



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

Meeting No -NC/3/MEET/Jul/202526/6

Meeting Date -31/07/2025

Minutes of the Norms Committee-3 Meeting No.NC/3/MEET/Jul/202526/6 dated 31/07/2025 under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

2. The 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	Smt. Skina Rani, FTDO	DGFT (HQ)

3. The Norms Committee has taken decisions only with respect to the 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 regularisation of the case.

4. RAs shall ensure compliance with SION, General Notes and Chapter Notes wherever applicable.

5. RAs shall also ensure that authorisation 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 with the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21, and Para 4.51 of HBP shall be made.

Case No.	1 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM REVW00001550AM26
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016

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:-

Sl.No.	Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1	Soltel CFC Free / Vertine CFC Free / Pulveril / Neovent Inhaler 25 mcg (120MD) Salmeterol / SOLTEL CFC-FREE INHALER 25 MCG (with 63 mcl Aerosol Valve, 14 ml Aluminium Can, 0.42	1 Number	15	63 mcl Aerosol Valves	As per packing policy and General Notes.
			24	14 ml Aluminium Can	As per packing policy and

	Actuator 134 A HFA 12.544 gms, Alcohol 0.256 gms)				General Notes.
			43	0.42 mm OD Actuators With Dust Covers / Caps	As per packing policy and General Notes.
			61	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.408 gm.
			81	ETHANOL	0.256 gm.
2	Foratec Inhaler (CFC Free) (120 MD) / FOROTEL Inhaler (120 MD)/ Formoterol 12 mcg Inhaler (CFC Free) (120MD) (with 40mcl Aerosol Valve, 10ml Aluminium Can with 0.48mm Actuator 134 A HFA 7.84 gms, Alcohol 0.16 gms)	1 Number	1	40 mcl Aerosol Valves	As per packing policy and General Notes.
			21	10 ml Aluminium Can	As per packing policy and General Notes.
			44	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			62	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	5.88 gm.
			82	ETHANOL	0.160 gm.
3	Airflusal 25/250 mcg / Fluticort Plus / Seroflo 25/250mcg / Seroflo 250mcg Inhaler (120	1 Number	10	61mcl Aerosol Valves	As per packing policy and General

	MD) Salmeterol 25 mcg (&Fluticasone Propionate 250 mcg Inhaler (120MD) with 61mcl Aerosol Valve,14 ml Aluminium Can with 0.48 mm Actuator 134 A HFA 12.50 gms)				Notes.
			25	14 ml Aluminium Can	As per packing policy and General Notes.
			45	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			63	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	8.982 gm.
4	Airflusal 25/125 mcg / Fluticort Plus 125mcg HFA / Seroflo 25/125mcg / Seroflo 125mcg / Salmeterol 25 mcg & Fluticasone (Propionate125 mcg Inhaler (120MD) with 61 mcl Aerosol Valve, 14 ml Aluminium Can with 0.48 mm Actuator134 AHFA 12.50 gms)	1 Number	11	61 mcl Aerosol Valves	As per packing policy and General Notes.
			26	14 ml Aluminium Can	As per packing policy and General Notes.
			46	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			64	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	8.982 gm.
5	Beclate / Beclort HFA / Beclometasone Dipropionate / Aircort /	1 Number	16	63 mcl Aerosol Valves	As per packing policy and

	Beclometasone Pressurised Inhalation / Beclocross (/Beclocip HFA / BECLOMARC FC Free 50 MCG Inhaler (200MD) with 63 mcl Aerosol Valve, 19 ml Aluminium Can with 0.48 mm Actuator 134A HFA 17.772 gms, Alcohol 0.456 gms)				General Notes.
			31	19 ml Aluminium Can	As per packing policy and General Notes.
			47	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			65	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	14.817 gm.
			83	ETHANOL	0.456 gm.
6	Beclate / Beclort HFA / Beclometasone Dipropionate / Aircort / Beclometasone Pressurised Inhalation / Beclocross / (Beclocip HFA / BECLOMARC FC Free 100 MCG Inhaler (200 MD) with 63 mcl Aerosol Valve, 19 ml Aluminium Can with 0.48 mm Actuator 134 A HFA 17.304 gms, Alcohol 0.912 gms)	1 Number	17	63 mcl Aerosol Valves	As per packing policy and General Notes.
			32	19 ml Aluminium Can	As per packing policy and General Notes.
			48	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			66	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	14.442 gm.

			84	ETHANOL	0.912 gm.
7	Beclate / Beclort HFA / Beclometasone Dipropionate / Aircort / Beclometasone Pressurised Inhalation / Beclocross (/ Beclocip HFA / BECLOMARC FC Free 200 MCG Inhaler (200 MD) with 63 mcl Aerosol Valve ,19 ml Aluminium Can with 0.48 mm Actuator134 A HFA 16.368 gms, Alcohol 1.824 gms)	1 Number	18	63 mcl Aerosol Valves	As per packing policy and General Notes.
			33	19 ml Aluminium Can	As per packing policy and General Notes.
			49	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			67	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	13.683 gm.
			85	ETHANOL	1.824 gm.
8	Beclate / Beclort HFA / Beclometasone Dipropionate / Aircort / Beclometasone Pressurised Inhalation / Beclocross /(Beclocip HFA / BECLOMARC FC Free 250 MCG Inhaler (200 MD) with 63 mcl Aerosol Valve, 19 ml Aluminium Can with 0.48 mm Actuator134A HFA 15.900 gms, Alcohol 2.280 gms)	1 Number	19	63 mcl Aerosol Valves	As per packing policy and General Notes.
			34	19 ml Aluminium Can	As per packing policy and General Notes.
			50	0.48 mm OD Actuators With Dose Counter	As per packing policy and General

					Notes.
			68	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	13.30 gm.
			86	ETHANOL	2.28 gm.
9	Ciclesonide Inhaler 80 mcg (120 MD) Ciclohale 80 Inhaler (120 MD) Disbronc 80 Inhaler (120 MD)(with 50 mcl Aerosol Valve, 10 ml Aluminium Can, 0.33 Actuator 134A HFA 9.010 gms, Alcohol 0.576 gms)	1 Number	2	50 mcl Aerosol Valves	As per packing policy and General Notes.
			22	10 ml Aluminium Can	As per packing policy and General Notes.
			41	0.33 mm OD Actuators With Dust Covers /Caps	As per packing policy and General Notes.
			69	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	6.761 gm.
			87	ETHANOL	0.58 gm.
10	Ciclesonide Inhaler 160 mcg (120 MD) Ciclohale 160 Inhaler (120 MD) Disbronc 160 Inhaler (120 MD) (with 50 mcl Aerosol Valve, 10 ml Aluminium Can, 0.33 Actuator 134A HFA 8.995 gms, Alcohol 0.576 gms)	1 Number	3	50 mcl Aerosol Valves	As per packing policy and General Notes.
			23	10 ml Aluminium Can	As per packing policy and General Notes.

			42	0.33 mm OD Actuators With Dust Covers /Caps	As per packing policy and General Notes.
			70	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	6.746 gm.
			88	ETHANOL	0.58 gm.
11	Aerodini / Bulmol / Salcross HFA / Asthalin / Salair Salbutamol Pressurised Inhalation BP / (SALBUREX 100 mcg Inhaler (200 MD) with 50 mcl Aerosol Valve, 19 ml Aluminium Can, 0.48 Actuator 134A HFA 18.20 gms)	1 Number	4	50 mcl Aerosol Valves	As per packing policy and General Notes.
			35	19 ml Aluminium Can	As per packing policy and General Notes.
			51	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			71	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	15.20 gm.
12	Budespray HFA / Budecort Budesonide / BUDEMAR 200 mcg Inhaler (200 MD) (with 58mcl Aerosol Valve, 19 ml Aluminium Can, 0.48 Actuator 134A HFA 18.20 gms)	1 Number	6	58 mcl Aerosol Valves	As per packing policy and General Notes.
			36	19 ml Aluminium Can	As per packing policy and

					General Notes.
			52	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			72	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	15.20 gm.
13	Budespray HFA / Budecort Budesonide / BUDEMAR 200 mcg Inhaler (200 MD) (with 58mcl Aerosol Valve, 19 ml Aluminium Can, 0.48 Actuator 134A HFA 18.20 gms)	1 Number	7	58 mcl Aerosol Valves	As per packing policy and General Notes.
			37	19 ml Aluminium Can	As per packing policy and General Notes.
			53	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			73	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	15.20 gm.
14	Formoterol Fumarate and Budesonide Inhaler 6/100 mcg (120MD) / Foracort 100 Inhaler (120 MD) (with 58mcl Aerosol Valve, 19 ml Aluminium Can, 0.48 Actuator 134A HFA 12.20 gms)	1 Number	8	58 mcl Aerosol Valves	As per packing policy and General Notes.
			38	19 ml Aluminium Can	As per packing

					policy and General Notes.
			54	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			74	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.15 gm.
15	Formoterol Fumarate and Budesonide Inhaler 6/200 mcg (120MD) / Foracort 100 Inhaler (120MD) (with 58mcl Aerosol Valve, 19 ml Aluminium Can, 0.48 Actuator 134A HFA 12.20 gms)	1 Number	9	58 mcl Aerosol Valves	As per packing policy and General Notes.
			39	19 ml Aluminium Can	As per packing policy and General Notes.
			55	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			75	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.15 gm.
16	Beclomethasone Dipropionate 50 mcg and Salbutamol 100 mcg Aerocort HFA / Aeroday / Asmabron HFA (Asthalin B Inhaler (200 MD) with 50 mcl Aerosol Valve,	1 Number	5	50 mcl Aerosol Valves	As per packing policy and General Notes.
			40	19 ml Aluminium Can	As per

	19 ml Aluminium Can, 0.48 Actuator 134A HFA 14.04 gms, Ethanol 0.36 gms)				packing policy and General Notes.
			56	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			76	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	11.70 gm.
			89	ETHANOL	0.36 gm.
17	Fluticasone Propionate / Floair 50mcg Inhaler (120 MD) Flohale / TRUFLO 50 Inhaler (120 MD) (with 61mcl Aerosol Valve, 14 ml Aluminium Can, 0.48 Actuator 134A HFA 12.50 gms, Ethanol 0.256 gms)	1 Number	12	61 mcl Aerosol Valves	As per packing policy and General Notes.
			27	14 ml Aluminium Can	As per packing policy and General Notes.
			57	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			77	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.405 gm.
			90	ETHANOL	0.26 gm.
18	Fluticasone Propionate 125 mcg Inhaler (120	1 Number	13	61 mcl Aerosol Valves	As per packing

	MD) Flohale / TRUFLO 125 Inhaler (120MD) (with 61mcl Aerosol Valve, 14 ml Aluminium Can, 0.48 Actuator 134A HFA 12.50 gms, Ethanol 0.256 gms)				policy and General Notes.
			28	14 ml Aluminium Can	As per packing policy and General Notes.
			58	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			78	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.405 gm.
			91	ETHANOL	0.26 gm.
19	Fluticasone Propionate 250 mcg Inhaler (120 MD) Flohale / TRUFLO 250 Inhaler (120 MD) (with 61mcl Aerosol Valve, 14ml Aluminium Can, 0.48 Actuator 134A HFA 12.50 gms, Ethanol 0.256 gms)	1 Number	14	61mcl Aerosol Valves	As per packing policy and General Notes.
			29	14 ml Aluminium Can	As per packing policy and General Notes.
			59	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			79	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.405 gm.

			92	ETHANOL	0.26 gm.
20	Fluticort Plus – 50 mcg HFA / Salmeterol 25 mcg and Fluticasone Propionate 50 mcg / Flunacross S - (50 mcg HFA Inhaler (120 MD) with 63 mcl Aerosol Valve, 14 ml Aluminium Can, 0.48 Actuator 134A HFA 12.50 gms, Ethanol 0.256 gms)	1 Number	20	63 mcl Aerosol Valves	As per packing policy and General Notes.
			30	14 ml Aluminium Can	As per packing policy and General Notes.
			60	0.48 mm OD Actuators With Dose Counter	As per packing policy and General Notes.
			80	1,1,1,2,Tetrafluoroethane (HFA 134A Propellant)	9.405 gm.
			93	ETHANOL	0.26 gm.

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

Case No.	2 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MANNITAB PHARMA SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005338AM24
RA File Number	31AX04000075 AM24
Licence No and Date	3111002606/31/08/2023
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.
Mannitol Fine Grade F1, F2 & F3) in White Powder Form (16-25 Micron)	176.0 MT.	1	Mannitol Raw material in White Powder Form (100-150 Micron)	179.52 MT.

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

Case No.	3 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005992AM24
RA File Number	03AX04002781 AM24
Licence No and Date	0311027528/03/10/2023
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. Percentage Yield on molar basis for each step of manufacturing process may be furnished.	

Case No.	4 / NC/3/MEET/Jul/202526/6
Case Status	Case Rejected
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM REVIW00000628AM25
RA File Number	03AX04003995 AM24
Licence No and	0311029148/06/12/2023

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

Case No.	5 / NC/3/MEET/Jul/202526/6
Case Status	Case Rejected
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM REVIW00000622AM25
RA File Number	34AX04000854 AM24
Licence No and Date	3411004626/16/02/2024
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, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	6 / NC/3/MEET/Jul/202526/6				
Case Status	Case Approved				
Party Name	EAST AFRICAN INDIA OVERSEAS				
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025				
HQ File Number	HQRNORM REVIW00001000AM26				
RA File Number	05AX04003662 AM24				
Licence No and Date	0511024074/26/02/2024				
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.

Cefiprin 200 Tablet (Cefixime 200 mg Tablet (Pack Size - 1 X 10'S))	1 Number	1	Cefixime Trihydrate	228.294 mg/Tablet
Cefiprin 400 Tablet (Cefixime 400 mg Tablet (Pack Size - 1 X 10'S))	1 Number	2	Cefixime Trihydrate	456.588 mg/Tablet
Virexim 400 Capsule (Cefixime 400 mg Capsule (Pack Size - 10 X 10'S))	1 Number	3	Cefixime Trihydrate	456.588 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	7 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM REVIW00000986AM26
RA File Number	05AX04003663 AM24
Licence No and Date	0511023926/26/02/2024
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 following information / documents from the firm: 1. Shipping Bill and Bill of Entry.	

Case No.	8 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
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 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">3-Methoxy-2-methylbenzoyl chloride (MMBC) (CAS No.: 24487-91-0)</td><td rowspan="2">1 kg.</td><td>1</td><td>2-Chloro-6-Methoxy Toluene (MCT) (CAS No.:3260-88-6)</td><td>1.10 kg.</td></tr><tr><td>2</td><td>Tetrahydrofuran (THF) (CAS No.: 109-99-9)</td><td>0.22 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	3-Methoxy-2-methylbenzoyl chloride (MMBC) (CAS No.: 24487-91-0)	1 kg.	1	2-Chloro-6-Methoxy Toluene (MCT) (CAS No.:3260-88-6)	1.10 kg.	2	Tetrahydrofuran (THF) (CAS No.: 109-99-9)	0.22 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.														
3-Methoxy-2-methylbenzoyl chloride (MMBC) (CAS No.: 24487-91-0)	1 kg.	1	2-Chloro-6-Methoxy Toluene (MCT) (CAS No.:3260-88-6)	1.10 kg.														
		2	Tetrahydrofuran (THF) (CAS No.: 109-99-9)	0.22 kg.														
RA concerned may take further necessary action as per above decision of NC.																		

Case No.	9 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00004984AM25			
RA File Number	07AX04001544 AM25			
Licence No and Date	0711013122/23/12/2024			
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/202425/18 dated 17/03/2025 against advance authorization No. 0711009558 dated 27/10/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160 MG ODT	1 kg.	1	Phloroglucinol Dihydrate EP	0.359 kg.

PREMIX ((EACH 450 mg PREMIX CONTAINS 160 mg Phloroglucinol) contents 534 kg of Phloroglucinol))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	10 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00004983AM25
RA File Number	03AX04004795 AM25
Licence No and Date	0311039828/23/12/2024
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:- Complete chemistry, chemical reaction and stichometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	11 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00004974AM25
RA File Number	08AX04001582 AM25
Licence No and Date	0811013569/23/12/2024
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.
Ephedrine Sulfate Injection, USP 50 mg/mL, 1 Ml	1 Number	1	Ephedrine Sulfate USP	55.00 mg.

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

Case No.	12 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	DR.REDDY'S LABORATORIES LTD			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00004969AM25			
RA File Number	09AX04000856 AM25			
Licence No and Date	0911008680/23/12/2024			
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/202425/19 dated 27/03/2025 against advance authorization No. 0911007744 dated 16/08/2024, 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.
Aspirin and Extended-Release Dipyridamole Capsules 25 mg/200 mg Pack Size:60s (Consist of 1080 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.	13 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	VINEET LABORATORIES LIMITED			
Meeting Number	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			

and Date				
HQ File Number	HQRNORM APPLY 00004966AM25			
RA File Number	09AX04000835 AM25			
Licence No and Date	0911008679/23/12/2024			
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/202526/3 dated 04/06/2025 against advance authorization No. 0311038141 dated 22/10/2024, 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.
N Butyl Lithium 30% w/w in Hexane solution	1 kg.	1	N-Butyl Chloride	0.540 kg.
		2	Lithium Metal	0.0812 kg.
		3	n-Hexane	1.450 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	14 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	RUBICON RESEARCH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00004993AM25			
RA File Number	03AX04004754 AM25			
Licence No and Date	0311039832/23/12/2024			
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/202526/2 dated 08/05/2025 against advance authorization No. 0311037482 dated 27/09/2024, 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.

Naloxon HCL Nasal Spray 4 mg/Spray 125 ml (Packing metrial Cont_Holder-PP-White as per export qty))	900000 Numbers	1	Cont_Holder-PP-White	Relevant as per Packing Policy & General Notes with accountability.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	15 / NC/3/MEET/Jul/202526/6										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025										
HQ File Number	HQRNORM APPLY 00005012AM25										
RA File Number	07AX04001543 AM25										
Licence No and Date	0711013126/24/12/2024										
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. 0711011543 dated 11/06/2024, 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Bromocriptine Tablets 2.5 mg.</td><td>1 Number</td><td>1</td><td>Bromocriptine Mesilate BP/EP/IP/USP</td><td>2.927 mg/Tablet.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Bromocriptine Tablets 2.5 mg.	1 Number	1	Bromocriptine Mesilate BP/EP/IP/USP	2.927 mg/Tablet.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Bromocriptine Tablets 2.5 mg.	1 Number	1	Bromocriptine Mesilate BP/EP/IP/USP	2.927 mg/Tablet.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	16 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	SANOFI CONSUMER HEALTHCARE INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005009AM25			
RA File Number	03AX04004794 AM25			

Licence No and Date	0311039854/24/12/2024			
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/202324/6 dated 14/06/2023 against advance authorization No. 0311021689 dated 24/02/2023, 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.
Festal Dragees (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 3738.32 Kgs Strength of Pancreatin 192 mg/Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg

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

Case No.	17 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005027AM25			
RA File Number	09AX04000761 AM25			
Licence No and Date	0911008698/24/12/2024			
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/202526/3 dated 04/06/2025 against advance authorization No. 0911007027 dated 03/04/2024, 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.
Atinvcitinib((or) 1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-carboxamide (L-005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	1.975 kg
		2	4,5-bis (Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.125 kg

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

Case No.	18 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	DR. DALAVAI'S LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005024AM25
RA File Number	07AX04001494 AM25
Licence No and Date	0711013142/24/12/2024

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/202526/2 dated 08/05/2025 against advance authorization No. 0711012501 dated 07/10/2024, 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.
Minoxidil Intermediate (2,4-Diamino-6-Chlro Pyrimidine)	1 kg.	1	Barbituric Acid	1.00 kg.

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

Case No.	19 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005013AM25
RA File Number	07AX04001546 AM25
Licence No and Date	0711013127/24/12/2024
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/202526/1 dated 25/04/2025 against advance authorization No. 0711012350 dated 18/09/2024, 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.
Dicloxacillin Capsules 500 mg.	1 Number	1	Dicloxacillin Sodium BP/EP/USP	535.0 mg/500 mg Capsule

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

Case No.	20 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005050AM25
RA File Number	07AX04001565 AM25
Licence No and Date	0711013151/25/12/2024

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 chemistry with molecular weight and Percentage Yield on molar basis.
2. Justification for requirement of various enzymes supported by technical literature, and their recovery.
3. Past production/consumption data certified by C.A.

Case No.	21 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	ARESKO LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025

HQ File Number	HQRNORM APPLY 00005075AM25
RA File Number	05AX04002970 AM25
Licence No and Date	0511029889/26/12/2024
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 for each export item as per Annexures to Appendix 4E.	

Case No.	22 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005067AM25
RA File Number	03AX04004577 AM25
Licence No and Date	0311039919/26/12/2024
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:- Complete chemistry, chemical reaction, and stichometric balance on molar basis with Molecular weight and percentage yield for each step of reaction.	

Case No.	23 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005068AM25
RA File Number	03AX04004874 AM25
Licence No and Date	0311039920/26/12/2024
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:-

Complete chemistry, chemical reaction, and stichometric balance on molar basis with Molecular weight and percentage yield for each step of reaction.

Case No.	24 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005073AM25
RA File Number	07AX04001547 AM25
Licence No and Date	0711013156/26/12/2024

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. 0711011047 dated 12/04/2024, 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.
Premix Of Nifuroxazide (Each gm of Premix contains Nifuroxazide 0.552 gm)	12600 kg.	1	Nifuroxazide BP/EP	7024.752 kg.

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

Case No.	25 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005077AM25
RA File Number	03AX04004815 AM25
Licence No and Date	0311039942/26/12/2024

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/202526/3 dated 04/06/2025 against advance authorization No. 0311037957 dated 15/10/2024, 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.
Azithromycin Dihydrate	1 kg	1	Azithromycin Amine	0.9434 kg.

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

Case No.	26 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005116AM25
RA File Number	03AX04004920 AM25
Licence No and Date	0311039980/27/12/2024

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. 0311035328 dated 10/07/2024, 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.
Felodipine ER Tablets 2.5 mg 100s ((9,000 Bottles X 100 Per Bottles = 9,00,000 Tablets) (Total Weight of Export Product = 2.250 Kgs) (Exempts imported input/material weight inclusive of wastage = 2.368 Kgs))	1 Number Tablet	1	Felodipine	2.55 mg/2.5 mg Tablet
Felodipine ER Tablets 5.0 mg 100s	1 Number	2	Felodipine	5.10 mg/5 mg Tablet

((30,000 Bottles X 100 Per Bottles = 30,00,000 Tablets) (Total Weight of Export Product = 15.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 15.789 Kgs))	Tablet			
Felodipine ER Tablets 10 mg 100s ((15,000 Bottles X 100 Per Bottles = 15,00,000 Tablets) (Total Weight of Export Product = 15.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 15.789 Kgs))	1 Number Tablet	3	Felodipine	10.20 mg/10 mg Tablet

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

Case No.	27 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	VITAL LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005107AM25			
RA File Number	03AX04004914 AM25			
Licence No and Date	0311039977/27/12/2024			
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/202526/2 dated 08.05.2025 against advance authorization No.0311039829 dated 23.12.2024, 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.
Lumefantrine PH.I	1 kg.	1	9 H Fluorene	0.814 kg.
		2	Para Chloro Benzaldehyde	0.336 kg.
		3	Methanol	3.305 kg.

		4	Methylene Dichloride (MDC)	1.83 kg.
		5	Isopropyl Alcohol	0.110 kg.
		6	Dimethyl Formamide	0.555 kg.
		7	Chloro Acetyl Chloride	0.380 kg.
		8	Sodium Borohydride Powder	0.040 kg.
		9	Dibutyl Amine	0.390 kg.
		10	N-Butanol	0.20 kg.
		11	Ethyl Acetate	0.88 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	28 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005225AM25
RA File Number	05AX04003442 AM25
Licence No and Date	0511029973/30/12/2024

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.
Levonorgestrel EP 1.5 MG Tablet	1 Number	1	Levonorgestrel EP	1.53 mg/Tablet

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

Case No.	29 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005191AM25
RA File Number	09AX04000853 AM25
Licence No and Date	0911008726/30/12/2024

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.
Dalbavancin for Injection 500 mg per Vial (Each Vial contains 500 mg of Dalbavancin)	1 Number	1	Dalbavancin Hydrochloride	535.50 mg.

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

Case No.	30 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MEDIPRAT INTERNATIONAL (INDIA)
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005167AM25
RA File Number	05AX04003369 AM25
Licence No and Date	0511029942/30/12/2024

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.
Cocarboxylase HCL 50 MG / 2 ML Injection	1 Number	1	CAS 154-87-0 Cocarboxylase HCL	55.00 mg/Vial

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

Case No.	31 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005164AM25
RA File Number	05AX04003326 AM25
Licence No and Date	0511029939/30/12/2024

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/202526/3 dated 04/06/2025 against advance authorization No. 0511028402 dated 18/10/2024, 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.
Doxepin Hydrochloride Capsules USP 10 mg.	1 Number	1	Doxepin HCL	11.353 mg
Doxepin Hydrochloride Capsules USP 25 mg.	1 Number	2	Doxepin HCL	28.384 mg
Doxepin Hydrochloride Capsules USP 50 mg.	1 Number	3	Doxepin HCL	56.766 mg
Doxepin Hydrochloride Capsules	1 Number	4	Doxepin HCL	85.152 mg

USP 75 mg.				
Doxepin Hydrochloride Capsules USP 100 mg.	1 Number	5	Doxepin HCL	113.538 mg

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

Case No.	32 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005272AM25
RA File Number	03AX04004968 AM25
Licence No and Date	0311040043/31/12/2024

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:-

Sl. No	Export Product	Quantity
1	Medical Cream and Ointment (Imiquimod Cream 5% 0.25 Gm 24? Sachets Total 1 Number Wet 390 Kgs. (Net Cont. Imiquimod 19.50 Kgs, Polysorbate 15.60 Kgs, Sorbitan 2.34 Kgs))	

S. No	Import Product	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 & General Notes.

Note:

- i. 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.	33 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SAPTAGIR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005275AM25
RA File Number	09AX04000908 AM25
Licence No and Date	0911008741/31/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	34 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	VITAL LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005281AM25			
RA File Number	03AX04004988 AM25			
Licence No and Date	0311040054/31/12/2024			
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.
Artemether PH.I/ USP	1 kg.	1	Artemisinin	1.04 kg.
		2	Trimethyl Ortho Acetate	0.50 kg.

Artesunate PH.I	1 kg.	3	Artemisinin	0.80 kg.
Dihydro Artemisinin	1 kg.	4	Artemisinin	0.92 kg.

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

Case No.	35 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	VITAL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005282AM25
RA File Number	03AX04004989 AM25
Licence No and Date	0311040055/31/12/2024

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.
Artemether PH.I/ USP	1 kg.	1	Artemisinin	1.04 kg.
		2	Trimethyl Ortho Acetate	0.50 kg.
Artesunate PH.I	1 kg.	3	Artemisinin	0.80 kg.
Dihydro Artemisinin	1 kg.	4	Artemisinin	0.92 kg.

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

Case No.	36 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025													
HQ File Number	HQRNORM APPLY 00005289AM25													
RA File Number	03AX04005012 AM25													
Licence No and Date	0311040059/31/12/2024													
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. 0311027099 dated 14/09/2023, 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 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>Acetyl Salicylic acid 75 mg Film coated Tablets (Net Wt. Acetyl Salicylic Acid 900.00 KGS))</td> <td>1 Number</td> <td>1</td> <td>Acetyl Salicylic Acid</td> <td>76.50 mg/Tablet</td> </tr> </tbody> </table> Note: The Committee also recommended making new SION for above export product. RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Acetyl Salicylic acid 75 mg Film coated Tablets (Net Wt. Acetyl Salicylic Acid 900.00 KGS))	1 Number	1	Acetyl Salicylic Acid	76.50 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Acetyl Salicylic acid 75 mg Film coated Tablets (Net Wt. Acetyl Salicylic Acid 900.00 KGS))	1 Number	1	Acetyl Salicylic Acid	76.50 mg/Tablet										

Case No.	37 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	ALCHYMARS ICM SM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005290AM25
RA File Number	04AX04000666 AM25
Licence No and Date	0411008818/31/12/2024
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. 0411005827 dated 07/08/2023, 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.
Clindamycin Hydrochloride Active Pharmaceutical Ingredient	1 kg	1	Lincomycin Hydrochloride Raw Material	1.43 kg

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

Case No.	38 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	SCL LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005308AM25
RA File Number	30AX04000553 AM25
Licence No and Date	3011006288/31/12/2024

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/202526/1 dated 25/04/2025 against advance authorization No. 3011004726 dated 29/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
QUETI-VII-R (Crude quetiapine fumarate)[2-[2-(4-dibenzo [b,f] [1,4] thiazepin-11-yl-1-piperazinyl) ethoxy]	1 kg.	1	2-Iodo benzoic acid	0.94 kg.
		2	2-Amino thiophenol	0.50 kg.

ethanolfumarate (2(QUETI-VII-R (Crude quetiapine fumarate) 2-[2-(4- dibenzo [b,f] [1,4]thiazepin-11-yl-1- piperaziny] ethoxy]ethanolfumarate (2:1))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005320AM25
RA File Number	03AX04004931 AM25
Licence No and Date	0311040073/01/01/2025

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.
Gentamicin Eye/Ear Drops 5 Ml (Each Vial Contains Gentamicin Sulphate 0.015 Gm Net Wt of Bulk Drug Is 11.220 Kgs))	1 Number Vial	1	Gentamicin Sulphate (API)	18.377 mg/Vial

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

Case No.	40 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred

Party Name	PARADISE HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005333AM25
RA File Number	34AX04000854 AM25
Licence No and Date	3411005897/01/01/2025
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. Percentage Yield on molar basis for each step of manufacturing process.	

Case No.	41 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SWATI CAMPHOR & SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005327AM25
RA File Number	05AX04003292 AM25
Licence No and Date	0511030017/01/01/2025
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:- Complete chemistry, chemical reaction and stichometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	42 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005322AM25
RA File Number	07AX04001616 AM25
Licence No and Date	0711013217/01/01/2025

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. 0711002737 dated 28/12/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Dobesilate Monohydrate BP/ Calcium Dobesilate Monohydrate Eur.Ph / Calcium Dobesilate	1 kg.	1	Hydroquinone	0.631 kg.
Etamsylate / Etamsylate EP	1 kg.	2	Hydroquinone	0.527 kg.

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

Case No.	43 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005321AM25
RA File Number	07AX04001584 AM25
Licence No and Date	0711013216/01/01/2025

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/202122/2 dated 02/07/2021 against advance authorization No. 0711000987 dated 27/04/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Calcium Lactate Gluconate	1 kg	1	Lactic Acid	0.560 kg.
		7	Calcium Gluconate	0.686 kg.
		8	Calcium Carbonate	0.310 kg.
Ferrous Lactate	1 kg	2	Lactic Acid	1.028 kg.
Magnesium Lactate	1 kg	3	Lactic Acid	1.19 kg.
Zinc Lactate	1 kg	4	Lactic Acid	0.990 kg.
Magnesium Lactate Gluconate	1 kg.	5	Lactic Acid	0.390 kg.
		10	Glucono Delta Lactone	0.617 kg.
Calcium Lactate	1 kg.	6	Lactic Acid	0.922 kg.
		9	Calcium Carbonate	0.50 kg.

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

Case No.	44 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005357AM25
RA File Number	08AX04001575 AM25
Licence No and Date	0811013686/02/01/2025
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.
Aztreonam for Injection USP/BP/IP/CEP/EP/ChP 1 gm.	1 Number	1	Aztreonam for Injection USP/BP/IP/CEP/EP/ChP (Bulk Drug) (Dry Mixture for Sterile Aztreonam & Arginine)	1.10 gm.

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

Case No.	45 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005355AM25
RA File Number	03AX04005058 AM25
Licence No and Date	0311040130/02/01/2025
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. End use of export product. 2. Justification of low yield of reaction (66%).	

Case No.	46 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005418AM25
RA File Number	08AX04001666 AM25
Licence No and Date	0811013691/03/01/2025

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/202324/26 dated 22/03/2024 against advance authorization No. 0811010634 dated 01/02/2024, 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.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1000 mg per 100 ml. (10 mg/ml.)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial

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

Case No.	47 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	STERIL-GENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005419AM25
RA File Number	04AX04000935 AM25
Licence No and Date	0411008828/03/01/2025

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 for Injection USP 100 mg / Vial (Lyophilized) 20 Ml Vial (Injection)	1 Number	1	Doxycycline Hyclate (Drug)	118.80 mg/Vial

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

Case No.	48 / NC/3/MEET/Jul/202526/6
Case Status	Case Withdrawn
Party Name	NATURAL AND ESSENTIAL OILS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005447AM25
RA File Number	07AX04001593 AM25
Licence No and Date	0711013254/03/01/2025
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that export product applied by the firm pertains to Norms Committee-6, therefore, it has been decided that the application of the firm may be transferred to Norms Committee-6 for the fixation of ad-hoc norms.	

Case No.	49 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	LEBEN LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005456AM25			
RA File Number	03AX04004828 AM25			
Licence No and Date	0311040186/06/01/2025			
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. 0311033331 dated 24/04/2024, 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.

Doxyleb Capsule (Doxycycline Hyclate Capsule BP) 100 mg. (In Packing of 10 X 10's , 10X100's, 1000's Qty Consumed of Exempt Material Doxycycline Hyclate BP- 115.400 mg / CAPSULE)	1 Number	1	Doxycycline Hyclate BP	115.40 mg.
Note: The Committee also recommended making a new SION for above export product. RA concerned may take further necessary action as per above decision of NC.				

Case No.	50 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005473AM25
RA File Number	02AX04000630 AM25
Licence No and Date	0211007901/06/01/2025
Norms Committee Decision: The Committee considered the case as per the agenda and observed that the Authorisation has been issued under Para 4.07 of the HBP. Para 4.07 (iii) of HBP prescribes that: No Authorisation under this paragraph will be issued by the Regional Authority for items listed in paragraph 4.11 of FTP. Further, Para 4.11 of the FTP states the following: Ineligible categories of import on Self Declaration basis (a) Import of the following products shall not be permissible on a self-declaration basis: ix. Vitamins except for use in the pharmaceutical industry; From the above combined reading of Para 4.07 of HBP and Para 4.11 of the FTP, it is observed that the applicant intends to import Ascorbic Acid for the manufacture and export of Ferrous Ascorbate, which is not for use in the pharmaceutical industry. Therefore, the Committee decided to seek complete details from the applicant and the RA concerned as to how this Authorisation was issued when the import of Vitamins is not permitted for any industry other than the pharmaceutical industry.	

Case No.	51 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	VIJAYASRI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025

HQ File Number	HQRNORM APPLY 00005468AM25
RA File Number	09AX04000871 AM25
Licence No and Date	0911008760/06/01/2025
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 and balanced chemical reactions with molar weight and Percentage Yield on molar basis. 2. Requirement and recovery of solvents at each step.	

Case No.	52 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005458AM25
RA File Number	03AX04005082 AM25
Licence No and Date	0311040145/06/01/2025
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:-	

mg. Ampicillin Base. Net content of Import/Exempt Material Used In Export Product 1) Ampicillin Trihydrate BP (Compacted) -1155.411 Kg (Excl. 2% Wastage))				
Lampyklox Capsule. Ampicillin Trihydrate and Cloxacillin Sodium Capsules (250 mg + 250 mg) (Each Capsule Contains Ampicillin Trihydrate Equivalent to 250 mg of Ampicillin and Cloxacillin Sodium Equivalent To 250 mg Cloxacillin. Consumes Qty 1) Ampicillin Trihydrate BP (Compacted) - 1606.736 kg (Excl. 2% Wastage))	1 Number	3	Ampicillin Trihydrate BP Compacted	294.5 mg.
Lampyklox Dry Syrup. Ampicillin Trihydrate and Cloxacillin Sodium Suspension ((Each 5 ml Reconstituted Suspension Contains Ampicillin Trihydrate BP Equivalent to Ampicillin BP 125 Mg). Net Content of Import / Exempt Material Used in Export Product 1) Ampicillin Trihydrate BP (Compacted)- 121.275kgs (Excl 2% Wastage)) 100 ml Bottle.	1 Number Bottle	4	Ampicillin Trihydrate BP Compacted	2945.0 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	53 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	HARMONY ORGANICS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005457AM25
RA File Number	31AX04000364 AM25
Licence No and	3111004275/06/01/2025

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.
Cinnamic Alcohol	1 kg.	1	Sodium Borohydride	0.10 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	54 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	LIVEALTH BIOPHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005476AM25			
RA File Number	03AX04005038 AM25			
Licence No and Date	0311040211/06/01/2025			
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.
Hesperin Diosmin Micronized 50 MG /450 MG TABLETS 3X10 TABS ALU ALU (20262 PACKS OF 3X10 TABS))	607860 Numbers	1	Diosmin Plus Hesperidin (90:10))	310 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005453AM25
RA File Number	03AX04004912 AM25
Licence No and Date	0311040176/06/01/2025

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:-

Sl. No	Export Product	Quantity
1	MEDICAL CREAM AND OINTMENT (Betamethasone Dipropionate Cream USP 0.05% 15 gm tube (Tot Wt: 946.04 Kgs (Net Cont: Sod 2.84 Kgs, Poly 17.03 Kgs, Ceto 68.11 Kgs, Wh Petro 141.91 Kgs, Min 56.76 Kgs, Pre 0.95 Kgs, Prop 47.30 Kgs, Beta 0.66 Kgs, Tube 63069 Nos)))	1 Number
2	MEDICAL CREAM AND OINTMENT(Betamethasone Dipropionate Cream USP 0.05% 45 gm tube (Tot Wt: 4455 Kgs (Net Cont: Sod 13.77 Kgs, Poly 80.19 Kgs, Ceto 320.76 Kgs, Wh Petro 668.25 Kgs, Min 267.30 Kgs, Pre 4.46 Kgs, Prop 222.75 Kgs, Beta 3.12 Kgs, Tube 99000 Nos)))	1 Number

S. No	Import Product	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 & General Notes.

Note:

- i. 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.	56 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005495AM25
RA File Number	08AX04001675 AM25
Licence No and Date	0811013728/07/01/2025

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/202526/3 dated 04/06/2025 against advance authorization No. 0811011115 dated 27/03/2024, 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.
Magnesium Sulfate In Water for Injection (0.325 mEq mg ++ / ml) 40 mg /mL 2 g Total	1 Number	1	Magnesium Sulfate Heptahydrate PhEur	2.00 gm.
Magnesium Sulfate In Water for Injection (0.325 mEq mg ++ / ml) 40 mg /mL 4 g Total	1 Number	2	Magnesium Sulfate Heptahydrate PhEur	4.00 gm.

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

Case No.	57 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025

and Date														
HQ File Number	HQRNORM APPLY 00005518AM25													
RA File Number	03AX04004853 AM25													
Licence No and Date	0311040267/08/01/2025													
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 rowspan="2">Nitrofurantoin Anhydrous</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>5-Nitrofurfural Diacetate</td> <td>1.13 kg.</td> </tr> <tr> <td>2</td> <td>1-Aminohydantion HCl</td> <td>0.59 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Nitrofurantoin Anhydrous	1 kg.	1	5-Nitrofurfural Diacetate	1.13 kg.	2	1-Aminohydantion HCl	0.59 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Nitrofurantoin Anhydrous	1 kg.	1	5-Nitrofurfural Diacetate	1.13 kg.										
		2	1-Aminohydantion HCl	0.59 kg.										

Case No.	58 / NC/3/MEET/Jul/202526/6														
Case Status	Case Approved														
Party Name	AEGIS LIFESCIENCES PRIVATE LIMITED														
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025														
HQ File Number	HQRNORM APPLY 00005511AM25														
RA File Number	08AX04001694 AM25														
Licence No and Date	0811013741/08/01/2025														
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>SURGI-ORC ORIGINAL 2X3 10000</td> <td></td> <td>1</td> <td>Oxidized Cellulose Sheet,</td> <td>10000 Pieces</td> </tr> </tbody> </table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SURGI-ORC ORIGINAL 2X3 10000		1	Oxidized Cellulose Sheet,	10000 Pieces
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
SURGI-ORC ORIGINAL 2X3 10000		1	Oxidized Cellulose Sheet,	10000 Pieces											

INCH (Oxidized Regenerated Pieces Cellulose)			5.1 x 7.6 cm	
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RA concerned may take further necessary action as per above decision of NC.

Case No.	59 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005552AM25
RA File Number	08AX04001721 AM25
Licence No and Date	0811013766/09/01/2025

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/202425/9 dated 10/10/2024 against advance authorization No. 0811007029 dated 16/01/2023, 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.
Esmolol Hydrochloride in Sodium Chloride Injection 2,500 mg /250 ml (10 mg/ml)	1 Number	1	ESMOLOL	2625 mg.
Esmolol Hydrochloride in Sodium Chloride Injection [Double Strength] 2,000 mg/100 ml (20 mg/ml)	1 Number	2	ESMOLOL	2100 mg.

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

Case No.	60 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved

Party Name	VINEET LABORATORIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025																
HQ File Number	HQRNORM APPLY 00005559AM25																
RA File Number	09AX04000933 AM25																
Licence No and Date	0911008809/09/01/2025																
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/202526/3 dated 04/06/2025 against advance authorization No. 0311038141 dated 22/10/2024, 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 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 rowspan="3">N Butyl Lithium 30% w/w in Hexane Solution</td><td rowspan="3">1 kg.</td><td>1</td><td>N Butyl Chloride</td><td>0.540 kg.</td></tr> <tr> <td>2</td><td>Lithium Metal</td><td>0.0812 kg.</td></tr> <tr> <td>3</td><td>n-Hexane</td><td>1.450 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N Butyl Lithium 30% w/w in Hexane Solution	1 kg.	1	N Butyl Chloride	0.540 kg.	2	Lithium Metal	0.0812 kg.	3	n-Hexane	1.450 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
N Butyl Lithium 30% w/w in Hexane Solution	1 kg.	1	N Butyl Chloride	0.540 kg.													
		2	Lithium Metal	0.0812 kg.													
		3	n-Hexane	1.450 kg.													

Case No.	61 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005564AM25
RA File Number	03AX04004855 AM25
Licence No and Date	0311040319/09/01/2025
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	62 / NC/3/MEET/Jul/202526/6															
Case Status	Case Approved															
Party Name	USV PRIVATE LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025															
HQ File Number	HQRNORM APPLY 00005565AM25															
RA File Number	03AX04005196 AM25															
Licence No and Date	0311040320/09/01/2025															
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/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0311000899 dated 12//01/2021, 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>Perphenazine Tablets USP 8 MG 100 S</td><td>1 Tablet</td><td>1</td><td>Perphenazine USP</td><td>8.16 mg/8 mg Tablet</td></tr><tr><td>Perphenazine Tablets USP 16 MG 100 S</td><td>1 Tablet</td><td>2</td><td>Perphenazine USP</td><td>16.32 mg/16 mg Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Perphenazine Tablets USP 8 MG 100 S	1 Tablet	1	Perphenazine USP	8.16 mg/8 mg Tablet	Perphenazine Tablets USP 16 MG 100 S	1 Tablet	2	Perphenazine USP	16.32 mg/16 mg Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Perphenazine Tablets USP 8 MG 100 S	1 Tablet	1	Perphenazine USP	8.16 mg/8 mg Tablet												
Perphenazine Tablets USP 16 MG 100 S	1 Tablet	2	Perphenazine USP	16.32 mg/16 mg Tablet												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	63 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005567AM25
RA File Number	05AX04003524 AM25
Licence No and Date	0511030211/09/01/2025
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/202526/1 dated 25/04/2025 against advance authorization No. 0510413195 dated 03/01/2020, 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.
Sclareolide	1 kg.	1	Sclareol	1.29 kg.

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

Case No.	64 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005550AM25
RA File Number	03AX04004964 AM25
Licence No and Date	0311040297/09/01/2025
Norms Committee Decision:	
NC decided to defer the case for next meeting.	

Case No.	65 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005547AM25
RA File Number	08AX04001719 AM25
Licence No and Date	0811013761/09/01/2025
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. 0811011484 dated 09/05/2024, 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.
Ropivacaine Hydrochloride Inj 200 mg/100 ML	1 Vial	1	Ropivacaine	210 mg/Vial
Ropivacaine Hydrochloride Inj 400 mg/200 mL	1 Vial	2	Ropivacaine	420 mg/Vial
Ropivacaine Hydrochloride Inj 500 mg/100 mL	1 Vial	3	Ropivacaine	525 mg/Vial

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

Case No.	66 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	STYRAX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005543AM25
RA File Number	09AX04000950 AM25
Licence No and Date	0911008795/09/01/2025

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 and balanced chemical reactions with molecular weight and Percentage Yield on molar basis.
2. Technical justification for requirement of import item no. 2 and its recovery.

Case No.	67 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	SANOFI CONSUMER HEALTHCARE INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005571AM25

RA File Number	03AX04005178 AM25			
Licence No and Date	0311040324/10/01/2025			
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/202324/6 dated 14/06/2023 against advance authorization No. 0311021689 dated 24/02/2023, 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.
Festal Dragees (Tablets) Enterosoluble 10x10s ((Total Net Content of Pancreatin in Export Quantity 18691.60 KGS Strength of Pancreatin 192 MG /Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	68 / NC/3/MEET/Jul/202526/6			
Case Status	Case Approved			
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025			
HQ File Number	HQRNORM APPLY 00005592AM25			
RA File Number	31AX04000333 AM25			
Licence No and Date	3111004304/10/01/2025			
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.
DNOVO BP818 DGE (Tetra Methyl Bisphenol F	1 kg.	1	Phenol	0.96 kg.
		2	Methanol	0.10 kg.

Diglycidyl Ether)		3	Paraformaldehyde	0.13 kg.
		4	Epichlorohydrine	0.60 kg.
		5	Caustic Soda Lye	0.228 kg.
		6	Toluene	0.20 kg.
		7	Catalyst	0.004 kg.

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

Case No.	69 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005596AM25
RA File Number	05AX04003551 AM25
Licence No and Date	0511030251/10/01/2025
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. Step wise complete and balanced chemical reactions with molecular weight and Percentage Yield on molar basis. 2. Detailed working for import item no 3, 6 and 7. 3. Consumption Coefficient (CC) for API used.	

Case No.	70 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025

and Date														
HQ File Number	HQRNORM APPLY 00005622AM25													
RA File Number	03AX04005211 AM25													
Licence No and Date	0311040388/13/01/2025													
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. 8/82-ALC4/2018 dated 31/08/2018 against advance authorization No. 0510405339 dated 12/01/2018, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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>Bimatoprost Ophthalmic Solution 0.3 mg /ml - 3 ml (Each ml contains Bimatoprost 0.3 mg) (2,50,000 Nos) (Net Content : Bimatoprost -0.225 KGS)</td> <td>1 Number</td> <td>1</td> <td>Bimatoprost</td> <td>0.90 mg/3 ml Vial</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Bimatoprost Ophthalmic Solution 0.3 mg /ml - 3 ml (Each ml contains Bimatoprost 0.3 mg) (2,50,000 Nos) (Net Content : Bimatoprost -0.225 KGS)	1 Number	1	Bimatoprost	0.90 mg/3 ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Bimatoprost Ophthalmic Solution 0.3 mg /ml - 3 ml (Each ml contains Bimatoprost 0.3 mg) (2,50,000 Nos) (Net Content : Bimatoprost -0.225 KGS)	1 Number	1	Bimatoprost	0.90 mg/3 ml Vial										

Case No.	71 / NC/3/MEET/Jul/202526/6													
Case Status	Case Approved													
Party Name	ADCOCK INGRAM LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025													
HQ File Number	HQRNORM APPLY 00005635AM25													
RA File Number	07AX04001696 AM25													
Licence No and Date	0711013341/13/01/2025													
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>IBUPROFEN 200 mg + CODEINE PHOSPHATE</td> <td>1 Number</td> <td>1</td> <td>IBUPROFEN BP/USP/EP</td> <td>204.00 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	IBUPROFEN 200 mg + CODEINE PHOSPHATE	1 Number	1	IBUPROFEN BP/USP/EP	204.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
IBUPROFEN 200 mg + CODEINE PHOSPHATE	1 Number	1	IBUPROFEN BP/USP/EP	204.00 mg.										

12.8mg Tablets (IBUPROFEN 200 mg + CODEINE PHOSPHATE 13.169mg Tablets (IBU-600.00+COD-39.507 KGS, No of Tabs 3000000) BP/USP/EP)	1 Number	2	CODEINE PHOSPHATE BP/EP/USP/ PH.EUR	13.056 mg.
CO-CODAMOL 15 mg / 500 mg TABLETS (CO-CODAMOL 15.432 mg / 500 mg TABLETS (PARA 500 mg + CODEINE PHOSPHATE 15.432 mg) (PARA-15000+COD-462.960 KGS (No of Tabs 30000000) BP/EP/USP/ PH.EUR)		3	CODEINE PHOSPHATE BP/USP/EP/ PH.EUR	15.30 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	72 / NC/3/MEET/Jul/202526/6													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025													
HQ File Number	HQRNORM APPLY 00005634AM25													
RA File Number	05AX04003571 AM25													
Licence No and Date	0511030286/13/01/2025													
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>Visallergol Eye Drops 0.2%, 2.5 ml (Visallergol Eye Drops 0.2%, 2.5 ml)</td><td>1 Number</td><td>1</td><td>Olopatadine HCL</td><td>5.61 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Visallergol Eye Drops 0.2%, 2.5 ml (Visallergol Eye Drops 0.2%, 2.5 ml)	1 Number	1	Olopatadine HCL	5.61 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Visallergol Eye Drops 0.2%, 2.5 ml (Visallergol Eye Drops 0.2%, 2.5 ml)	1 Number	1	Olopatadine HCL	5.61 mg.										

Oftahist (Olopatadine Eye Solution 0.1 Percent in 5ml Vial)(Oftahist (Olopatadine Eye Solution 0.1 Percent in 5ml Vial))	1 Number	2	Olopatadine HCL	5.61 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	73 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	VINDHYA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005621AM25
RA File Number	09AX04000885 AM25
Licence No and Date	0911008835/13/01/2025
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. Percentage Yield on molar basis at each step of manufacturing process with technical literature in support of it. 2. Justification for requirement of import items no 3 & 4. 3. Regeneration and recovery of import item no. 4.	

Case No.	74 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005644AM25
RA File Number	03AX04005232 AM25
Licence No and Date	0311040406/14/01/2025
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/202526/2 dated 08/05/2025 against advance	

authorization No. 0311029676 dated 27/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Propafenone HCL ER Capsules USP 225 MG 60 s us (Ris ((6,999 Bottles X 60 Capsules Per Bottles = 4,19940 Capsules) (Total Weight of Export Product = 94.487 Kgs)	1 Number Capsule	1	Propafenone Hydrochloride	229.5 mg/Capsule
Propafenone HCL ER Capsules USP 325 MG 60s us (Ris ((14,585 Bottles X 60 Capsules Per Bottles = 8,75,100 Capsules) (Total Weight of Export Product = 284.408 Kgs)	1 Number Capsule	2	Propafenone Hydrochloride	331.5 mg/Capsule
Propafenone HCL ER Capsules USP 425 MG 60 s us (Ris((2,333 Bottles X 60 Capsules Per Bottles = 1,39,980 Capsules) (Total Weight of Export Product = 59.492 Kgs)	1 Number Capsule	3	Propafenone Hydrochloride	433.5 mg/Capsule

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

Case No.	75 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005657AM25
RA File Number	07AX04001691 AM25
Licence No and Date	0711013347/15/01/2025
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.
Clindamycin Hydrochloride 300 mg Capsules ([Each Capsule contains Clindamycin Hydrochloride 325.78 mg equivalent to Clindamycin 300 mg] 990.432 KG)	1 Number	1	Clindamycin Hydrochloride	332.29 mg.

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

Case No.	76 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00005654AM25
RA File Number	05AX04003570 AM25
Licence No and Date	0511030315/15/01/2025

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.
ROCURONIUM BROMIDE INJECTION 50 MG /5 ML, (5 mL)	1 Number	1	ROCURONIUM BROMIDE USP	55.735 mg/5 ml Vial
Rocuronium Bromide Injection 100 MG / 10 ML, (10 mL)	1 Number	2	ROCURONIUM BROMIDE USP	110.326 mg/10 ml Vial

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

Case No.	77 / NC/3/MEET/Jul/202526/6
Case Status	Case Deferred
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00006239AM25
RA File Number	32AX04000749 AM25
Licence No and Date	3211008445/14/02/2025
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 export product “Secondary Butyl Quinoline” (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 redients 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 also directed to provide their comments on the same.	

Case No.	78 / NC/3/MEET/Jul/202526/6													
Case Status	Case Approved													
Party Name	VEKO CARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025													
HQ File Number	HQRNORM APPLY 00006288AM25													
RA File Number	03AX04005901 AM25													
Licence No and Date	0311041469/18/02/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.0311030597 dated 01/02/2024, 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> </td><td> </td><td> </td><td> </td><td> </td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										

TYLODOX GOLD WSP (Pack size 1 Kgs Jar)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.
		3	Doxycycline Hyclate BP/EP/USP	0.202 kg.
TYLODOX GOLD WSP (Pack size 100 Gms sachet)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	2	Tylosin Tartrate BP/USP /EP	10.1 gm.
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm.
GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar) (Each gram powder contains: Doxycycline Hyclate BP 200 mg, Gentamycin Sulphate USP 100mg)	1 Number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg.
GENTADOX GOLD 100 /200 (pack Size 100 Gms Sachet) (Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	6	Doxycycline Hyclate BP/EP/USP	20.2 gm.
NEODOX GOLD WSP (pack Size 1 Kgs Jar)(Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	7	Doxycycline Hyclate BP/EP/USP	0.101 kg.
NEODOX -GOLD WSP (pack Size 100 Gms Sachet) (Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	8	Doxycycline Hyclate BP/EP/USP	10.1 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Jul/202526/6
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025
HQ File Number	HQRNORM APPLY 00006528AM25
RA File Number	03AX04006116 AM25
Licence No and Date	0311041802/04/03/2025
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.
ACEPRO-MAL Oral Paste / Acepromazine Oral paste, Each ml contains: Acepromazine maleate USP 12 mg (Pack Size 30ml) (Net wt. of Acepromazine maleate USP 1872.00 Grams)	5200 Numbers	1	Acepromazine maleate USP	1909.44 gm.
Radicate / SELGARD Spot On 6% For Cat (Pack size 0.75 ml x 6 Pipettes) (Each ml contains Selamectin BP / EP 60 mg, Net Weight = 1890.00 Grams)	7000 Numbers	2	Selamectin BP / EP / USP	1927.8 gm.
Radicate / SELGARD Spot On 6% For Cat (Pack size 0.75ml x 1 Pipettes) (Each ml contains Selamectin BP / EP 60 mg, Net Weight = 67.50 Grams)	1500 Numbers	3	Selamectin BP / EP / USP	68.85 gm.
Radicate / SELGARD Spot On 6% For Cat (Pack size 0.75 ml x 3 Pipettes) (Each ml contains Selamectin BP / EP 60 mg, Net Weight = 675.00 Grams)	5000 Numbers	4	Selamectin BP / EP / USP	688.5 gm.
Radicate Spot On 12% For Dog (Small Dog) (Pack size 0.5 x 1 Pipettes) (Each ml contains: Selamectin BP 12%, Net Weight = 90.00 Grams)	1500 Numbers	5	Selamectin BP / EP / USP	91.8 gm.

Radicat Spot on 12% for Dog (Medium Dog) (Pack size 1 ml x 1 pipettes), (Each ml contains: Selamectin BP 12%, Net Weight = 180.00 Grams)	1500 Numbers	6	Selamectin BP / EP / USP	183.6 gm.
Radicat Spot on 12% for Dog (Large Dog) (Pack size 2 ml x 1 pipettes), (Each ml contains: Selamectin BP 12%, Net Weight = 192.00 Grams)	800 Numbers	7	Selamectin BP / EP / USP	195.84 gm.
Radicat Spot on 12% for Dog (Extra Large Dog) (Pack size 3 ml x 1 pipettes), (Each ml contains: Selamectin BP 12%, Net Weight = 288.00 Grams)	800 Numbers	8	Selamectin BP / EP / USP	293.76 gm.
Radicat Spot On 12% For Dog (Small Dog) (Pack size 0.5ml x 6 Pipettes) (Each ml contains: Selamectin BP 12%, Net Weight = 270.00 Grams)	750 Numbers	9	Selamectin BP / EP / USP	275.4 gm.
Radicat Spot On 12% For Dog (Medium Dog) (Pack size 1ml x 6 Pipettes) (Each ml contains: Selamectin BP 12%, Net Weight = 540.00 Grams)	750 Numbers	10	Selamectin BP / EP / USP	550.8 gm.
Radicat Spot On 12% For Dog (Large Dog) (Pack size 2ml x 6 Pipettes) (Each ml contains: Selamectin BP 12%, Net Weight = 1080.00 Grams)	750 Numbers	11	Selamectin BP / EP / USP	1101.6 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	80 / NC/3/MEET/Jul/202526/6
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Case Status	Case Approved										
Party Name	B M CHEMIE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025										
HQ File Number	HQRNORM APPLY 00006830AM25										
RA File Number	03AX04006075 AM25										
Licence No and Date	0311042394/24/03/2025										
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>Progesterone BP Micronised</td><td>1 kg.</td><td>1</td><td>(20S)- 21-Hydroxy-20-Methylpregn-4EN-3-One</td><td>1.167 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Progesterone BP Micronised	1 kg.	1	(20S)- 21-Hydroxy-20-Methylpregn-4EN-3-One	1.167 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Progesterone BP Micronised	1 kg.	1	(20S)- 21-Hydroxy-20-Methylpregn-4EN-3-One	1.167 kg.							

Case No.	81 / NC/3/MEET/Jul/202526/6										
Case Status	Case Approved										
Party Name	B M CHEMIE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202526/ 6 and 31/07/2025										
HQ File Number	HQRNORM APPLY 00001231AM26										
RA File Number	03AX04001069 AM26										
Licence No and Date	0311044422/02/06/2025										
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>Progesterone BP Micronised</td><td>1 kg.</td><td>1</td><td>(20S)- 21-Hydroxy-20-Methylpregn-4EN-3-One</td><td>1.167 kg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Progesterone BP Micronised	1 kg.	1	(20S)- 21-Hydroxy-20-Methylpregn-4EN-3-One	1.167 kg.
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