



Government of India
Ministry of Commerce and Industry
Department of Commerce

DIRECTORATE GENERAL OF FOREIGN TRADE
(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Sep/202223/7

DATED: 16/09/2022

Please Note

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

Meeting No. NC/3/MEET/Sep/202223/7 dated 16/09/2022 of Norms Committee - III for the year 2022-23 was held on 16/09/2022 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	AJAY KUMAR,Deputy Director	Directorate General of Foreign Trade, Delhi
3	SHAISH KUMAR,Technical Authority	Technical Consultant,DGFT
4	DINESHNARAIN MATHUR,Technical Authority	Technical Consultant,DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved

Party Name	ASCENT FINECHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022			
HQ File Number	HQRNORM REVIW00166247AM22			
RA File Number	082404000415 AM14			
Licence No and Date	0810127686/03/01/2014			
Norms Committee Decision: Shri Anil Jain, CEO, Shri Ketan Doshi, General Manager (R&C) and Shri D.K. Singh, A.R. ; attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
RASPBERRY KETONE/ 4-(4-HYDROXYPHYENYL) BUTANE - 2 - ONE WHITE CRYSTALLINE POWDER (Assay NLT 99%)	1 kg	1	p-HYDROXY BENZALDEHYDE (LIGHT YELLOW CRYSTALLINE POWDER), PARA HYDROXY BENZALDEHYDE, 4-HYDROXY BENZALDEHYDE	1.69 kg
		2	ACETONE (COLORLESS LIQUID)	1.50 kg
		3	G2PAC ASSEMBLY 700 LITER / 250 KGS (35 inch x 35 inch x 35 inch polypropylene woven fabric bags)	Relevant as per packing policy
RA concerned may take further necessary action as per above decision of NC.				

Case No.	2 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000284AM23
RA File Number	092404000563 AM15
Licence No and Date	0910061513/08/01/2015
Norms Committee Decision: Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:	

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Enoxaparin Sodium Injection 40mg Pre filled Syringes Injectable	1 Number	1	Heparin Sodium Powder	79.466 mg
			2	Barrel Syringes Glass	Net + 5% wastage
			3	Needle Shield Rubber	Net to Net
			4	Plunger Stoppers Rubber	Net + 11.55% wastage
			5	Plunger Rods Plastic	Net + 2.5% wastage
			6	Preventis Plastic	Net to Net
			7	Anti Factor Xa Test Kits	Consumables, Accessories, etc. not allowed under policy
			8	Anti Factor IIa Test Kits	Consumables, Accessories, etc. not allowed under policy
			9	Analytical Columns Kits	Consumables, Accessories, etc. not allowed under policy
			10	Analytical Guard Columns Kits	Consumables, Accessories, etc. not allowed under policy
			11	Medical Grade Paper Paper	Consumables, Accessories, etc. not allowed under policy
			12	Tubing Plastic	Consumables, Accessories, etc. not allowed under policy
			13	Anti Factor Xa Kits	Consumables, Accessories, etc. not allowed under policy
			14	Anti Factor IIa Kits	Consumables, Accessories, etc. not allowed under policy
			15	N.M.R. Standard Kits	Consumables, Accessories, etc. not allowed under policy

			16	Mol. Wt. Standard Kits	Consumables, Accessories, etc. not allowed under policy
2	Enoxaparin Sodium Injection 60mg Pre filled Syringes Injectable	1 Number	1	Heparin Sodium Powder	119.187 mg
			2	Barrel Syringes Glass	Net + 5% wastage
			3	Needle Shield Rubber	Net to Net
			4	Plunger Stoppers Rubber	Net + 10.85% wastage
			5	Plunger Rods Plastic	Net + 1.65% wastage
			6	Preventis Plastic	Net to Net
			7	Anti Factor Xa Test Kits	Consumables, Accessories, etc. not allowed under policy
			8	Anti Factor IIa Test Kits	Consumables, Accessories, etc. not allowed under policy
			9	Analytical Columns Kits	Consumables, Accessories, etc. not allowed under policy
			10	Analytical Guard Columns Kits	Consumables, Accessories, etc. not allowed under policy
			11	Medical Grade Paper Paper	Consumables, Accessories, etc. not allowed under policy
			12	Tubing Plastic	Consumables, Accessories, etc. not allowed under policy
			13	Anti Factor Xa Kits	Consumables, Accessories, etc. not allowed under policy
			14	Anti Factor IIa Kits	Consumables, Accessories, etc. not allowed under policy
			15	N.M.R. Standard Kits	Consumables, Accessories, etc. not allowed under policy

			16	Mol. Wt. Standard Kits	Consumables, Accessories, etc. not allowed under policy
RA concerned may take further necessary action as per above decision of NC.					

Case No.	3 / NC/3/MEET/Sep/202223/7				
Case Status	Case Approved				
Party Name	ASCENT FINECHEM PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022				
HQ File Number	HQRNORM REVIW00166244AM22				
RA File Number	082404000397 AM15				
Licence No and Date	0810134800/13/03/2015				
Norms Committee Decision:					
Shri Anil Jain, CEO, Shri Ketan Doshi, General Manager (R&C) and Shri D.K. Singh, A.R. ; attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:					

Case No.	4 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00166233AM22
RA File Number	082404000104 AM17
Licence No and Date	0810138218/28/06/2016

Norms Committee Decision:

Shri Anil Jain, CEO, Shri Ketan Doshi, General Manager (R&C) and Shri D.K. Singh, A.R. ; attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
RASPBERRY KETONE/ 4-(4-HYDROXYPHYENYL) BUTANE - 2 - ONE WHITE CRYSTALLINE POWDER (Assay NLT 99%)	1 kg	1	p-HYDROXY BENZALDEHYDE (LIGHT YELLOW CRYSTALLINE POWDER), PARA HYDROXY BENZALDEHYDE, 4-HYDROXY BENZALDEHYDE	1.69 kg
		2	ACETONE (COLORLESS LIQUID)	1.50 kg
		3	G2PAC ASSEMBLY 700 LITER / 250 KGS (35 inch x 35 inch x 35 inch polyprpelene woven fabric bags)	Relevant as per packing policy

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

Case No.	5 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001184AM23
RA File Number	092404000181 AM19
Licence No and	0910066442/11/07/2018

Date	
Norms Committee Decision: Shri M. Ravi Kumar, DGFT (Exim) and Shri V. Jaya Prakash, Manager (Impex) attended the Personal Hearing and explained their case. The Committee after deliberation decided to call for following information from the firm: i. Details on import item - Clavulanate Potassium +Syloid for kg Activity is not given as per discussion in PH. ii. Consumption coefficient for 1 kg Amoxycilin Trihydrate Bulk. (iii) Wastage applied on Tablets / Capsules from API.	

Case No.	6 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001185AM23
RA File Number	092404000345 AM19
Licence No and Date	0910066762/25/10/2018
Norms Committee Decision: Shri M. Ravi Kumar, DGFT (Exim) and Shri V. Jaya Prakash, Manager (Impex) attended the Personal Hearing and explained their case. The Committee after deliberation decided to call for following information from the firm: i. Details on import item - Clavulanate Potassium +Syloid for kg Activity is not given as per discussion in PH. ii. Consumption coefficient for 1 kg Amoxycilin Trihydrate Bulk. (iii) Wastage applied on Tablets / Capsules from API.	

Case No.	7 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001186AM23
RA File Number	092404000386 AM19

Licence No and Date	0910066874/20/11/2018
Norms Committee Decision: Shri M. Ravi Kumar, DGFT (Exim) and Shri V. Jaya Prakash, Manager (Impex) attended the Personal Hearing and explained their case. The Committee after deliberation decided to call for following information from the firm: i. Details on import item - Clavulanate Potassium +Syloid for kg Activity is not given as per discussion in PH. ii. Consumption coefficient for 1 kg Amoxicilin Trihydrate Bulk. (iii) Wastage applied on Tablets / Capsules from API.	

Case No.	8 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000283AM23
RA File Number	092404000491 AM19
Licence No and Date	0910067225/27/02/2019

Norms Committee Decision:

Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Enoxaparin Sodium Injection 30mg/0.3ml, Pre-filled Syringes	1 Number	1	Heparin Sodium	59.6 mg
			2	0.5ml Barrel Syringes	Net + 5% wastage
			3	0.5ml Needle Shield	Net to Net
			4	0.5ml Plunger Stoppers	Net + 12% wastage
			5	0.5ml Plunger Rods	Net + 2.5% wastage

			6	0.5ml Preventis Needle shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 100mg/1.0ml Pre-filled Syringes	1 Number	7	Heparin Sodium	198.664 mg
			8	1ml Barrel Syringes	Net + 5% wastage
			9	1ml Needle Shield	Net to Net
			10	1ml Plunger Stoppers	Net + 12% wastage
			11	1ml Plunger Rods	Net + 2.5% wastage
			12	1ml Preventis Needle shielding System	Net + 3% wastage

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

Case No.	9 / NC/3/MEET/Sep/202223/7				
Case Status	Case Deferred				
Party Name	GLAND PHARMA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022				
HQ File Number	HQRNORM REVIW00000141AM23				
RA File Number	092404000043 AM20				
Licence No and Date	0910067519/14/05/2019				
Norms Committee Decision:					
Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:					
Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Enoxaparin Sodium	1 Number	1	Heparin Sodium	39.733 mg

	Injection 20mg Pre-filled Syringes		2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 30mg Pre-filled Syringes	1 Number	1	Heparin Sodium	59.6 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
3	Enoxaparin Sodium Injection 40mg Pre-filled Syringes	1 Number	1	Heparin Sodium	79.466 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 11.55% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
4	Enoxaparin Sodium Injection 60mg Pre-filled Syringes	1 Number	1	Heparin Sodium	119.187 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net

			4	Plunger Stoppers	Net + 10.85% wastage
			5	Plunger Rods	Net + 1.65% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
5	Enoxaparin Sodium Injection 80mg Pre-filled Syringes	1 Number	1	Heparin Sodium	158.93 mg
			2	Barrel Syringes	Net + 4.65% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
6	Enoxaparin Sodium Injection 100mg Pre-filled Syringes	1 Number	1	Heparin Sodium	198.664 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
7	Enoxaparin Sodium Injection 120mg Pre-filled Syringes	1 Number	1	Heparin Sodium	238.40 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage

8	Enoxaparin Sodium Injection 150mg Pre-filled Syringes	1 Number	5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
			1	Heparin Sodium	298.00 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
			RA concerned may take further necessary action as per above decision of NC.		

Case No.	10 / NC/3/MEET/Sep/202223/7				
Case Status	Case Approved				
Party Name	PIRAMAL ENTERPRISES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022				
HQ File Number	018205000182AM20				
RA File Number	039504000143 AM20				
Licence No and Date	0310829108/17/05/2019				
Norms Committee Decision:					
Shri Devesh Desai, Associate Vice President, Shri Sunil Kumar Jain, General Manager – Production and Shri Prashant Khilare, Manager Commercial; attended the Personal Hearing and explained their case. The Committee after deliberations decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					

1	Atorvastatin Calcium Tablets USP 10mg (Net wt. of Import Sr. No. 1 is 1180.35 kgs, Sl. No. 2 is 8152.45 kg, Sr. No. 3 is 2272.66 kg, Sr. No. 4 is 1190000 Nos., Sr. No. 8 is 1190000 Nos.)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	PLASTIC BOTTLES 75CC WHITE HDPE ROUND 38MM	Relevant as per packing policy
			8	PLASTIC CAPS / CLOSURES PP 38MM-400 BLUE CR	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 10mg (Net wt. of Import Sr. No. 1 is 826.50kgs, Sr. No. 2 is 5709 kg, Sr. No. 3 is 1591.50 kg, Sr. No. 5 is 750000 Nos., Sr. No. 9 is 75000 Nos.)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			5	PLASTIC BOTTLES 250CC WHITE HDPE ROUND 38MM	Relevant as per packing policy
			9	PLASTIC CAPS / CLOSURES PP 53MM - 400 BLUE PP	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg (Net wt. of Import Sr. No. 1 is 3041.13 kgs, Sr. No. 2 is 20865.2 kgs, Sr. No. 3 is 5818.19 kg, Sr. No. 4 is 1533000 Nos., Sr. No. 8 is 1533000 Nos.)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	PLASTIC BOTTLES 75CC	Relevant as per

				WHITE HDPE ROUND 38MM	packing policy
			8	PLASTIC CAPS / CLOSURES PP 38MM-400 BLUE CR	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg (Net wt. of Import Sr. No. 1 is 5717.25kgs, Sr. No. 2 is 39891.35kg, Sr. No. 3 is 11123.51kg, Sr. No. 4 is 1441000 Nos., Sr. No. 8 is 1441000 Nos.)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	PLASTIC BOTTLES 75CC WHITE HDPE ROUND 38MM	Relevant as per packing policy
			8	PLASTIC CAPS / CLOSURES PP 38MM-400 BLUE CR	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 80mg (Net wt. of Import Sr. No. 1 is 3062.96kgs, Sr. No. 2 is 20801.62 kg, Sr. No. 3 is 5800.89 kg, Sr. No. 6 is 386000 Nos., Sr. No. 8 is 386000 Nos.)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			6	PLASTIC BOTTLES 120CC WHITE HDPE ROUND 38MM	Relevant as per packing policy
			8	PLASTIC CAPS / CLOSURES PP 38MM-400 BLUE CR	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg (Net wt. of Import Sr. No. 1 is 1763.36kgs, Sr. No. 2 is 11975.60 kgs, Sr.	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg

	No. 3 is 3339.60 kg, Sr. No. 7 is 20000 Nos., Sr. No. 10 is 20000 Nos.)		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			7	PLASTIC BOTTLES 1500CC WHITE HDPE ROUND 38MM	Relevant as per packing policy
			10	PLASTIC CAPS CLOSURES PP 89MM 400 WHITE PLAIN	/ Relevant as per packing policy

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

1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada.
2. Export to USA only.
3. Firm holding Certificate of Manufacturing Exclusivity.

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

Case No.	11 / NC/3/MEET/Sep/202223/7				
Case Status	Case Approved				
Party Name	PIRAMAL ENTERPRISES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022				
HQ File Number	HQRNORM REVIW00001325AM23				
RA File Number	039504001121 AM20				
Licence No and Date	0310835077/26/02/2020				
Norms Committee Decision:					
Shri Devesh Desai, Associate Vice President, Shri Sunil Kumar Jain, General Manager – Production and Shri Prashant Khilare, Manager Commercial; attended the Personal Hearing and explained their case. The Committee after deliberations decided to revise adhoc norms as under:					

1	Atorvastatin Calcium Tablets USP 10mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 629.53kgs, Sr. No. 2 is 3486.56kg, Sr. No. 3 is 990.08kg, Sr. No. 4 is 634680 Nos., Sr. No. 8 is 634680 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 10mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 157.38kgs, Sr. No. 2 is 871.62kg, Sr. No. 3 is 247.52kg, Sr. No. 5 is 14280 Nos., Sr. No. 9 is 14280 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)	Relevant as per packing policy
			5	Blue 53mm Pp Cap Lp-E & Triseal F217hy (Plastics Caps/Closures PP 53MM-400 Blue PP)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 787.01kgs, Sr. No. 2 is 4374.12kg, Sr. No. 3 is 1241.46kg, Sr. No. 4 is 396720 Nos., Sr. No. 8 is 396720 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy

			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 1836.07kgs, Sr. No. 2 is 10169.51kg, Sr. No. 3 is 2887.80kg, Sr. No. 4 is 462770 Nos., Sr. No. 8 is 462770 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 80mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 1049.18kgs, Sr. No. 2 is 5839.10kg, Sr. No. 3 is 1656.89kg, Sr. No. 6 is 132220 Nos., Sr. No. 8 is 132220 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Plastic Bottles 120CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 786.90kgs, Sr. No. 2 is 4379.40kg, Sr. No. 3 is 1242.69kg, Sr. No. 7 is 8925 Nos., Sr. No. 10 is 8925 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white	Relevant as per packing policy

				HDPE Round 38mm)	
			5	CC8940AFS837 WHITE PP551 CT 89 400SP (Plastics Caps/Closures PP 89MM-400 White Plain)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions: 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada. 2. Export to USA only. 3. Firm holding Certificate of Manufacturing Exclusivity.					
RA concerned may take further necessary action as per above decision of NC.					

Case No.	12 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	PIRAMAL ENTERPRISES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001324AM23
RA File Number	039504001215 AM20
Licence No and Date	0310835591/11/04/2020
Norms Committee Decision:	
Shri Devesh Desai, Associate Vice President, Shri Sunil Kumar Jain, General Manager – Production and Shri Prashant Khilare, Manager Commercial; attended the Personal Hearing and explained their case. The Committee after deliberations decided to revise adhoc norms as under:	

	Sr. No. 8 is 410000 Nos.))		3	Calcium Acetate	18.049 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 10mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 2733.21kgs, Sr. No. 2 is 15137.42kg, Sr. No. 3 is 4298.58kg, Sr. No. 5 is 248000 Nos., Sr. No. 9 is 248000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)	Relevant as per packing policy
			5	Blue 53mm Pp Cap Lp-E & Triseal F217hy (Plastics Caps/Closures PP 53MM-400 Blue PP)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 1031.57kgs, Sr. No. 2 is 5733.37kg, Sr. No. 3 is 1627.24kg, Sr. No. 4 is 520000 Nos., Sr. No. 8 is 520000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg (Pack Size 90 tabs)((Net wt.	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg

	of Import Sr. No. 1 is 3967.56kgs, Sr. No. 2 is 21975.30kg, Sr. No. 3 is 6240.24kg, Sr. No. 4 is 1000000 Nos., Sr. No. 8 is 1000000 Nos.))		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 38MM-400 Blue CR)	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 80mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 2444.02kgs, Sr. No. 2 is 13601.90kg, Sr. No. 3 is 3859.65kg, Sr. No. 6 is 308000 Nos., Sr. No. 8 is 308000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Plastic Bottles 120CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 38MM-400 Blue CR)	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 793.51kgs, Sr. No. 2 is 4416.20kg, Sr. No. 3 is 1253.13kg, Sr. No. 7 is 9000 Nos., Sr. No. 10 is 9000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	Relevant as per packing policy
			5	CC8940AFS837 WHITE PP551 CT 89 400SP (Plastics Caps/Closures PP 89MM-400 White Plain)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions:					

1. **Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada.**
2. **Export to USA only.**
3. **Firm holding Certificate of Manufacturing Exclusivity.**

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

Case No.	13 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	PIRAMAL ENTERPRISES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001326AM23
RA File Number	039504000075 AM21
Licence No and Date	0310836467/01/06/2020

Norms Committee Decision:

Shri Devesh Desai, Associate Vice President, Shri Sunil Kumar Jain, General Manager – Production and Shri Prashant Khilare, Manager Commercial; attended the Personal Hearing and explained their case. The Committee after deliberations decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Atorvastatin Calcium Tablets USP 10mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 2281.35kgs, Sr. No. 2 is 12634.87kg, Sr. No. 3 is 3587.93kg, Sr. No. 4 is 2300000 Nos., Sr. No. 8 is 2300000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy

2	Atorvastatin Calcium Tablets USP 10mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 440.84kgs, Sr. No. 2 is 2441.52kg, Sr. No. 3 is 693.32kg, Sr. No. 5 is 40000 Nos., Sr. No. 9 is 40000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)	Relevant as per packing policy
			5	Blue 53mm Pp Cap Lp-E & Triseal F217hy (Plastics Caps/Closures PP 53MM-400 Blue PP)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 1031.57kgs, Sr. No. 2 is 5733.37kg, Sr. No. 3 is 1627.24kg, Sr. No. 4 is 520000 Nos., Sr. No. 8 is 520000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 3174.05kgs, Sr. No. 2 is 17580.24kg, Sr. No. 3 is 4992.19kg, Sr. No. 4 is 800000 Nos., Sr. No. 8 is 800000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy

			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 80mg (Pack Size 90 tabs)((Net wt. of Import Sr. No. 1 is 396.76kgs, Sr. No. 2 is 2208.10kg, Sr. No. 3 is 626.57kg, Sr. No. 6 is 50000 Nos., Sr. No. 8 is 50000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Plastic Bottles 120CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg (Pack Size 1000 tabs)((Net wt. of Import Sr. No. 1 is 3526.72kgs, Sr. No. 2 is 19627.56kg, Sr. No. 3 is 5569.48kg, Sr. No. 7 is 40000 Nos., Sr. No. 10 is 40000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	Relevant as per packing policy
			5	CC8940AFS837 WHITE PP551 CT 89 400SP (Plastics Caps/Closures PP 89MM-400 White Plain)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions: 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada. 2. Export to USA only. 3. Firm holding Certificate of Manufacturing Exclusivity.					
RA concerned may take further necessary action as per above decision of NC.					

Case No.	14 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	PIRAMAL ENTERPRISES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001327AM23
RA File Number	039504000288 AM21
Licence No and Date	0310837797/20/08/2020

Norms Committee Decision:

Shri Devesh Desai, Associate Vice President, Shri Sunil Kumar Jain, General Manager – Production and Shri Prashant Khilare, Manager Commercial; attended the Personal Hearing and explained their case. The Committee after deliberations decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Atorvastatin Calcium Tablets USP 10mg (Pack Size 90 tabs) (Net wt. of Import Sr. No. 1 is 1454.336 kgs, Sr. No. 2 is 8054.601 kg, Sr. No. 3 is 2287.27 kg, Sr. No. 4 is 1466227 Nos., Sr. No. 8 is 1466227 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 10mg (Pack Size 1000 tabs) (Net	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg

	wt. of Import Sr. No. 1(is 1869.856 kgs, Sr. No. 2 is 10355.890 kg, Sr. No. 3 is 2940.769 kg, Sr. No. 5 is 169663 Nos., Sr. No. 9 is 169663 Nos.))		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)	Relevant as per packing policy
			5	Blue 53mm Pp Cap Lp-E & Triseal F217hy (Plastics Caps/Closures PP 53MM-400 Blue PP)	Relevant as per packing policy
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg (Pack Size 90 tabs) (Net wt. of Import Sr. No. 1(is 301.168 kgs, Sr. No. 2 is 1673.870 kg, Sr. No. 3 is 475.075 kg, Sr. No. 4 is 151815 Nos., Sr. No. 8 is 151815 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg (Pack Size 90 tabs) (Net wt. of Import Sr. No. 1(is 8102.726 kgs, Sr. No. 2 is 44878.925 kg, Sr. No. 3 is 12744.093 kg, Sr. No. 4 is 2042244 Nos., Sr. No. 8 is 2042244 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg

			4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 80mg (Pack Size 90 tabs) (Net wt. of Import Sr. No. 1(is 3324.196 kgs, Sr. No. 2 is 18500.438 kg, Sr. No. 3 is 5249.650 kg, Sr. No. 6 is 418922 Nos., Sr. No. 8 is 418922 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Plastic Bottles 120CC white HDPE Round 38mm	Relevant as per packing policy
			5	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	Relevant as per packing policy
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg (Pack Size 1000 tabs) (Net wt. of Import Sr. No. 1(is 3843.596 kgs, Sr. No. 2 is 21391.096 kg, Sr. No. 3 is 6069.90kg, Sr. No. 7 is 43594 Nos., Sr. No. 10 is 43594 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	Relevant as per packing policy
			5	CC8940AFS837 WHITE PP551 CT 89 400SP (Plastics Caps/Closures PP	Relevant as per packing policy

				89MM-400 White Plain)	
			6	Strippax Sorbent 50 C & 50 SG 1 gm (Silica gel desiccants)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions: 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada. 2. Export to USA only. 3. Firm holding Certificate of Manufacturing Exclusivity.					
RA concerned may take further necessary action as per above decision of NC.					

Case No.	15 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000277AM23
RA File Number	09AA04000173 AM22
Licence No and Date	0911000784/07/05/2021
Norms Committee Decision:	
Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:	

		4	Plunger Rods	Net + 2.5% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	16 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000276AM23
RA File Number	09AA04006940 AM21
Licence No and Date	0911000856/18/05/2021

Norms Committee Decision:

Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:

Export Product	Qty.	Sl. No.	Import items	Qty.
Low Molecular Weight Heparin Enoxaparin Sodium Injection USP, 40mg in 0.4ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 40mg, Water for Injection USP q.s. to 0.4ml)	4143333 Numbers	1	Heparin Sodium	329.25 kg
		2	Barrel Syringes	Net + 5% wastage
		3	Plunger Stoppers	Net + 11.55% wastage
		4	Plunger Rods	Net + 2.5% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	17 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000270AM23
RA File Number	09AA04007005 AM21
Licence No and Date	0911000882/20/05/2021

Norms Committee Decision:

Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:

Export Product	Qty.	Sl. No.	Import items	Qty.
Low Molecular Weight Heparin Enoxaparin Sodium Injection USP 80mg in 0.8ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 80mg, Water for Injection USP q.s. to 0.8ml)	2550000 Numbers	1	Heparin Sodium	405.27 kg
		2	Barrel Syringes	Net + 4.65% wastage
		3	Plunger Stoppers	Net + 12% wastage
		4	Plunger Rods	Net + 2.5% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	18 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022

HQ File Number	HQRNORM REVIW00000275AM23			
RA File Number	09AA04006941 AM21			
Licence No and Date	0911000880/20/05/2021			
Norms Committee Decision: Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:				
Export Product	Qty.	Sl. No.	Import items	Qty.
Low Molecular Weight Heparin Enoxaparin Sodium Injection USP 40mg in 0.4ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 40mg, Water for Injection USP q.s. to 0.4ml)	4143333 Numbers	1	Heparin Sodium	329.25 kg
		2	Barrel Syringes	Net + 5% wastage
		3	Plunger Stoppers	Net + 11.55% wastage
		4	Plunger Rods	Net + 2.5% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage
RA concerned may take further necessary action as per above decision of NC.				

Case No.	19 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000217AM23
RA File Number	09AA04006942 AM21
Licence No and Date	0911000887/21/05/2021
Norms Committee Decision: Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:	

Export Product	Qty.	Sl. No.	Import items	Qty.
Low Molecular Weight Heparin Enoxaparin Sodium Injection USP 40mg in 0.4ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 40mg, Water for Injection USP q.s. to 0.4ml)	4143333 Numbers	1	Heparin Sodium	329.25 kg
		2	Barrel Syringes	Net + 5% wastage
		3	Plunger Stoppers	Net + 11.55% wastage
		4	Plunger Rods	Net + 2.5% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	20 / NC/3/MEET/Sep/202223/7				
Case Status	Case Approved				
Party Name	GLAND PHARMA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022				
HQ File Number	HQRNORM REVIW00000143AM23				
RA File Number	09AA04005477 AM21				
Licence No and Date	0911000482/24/05/2021				
Norms Committee Decision:					
Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:					
Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Low Molecular Weight Heparin	4118180	1	Enoxaparin Sodium	181 kg

	Enoxaparin Sodium Injection USP, 40mg in 0.4ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 40mg, Water for Injection USP q.s. to 0.4ml)	Numbers	2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 11.55% wastage
			4	Plunger Rods	Net + 2.5% wastage
			5	Preventis Needle Shielding System	Net + 3% wastage
2	Low Molecular Weight Heparin Enoxaparin Sodium Injection USP 60mg in 0.6ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 60mg, Water for Injection USP q.s. to 0.6ml)	1455841 Numbers	1	Enoxaparin Sodium	96 kg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 10.85% wastage
			4	Plunger Rods	Net + 1.65% wastage
			5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	21 / NC/3/MEET/Sep/202223/7
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000272AM23
RA File Number	09AA04007003 AM21
Licence No and Date	0911000900/24/05/2021
Norms Committee Decision:	
Shri N. Prabhakar Rao, GM Commercial and Shri A. Jayateerth, DGM – Production attended the Personal Hearing and explained their case. The Committee after deliberation decided to revise adhoc norms as under:	

Export Product	Qty.	Sl. No.	Import items	Qty.
Low Molecular Weight Heparin Enoxaparin Sodium Injection USP 60mg in 0.6ml Pre-filled Syringe(Composition per syringe, Enoxaparin Sodium USP 60mg, Water for Injection USP q.s. to 0.6ml)	28,00,000 Numbers	1	Heparin Sodium	333.72 kg
		2	Barrel Syringes	Net + 5% wastage
		3	Plunger Stoppers	Net + 10.85% wastage
		4	Plunger Rods	Net + 1.65% wastage
		5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	22 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00397057AM22
RA File Number	08AA04017921 AM22
Licence No and Date	0811002234/04/08/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a Reminder to firm to submit its reply.	

Case No.	23 / NC/3/MEET/Sep/202223/7
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Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00397079AM22
RA File Number	08AA04018916 AM22
Licence No and Date	0811002280/09/08/2021
Norms Committee Decision: : Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a Reminder to firm to submit its reply.	

Case No.	24 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM APPLY 00170502AM22
RA File Number	08AA04022482 AM22
Licence No and Date	0811002393/25/08/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a Reminder to firm to submit its reply.	

Case No.	25 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00397092AM22
RA File Number	08AA04023464 AM22
Licence No and Date	0811002450/31/08/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a <u>Reminder</u> to firm to submit its reply.	

Case No.	26 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00397104AM22
RA File Number	08AA04025507 AM22
Licence No and Date	0811002517/06/09/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a <u>Reminder</u> to firm to submit its reply.	

Case No.	27 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022

HQ File Number	HQRNORM REVIW00001475AM23
RA File Number	08AA04022429 AM22
Licence No and Date	0811002501/06/09/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a Reminder to firm to submit its reply.	

Case No.	28 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001473AM23
RA File Number	08AA04029213 AM22
Licence No and Date	0811002696/27/09/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a Reminder to firm to submit its reply.	

Case No.	29 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00397111AM22
RA File Number	08AA04030678 AM22

Licence No and Date	0811002770/04/10/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a <u>Reminder</u> to firm to submit its reply.	

Case No.	30 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001209AM23
RA File Number	08AA04033169 AM22
Licence No and Date	0811002929/20/10/2021
Norms Committee Decision: Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm. Hence, it was decided to issue a <u>Reminder</u> to firm to submit its reply.	

Case No.	31 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00001474AM23
RA File Number	08AA04033170 AM22
Licence No and Date	0811002920/20/10/2021

Norms Committee Decision:

Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm.

Hence, it was decided to issue a **Reminder** to firm to submit its reply.

Case No.	32 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000529AM23
RA File Number	08AA04033768 AM22
Licence No and Date	0811002982/26/10/2021

Norms Committee Decision:

Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm.

Hence, it was decided to issue a **Reminder** to firm to submit its reply.

Case No.	33 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000528AM23
RA File Number	08AA04034748 AM22
Licence No and Date	0811003137/15/11/2021
Norms Committee Decision:	

Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm.

Hence, it was decided to issue a **Reminder** to firm to submit its reply.

Case No.	34 / NC/3/MEET/Sep/202223/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202223/ 7 and 16/09/2022
HQ File Number	HQRNORM REVIW00000530AM23
RA File Number	08AA04034735 AM22
Licence No and Date	0811003139/15/11/2021
Norms Committee Decision:	
Dr. Ajeet Singh, Vice President (R&D), Shri Sree Ram Kala, Vice President (Indirect Taxation) and Shri Keyur Kayastha, Sr. General Manager, Unit Logistic; attended the Personal Hearing and explained their case. The Representatives of firm in the Meeting stated that they will submit the hard copy of their reply. Reply is still awaited from the firm.	
Hence, it was decided to issue a <u>Reminder</u> to firm to submit its reply.	