81.6 mg./Tablet
		2	LUMEFANTRINE	489.60 mg./Tablet

Norms Proposed for 1 kg of ARTEMETHER

Export Item	Qty	S.No.	Import item	Qty. allowed
ARTEMETHER	1Kg	1	Artemisinin	1.04 Kg
		2	Sodium Borohydride	0.188 Kg
		3	Trimethyl Ortho Acetate 99% MIN	0.50 Kg.

Norms Proposed for 1 kg of LUMEFANTRINE

Export Item	Qty	S.No.	Import item	Qty. allowed
LUMEFANTRINE	1Kg	1	2, 7 DICHLORO A DIBUTYLAMINO METHYL 9 HFLUORENE-4- METHANOL DBA 99 PERCENT MIN	0.86896 kg
		2	4-chlorobenzaldehyde	0.3476 Kg

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

Case No.	140 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002839AM25
RA File Number	34AX04000893 AM24
Licence No and Date	3411005354/04/09/2024

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.
Amantadine Hydrochloride capsules USP 100mg (Net content of active	1 Number	1	Amantadine Hydrochloride USP	102 mg./100 mg.

ingredients 1030.00 kgs)				
Amantadine Hydrochloride Tablets USP 100mg (Net content of active ingredients 1010.00 kgs)	1 Number	2	Amantadine Hydrochloride USP	102 mg./100 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	141 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	PRIVI FINE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002840AM25
RA File Number	03AX04002673 AM25
Licence No and Date	0311036880/04/09/2024
Norms Committee Decision:	
The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that input Privial (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feeding ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP and the RA concerned is directed to provide its comments.	

Case No.	142 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	PRIVI FINE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002841AM25
RA File Number	03AX04002672 AM25
Licence No and Date	0311036881/04/09/2024
Norms Committee Decision:	
The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of	

information provided by the firm and it has been observed by the committee that input Anethole (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that "For export of perfumes, perfumery compounds and various feeding ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP and the RA concerned is directed to provide its comments.

Case No.	143 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	UNION PARK CHEMICALS BOMBAY PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002859AM25
RA File Number	03AX04002739 AM25
Licence No and Date	0311036906/05/09/2024

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.
OMEPRAZOLE SULPHIDE	1 kg.	1	3 5 LUTIDINE	0.80 kg.
		2	HYDROGEN PEROXIDE	1.00 kg.
		3	METHANOL	1.14 kg.
		4	CAUSTIC SODA LYE OR FLAKES	1.36 kg.
		5	TOLUENE	2.00 kg.
		6	ACETONE	0.85 kg.

		7	NITRIC ACID	Not an importable item.
		8	PARA ANISIDINE	0.57 kg.
		9	METHYLENE CHLORIDE	0.38 kg.
		10	AMMONIUM SULPHATE	1.24 kg.

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

Case No.	144 / NC/3/MEET/Mar/202425/19
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002874AM25
RA File Number	09AX04000408 AM25
Licence No and Date	0911007869/05/09/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	145 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002877AM25
RA File Number	08AX04000909 AM25
Licence No and Date	0811012561/05/09/2024
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.
Opipramol Dihydrochloride Tablets 50 MG (OPIPRAMOL HEUMANN 50 MG)(Each film coated tablet contains: Opipramol Dihydrochloride 50 mg Excipients....q.s. Net content of active ingredient Opipramol Dihydrochloride should not be less than 196.00 kgs in export product.)	1 Number	1	Opipramol Dihydrochloride	51 mg/Tablet
Opipramol Dihydrochloride Tablets 100 MG (OPIPRAMOL HEUMANN 100 MG)(Each film coated tablet contains:Opipramol Dihydrochloride 100 mg Excipients....q.s. Net content of active ingredient Opipramol Dihydrochloride should not be less than 192.00 kgs in export product.)	1 Number	2	Opipramol Dihydrochloride	102 mg/Tablet

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

Case No.	146 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00002883AM25
RA File Number	03AX04002788 AM25
Licence No and Date	0311036927/05/09/2024
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.
Beclometasone Dipropionate and Formoterol Fumarate Dihydrate Pressurised Inhalation Solution (100+6 mcg/actuation) 120MD ((Net weight of Beclometasone Dipropionate Ph.Eur is 2400.00 Grams))	200000 Numbers	1	Beclometasone Dipropionate Ph.Eur	11.322 kg.
Beclometasone Dipropionate and Formoterol Fumarate Dihydrate Pressurised Inhalation Solution (200+6 mcg/actuation) 120MD((Net weight of Beclometasone Dipropionate Ph.Eur is 2400.00 Grams))	100000 Numbers	2	Beclometasone Dipropionate Ph.Eur	
Beclometasone Dipropionate and Formoterol Fumarate Dihydrate Pressurised Inhalation Solution (100+6 mcg/actuation) 180MD((Net weight of Beclometasone Dipropionate Ph.Eur is 2700.00 Grams))	150000 Numbers	3	Beclometasone Dipropionate Ph.Eur	
Beclometasone Dipropionate and Formoterol Fumarate Dihydrate Pressurised Inhalation Solution (200+6 mcg/actuation) 180MD((Net weight of Beclometasone Dipropionate Ph.Eur is 3600.00 Grams))	100000 Numbers		Beclometasone Dipropionate Ph.Eur	

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

Case No.	147 / NC/3/MEET/Mar/202425/19
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Case Status	Case Approved
Party Name	TITAN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM APPLY 00003684AM25
RA File Number	03AX04003549 AM25
Licence No and Date	0311037997/16/10/2024

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.
FERROUS SULPHATE 325 MG AND SODIUM ASCORBATE 562.4 MG-30 TABLET PER BOTTLE (PACKED IN 303400 HDPE BOTTLES WITH CAPS)	1 Number	1	40 ML HDPE WHITE BOTTLES NECK	Relevant, as per Packing Policy & General Notes.
		2	WHITE CR CAP 28 MM HIS LINER	Relevant, as per Packing Policy & General Notes.
		3	KOLLIDON 90F	100 mg.
FERROUS SULPHATE 325 MG AND SODIUM ASCORBATE 562.4 MG-30 TABLET PER BOTTLE (PACKED IN 303400 HDPE BOTTLES WITH CAPS)	1 Number	4	40 ML HDPE WHITE BOTTLES NECK	Relevant, as per Packing Policy & General Notes.
		5	RED CAPS C.P.28	Relevant, as per Packing Policy & General Notes.
		6	KOLLIDON 90F	100 mg.
FERRO-GRAD (FERROUS SULFATE 325 MG - 30 TABLET PER BOTTLE) (PACKED IN 88500 BOTTLES WITHCAPS)	1 Number	7	40 ML HDPE WHITE BOTTLES NECK	Relevant, as per Packing Policy & General Notes.
		8	GREEN CAPS C.P.28	Relevant, as per

				Packing Policy & General Notes.
FERRO-GRAD F (FERROUS SULFATE 250 MG FOLIC ACID 300 MICROGRAMS-30 TABLET PER BOTTLE) (PACKED IN 46300 BOTTLES WITH CAPS)	1 Number	9	40 ML HDPE WHITE BOTTLES NECK	Relevant, as per Packing Policy & General Notes.
		10	CAPSULA C.P. 28 ARANCIA INCISA II-2 YGR/205-28RP	Relevant, as per Packing Policy & General Notes.

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

Case No.	148 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006515AM25
RA File Number	03AX04004432 AM25
Licence No and Date	0311039321/04/12/2024
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	
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		5	N NDimethylacetamide	1.678 kg.
		6	Sodium t pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.
		8	N-butyl lithium (25% in N-Haptane)	1.826 kg.

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

Case No.	149 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006516AM25
RA File Number	03AX04004476 AM25
Licence No and Date	0311039416/06/12/2024

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	n-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.

		5	N NDimethylacetamide	1.678 kg.
		6	Sodium t pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.
		8	N-butyl lithium (25% in N-Haptane)	1.826 kg.

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

Case No.	150 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006518AM25
RA File Number	03AX04005025 AM25
Licence No and Date	0311040113/02/01/2025

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	n-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.

		5	N NDimethylacetamide	1.678 kg.
		6	Sodium t pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.
		8	N-butyl lithium (25% in N-Haptane)	1.826 kg.

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

Case No.	151 / NC/3/MEET/Mar/202425/19
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 19 and 27/03/2025
HQ File Number	HQRNORM REVIW00006519AM25
RA File Number	03AX04005023 AM25
Licence No and Date	0311040114/02/01/2025

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.137 kg.
		2	n-Heptane	1.808 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.

		5	N NDimethylacetamide	1.678 kg.
		6	Sodium t pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.
		8	N-butyl lithium (25% in N-Haptane)	1.826 kg.

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