



Government of India
Ministry of Commerce and Industry
Department of Commerce
DIRECTORATE GENERAL OF FOREIGN TRADE

Meeting No -NC/3/MEET/Mar/202122/16

Meeting Date -08/04/2022

Minutes of the Norms Committee – 3 Meeting No. NC/3/MEET/Mar/202122/16 dated 08.04.2022, was actually held on 13.04.2022 under the Chairmanship of Dr. Amiya Chandra, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2015-20 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

Following members were present in the Meeting:

Sl. No.	Name & Designation	Department
1	Shri Shaish Kumar, Technical – 1	Consultant
2	Shri D.N. Mathur, Technical – 2	Consultant
In attendance		
1	Shri Ajay Kumar, Deputy Director	DGFT

2. The Norms Committee has taken decision only with respect to technical aspect/ wastage norms. While redeeming the application, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularization of the case.

The committee went through the Minutes of earlier Meeting No. NC/3/MEET/Mar/202122/15 dated 17.03.2022, was actually held on 23.03.2022.

MANUAL CASES

Case No.	A-01
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Enzal Chemicals (India) Pvt. Ltd., Mumbai
HQ F. No.	01/82/050/00235/AM06/DES-III
RLA F. No.	03/24/040/02582/AM05
Advance Authorization No. and Date	0310333535 dated 08.06.2005
Subject	Request of M/s Enzal Chemicals (India) Pvt. Ltd., Mumbai for fixation of adhoc norms against Advance Authorization No. 0310333535 dated 08.06.2005
Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: (i) Justification for low yield of 58.82% with copy of any authentic technical literature. (ii) Value of By-Product Ethyl Alcohol. (iii) Production / Consumption data for the year 2005-06 duly certified by GST.	

Case No.	A-02
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Mylan Laboratories Ltd, Hyderabad
HQ F. No.	01/82/050/00044/AM12/DES-III
RLA F. No.	09/24/040/00422/AM11
Advance Authorization No. and Date	0910045287 dated. 28.01.2011
Subject	Request of M/s Mylan Laboratories Ltd, Hyderabad for fixation of adhoc norms fixed against Advance Authorization No. 0910045287 dated. 28.01.2011

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

Export product	Qty.	Sl. No.	Import items	Qty.
DESMOPRESSIN ACETATE	1 kg	1	Rink amide Resin	6.50 kg
		2	Fmoc-Glycine	3.276 kg
		3	Fmoc-D-Arg(pbf)-OH	6.50 kg
		4	Fmoc-Proline	3.731 kg
		5	Fmoc-Cys(trt)-OH	5.85 kg
		6	Fmoc-Asn(trt)-OH	6.579 kg
		7	Fmoc-Gln(trt)-OH	6.74 kg
		8	Fmoc-Phe-OH	4.274 kg
		9	Fmco-Tyr(tBu)-OH	5.20 kg
		10	Mpa(trt)-OH	4.55 kg
		11	Diisopropylcarbodiimide	10.40 kg
		12	HBTU(O-Benzotriazole-N,N,N-tetramethyl-uronium-hexafluorophosphate)	3.90 kg

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

Case No.	A-03
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Inchem Laboratories Private Limited, Hyderabad
HQ F. No.	01/82/050/01497/AM19/DES-III
RLA F. No.	09/24/040/00230/AM19
Advance Authorization No. and Date	0910066657 dated 11.09.2018
Subject	Request of M/s Inchem Laboratories pvt Ltd, Hyderabad for enhancement in the quantity of import item in respect of adhoc norms fixed against Advance Authorization No. 0910066657 dated 11.09.2018

Decision: The Committee considered the request of firm and as per technical literature given by the firm with optimum yields of 60% X 75% X 79% X 41%, it was decided to revise adhoc norms as under:

Export product	Qty.	Import items	Qty.
4 Amino 3,5 Di chloroalpha (trimethyl)methyl amino) methyl benzene methanol hcl (Clenbuterol HCL)	1 kg	4 - Nitroacetophenone	3.60 kg

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

Case No.	A-04
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Inchem Laboratories Private Limited, Hyderabad
HQ F. No.	01/82/050/01498/AM19/DES-III
RLA F. No.	09/24/040/00261/AM19
Advance Authorization No. and Date	0910066658 dated 11.09.2018
Subject	Request of M/s Inchem Laboratories Private Limited, Hyderabad for enhancement in the quantity of import item in respect of adhoc norms fixed against Advance Authorization No. 0910066658 dated 11.09.2018

Decision: The Committee considered the request of firm and as per technical literature given by the firm with optimum yields of 75% X 79% X 41%, it was decided to revise adhoc norms as under:

Export product	Qty.	Import items	Qty.
4 Amino 3,5 Di chloroalpha (trimethyl)methyl amino) methyl benzene methanol hcl (Clenbuterol HCL)	1 kg	4-Amino acetophenone	1.77 kg

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

Case No.	A-05
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Sandhya Organic Chemicals Pvt. Ltd., Mumbai
HQ F. No.	01/82/050/00167/AM20/DES-III
RLA F. No.	03/95/040/01388/AM19
Advance Authorization No. and Date	0310828995 dated 14.05.2019
Subject	Request of M/s Sandhya Organic Chemicals Pvt. Ltd., Mumbai for enhancement in the quantity of import item No. 2 – Isodecyl Alcohol in respect of norms fixed against Advance Authorization No. 0310828995 dated 14.05.2019

Decision: The Committee considered the request of firm and as per stoichiometric balance given by the firm, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
DIPHENYL ISODECYL PHOSPHITE (DPDP)	1 kg	1	PHENOL	0.557 kg
		2	ISODECYL ALCOHOL	0.419 kg
		3	YELLOW PHOSPHORUS	0.087 kg

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

Case No.	A-06			
Meeting No.	NC/3/MEET/Mar/202122/16			
Date	08/04/2022			
Firm's Name	M/s DEEPAK NOVOCHEM TECHNOLOGIES LTD, Pune			
HQ F. No.	01/82/050/01187/AM19/DES-III 01/82/050/02262/AM19/DES-III			
RLA F. No.	31/83/040/00081/AM19 31/83/040/00157/AM19			
Advance Authorization No. and Date	3110067162 dated 24.08.2018 3110067278 dated 09.01.2019			
Subject	Request of M/s DEEPAK NOVOCHEM TECHNOLOGIES LTD, Pune for fixation of adhoc norms against Advance Authorization Nos. 3110067162 dated 24.08.2018 and 3110067278 dated 09.01.2019			
Decision: The Committee considered the request of firm and as per the justification given and GST certified data, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
ORTHO CRESOL	1 kg	1	OCP 50 (containing 58% O-Cresol & 38% Phenol)	0.809 kg
		2	Methanol	0.998 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	A-07
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Deepak Novochem Technologies Ltd, Pune
HQ F. No.	01/82/050/00522/AM17/DES-III 01/82/050/00109/AM18/DES-III
RLA F. No.	31/83/040/00178/AM16 31/83/040/00187/AM17
Advance Authorization No. and Date	3110066046 dated 14.03.2016 3110066649 dated 31.03.2017
Subject	Request of M/s Deepak Novochem Technologies Ltd, Pune for enhancement in the quantity of import item No. 1 - Meta Cresol (MC99) in respect of adhoc norms fixed against Advance Authorization No. 3110066046 dated 14.03.2016 and 3110066649 dated 31.03.2017
Decision: The Committee considered the request of firm and on the basis o calculation given, there is no technical justification for enhancement in norms. Hence, it was decided to reject the case maintaining status quo.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	A-08
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Nisarg Biosciences Pvt. Ltd., Hyderabad
HQ F. No.	01/82/050/00455/AM20/DES-III
RLA F. No.	09/24/040/00221/AM20
Advance Authorization No. and Date	0910067836 dated 25.07.2019
Subject	Request of M/s Nisarg Biosciences Pvt. Ltd., Hyderabad for fixation of adhoc norms against Advance Authorization No. 0910067836 dated 25.07.2019

Decision: The Committee considered the request of firm and based on the information provided by the firm and also GST data submitted by the firm, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
AMINOL or Jarocol AOL (2(1-3-Benzodioxal-5-ylamino Ethanol Hydrochloride / Hydroxyethyl 3,4, Methylonedioxyanilim Hydrochloride)	2000 kg	1	1,3-Benzodiazole or 1,2-METHYLENEDIOXY BENZENE	1800 kg
		2	2-CHLORO ETHYL CHLORO FORMATE/CHLORO ETHYL CHLORO FORMATE(CECF)	2520 kg

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

Case No.	A-09
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Songwon Speciality Chemicals India Pvt. Ltd., Vadodara
HQ F. No.	01/82/050/01146/AM19/DES-III
RLA F. No.	34/24/040/00232/AM19
Advance Authorization No. and Date	3410044578 dated 11.10.2018
Subject	Request of M/s Songwon Speciality Chemicals India Pvt. Ltd., Vadodara for revision of adhoc norms against Advance Authorization No. 3410044578 dated 11.10.2018

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

Export product	Qty.	Sl. No.	Import items	Qty.
EDOT (3,4 - Ethylenedioxythiophene) (Other Organo-Sulphur Compounds)	1 kg	1	Dimethyl Oxalate	1.30 kg
		2	Sodium Methoxide Powder	0.856 kg
		3	Sodium Methoxide Solution (30%) / Sodium Methylate Solution (30%)	1.52 kg
		4	Dimethylformamide	0.329 kg
		5	1,2-Dichloroethane / Ethylene Dichloride	1.76 kg
		6	Sulfolane	0.4186 kg
		7	Sodium Sulphide	2.081 kg

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

Case No.	A-10
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Chemplast Sanmar Limited (Formerly known as M/s Sanmar Speciality Chemicals Limited)
HQ F. No.	01/82/050/01845/AM21/DES-III
RLA F. No.	04/24/040/00277/AM19
Advance Authorization No. and Date	0410165628 dated 18.05.2019
Subject	Request of M/s Chemplast Sanmar Limited (Formerly known as M/s Sanmar Speciality Chemicals Limited) for enhancement in the quantity of import items in respect of adhoc norms fixed against Advance Authorization No. 0410165628 dated 18.05.2019

Decision: The Committee considered the request of firm and based on the justification given by the firm for low yield of 78%, it was decided to revise adhoc norms as under:

Export Product	Qty.	Sl. No.	Import items	Qty.
AE Phenol [4-(2-Amino-ethyl)-2-methoxy-phenol]	1 kg	1	Vanillin [4-hydroxy-3-methoxy-benzaldehyde]	1.124 kg
		2	Sodium Cyanide	0.416 kg
		3	Methyl Tetr Butyl Ether	0.25 kg

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

Case No.	A-11
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Adcock Ingram Ltd.
HQ F. No.	01/82/050/00666/AM09/DES-III
RLA F. No.	07/24/040/00142/AM09
Advance Authorization No. and Date	0710058154 dated 26.06.2008
Subject	Request of M/s Adcock Ingram Ltd. for fixation of adhoc norms against Advance Authorization No. 0710058154 dated 26.06.2008

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1.	Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg : 11029.500kgs + Caffeine 30mg :735.300Kgs Doxylamine Succinate 5mg. :122.550Kgs+ Codeine Phosphate 10mg : 245.100Kgs = 12132.45 and Colour yellow 14037. = Kgs 9.804 [No. of 24510000Tablets] (SYNDOL TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP / Ph. Eur grade	5.10 kg
			3.	COLOUR YELLOW 14037 IH	1.632 kg
2.	Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg Tablets [Paracetamol 450mg: 22059.000kgs + Caffeine 45mg : 2205.900Kgs+ Doxylamine Succinate 5mg. :245.100Kgs+ Codeine Phosphate 10mg : 490.200Kgs = 25000.200 Kgs + Colour Quinoline Yellow Lake. Kgs 223.531 +Colour Quinoline Yellow Ws. 119.119 Kgs] (ADCO DOL TABS) [No. of 49020000 Tablets]	1 million tablets	1.	DOXYLAMINE SUCCINATE USP / Ph. Eur grade	5.10 kg
			4.	COLOUR QUINOLINE YELLOW WS	2.43 kg
			5.	COLOUR QUINOLINE YELLOW LAKE IH	4.56 kg
3.	Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg: 11029.500kgs + Caffeine 50mg : 1225.500Kgs+ Doxylamine Succinate 5mg. :122.550Kgs+ Codeine Phosphate 10mg : 245.100Kgs = 12622.65gs+ Hyd Veg Oil Kgs 411.768+Col yellow 14037- 45.344 Kgs] (BETAPYN TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP / Ph. Eur grade	5.10 kg
			3.	COLOUR YELLOW 14037 IH	Do not match with MBF
			6.	HYDROGENATED VEGETABLE OIL / COTTONSEED OIL -RYLO TG 11 PHARMA KOSHER	Chapter 15 item, Not Allowed Under Para 4.07
4.	Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg : 11029.500kgs + Caffeine 45mg : 1102.950Kgs+ Doxylamine Succinate 5mg. :122.550Kgs+ Codeine Phosphate 10mg : 245.100Kgs =12500.100 Kgs+ Colour Green apple. Kgs 49.020] (PYNSTOP TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP / Ph. Eur grade	5.10 kg
			2.	COLOUR GREEN APPLE DEEP F1569	2.00 kg

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

Case No.	A-12
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Adcock Ingram Ltd.
HQ F. No.	01/82/050/01171/AM09/DES-III
RLA F. No.	07/24/040/00387/AM09
Advance Authorization No. and Date	0710060545 dated 21.10.2008
Subject	Request of M/s Adcock Ingram Ltd. for fixation of adhoc norms against Advance Authorization No. 0710060545 dated 21.10.2008

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1.	Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg : 3150.000 kgs + Caffeine 30mg : 210.000Kgs Doxylamine Succinate 5mg. : 35.000Kgs+ Codeine Phosphate 10mg : 70.000Kgs = 3697.064 and Colour yellow 14037. = Kgs 11.424+ Povidone/Kollidon K25= 225.053 Kgs [No. of 7000000 Table] (SYNDOL TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			2.	COLOUR YELLOW 14037 IH	1.632 kg
			6.	Povidone /Kollidon K25	31.552 kg
2.	Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg Tablets [Paracetamol 450mg: 42750.000kgs + Caffeine 45mg : 4275.00Kgs+ Doxylamine Succinate 5mg. : 475.00Kgs+ Codeine Phosphate 10mg : 950.000Kgs = 49114.050 Kgs + Col Qui Yel Lake. Kgs 433.200 +Col QuilYelWs. Kgs 230.850] [No. of 95000000Tablets](ADCO DOL TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			3.	COLOUR QUINOLINE YELLOW WS	2.43 kg
			4.	COLOUR QUINOLINE YELLOW LAKE IH	4.56 kg
3.	Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg: 4050.000kgs + Caffeine 50mg : 450.000Kgs+ Doxylamine Succinate 5mg. : 45.000Kgs+ Codeine Phosphate 10mg : 90.000Kgs = 4802.850gs+ Hyd Veg Oil Kgs 151.200+Col yellow 14037-16.650 Kgs] No. of 9000000 Tablets] (BETAPYN TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			2.	COLOUR YELLOW 14037 IH	Do not match with MBF
			5.	HYDROGENATED VEGETABLE OIL/COTTONSEED OIL RYLOTG 11 PHARMA KOSHER	Chapter 15 item, Not Allowed Under Para 4.07

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

Case No.	A-13
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Adcock Ingram Ltd.
HQ F. No.	01/82/050/01065/AM09/DES-III
RLA F. No.	07/24/040/00339/AM09
Advance Authorization No. and Date	0710060094 dated 24.09.2008
Subject	Request of M/s Adcock Ingram Ltd. for fixation of adhoc norms against Advance Authorization No. 0710060094 dated 24.09.2008

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1.	Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets [Paracetamol 450mg : 1799.991kgs + Caffeine 30mg :119.999Kgs Doxylamine Succinate 5mg. :20.000Kgs+ Codeine Phosphate 10mg : 40.000Kgs = 1981.590 and Colour yellow 14037. = Kgs 1.600 No. of 3999980Tablets] (SYNDOL TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			3.	COLOUR YELLOW 14037 IH	1.632 kg
2.	Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg Tablets [Paracetamol 450mg: 24322.500kgs + Caffeine 45mg : 2432.250Kgs+ Doxylamine Succinate 5mg. :270.250Kgs+ Codeine Phosphate 10mg : 540.500Kgs = 27943.310 Kgs + Colour Quinoline Yellow Lake. Kgs 246.468 +Colour Quinoline Yellow Ws. 131.342 Kgs] (ADCO	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			4.	COLOUR QUINOLINE YELLOW WS	2.43 kg
			5.	COLOUR QUINOLINE YELLOW LAKE IH	4.56 kg
3.	Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets No. of 16000000 Tablets][Paracetamol 450mg: 7200.000kgs + Caffeine 50mg : 800.000Kgs+ Doxylamine Succinate 5mg. :80.000Kgs+ Codeine Phosphate 10mg : 160.000Kgs = 8538.400gs+ Hyd Veg Oil Kgs 268.800+Col yellow 14037- 29.600 Kgs] (BETAPYN TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			3.	COLOUR YELLOW 14037 IH	Do not match with MBF
			6.	HYDROGENATED VEGETABLE OIL/COTTON SEED OIL RYLOTG 11 PHARMA KOSHER	Chapter 15 item, Not Allowed Under Para 4.07
4.	Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets No. of 23999960 Tablets] [Paracetamol 450mg : 10799.982kgs + Caffeine 45mg : 1079.998Kgs+ Doxylamine Succinate 5mg. :120.000Kgs+ Codeine Phosphate 10mg : 240.000Kgs =12287.980Kgs+ Colour Green apple. Kgs 48.000] (PYNSTOP TABS)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
			2.	COLOUR GREEN APPLE DEEP F-1569, F1620	2.00 kg

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

Case No.	A-14
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Vergo Pharma Research Laboratories Pvt. Ltd.
HQ F. No.	01/82/050/02531/AM19/DES-III 01/82/050/02533/AM19/DES-III 01/82/050/00212/AM20/DES-III 01/82/050/00825/AM20/DES-III 01/82/050/02532/AM19/DES-III 01/82/050/00824/AM18/DES-III 01/82/050/00731/AM20/DES-III 01/82/050/02534/AM19/DES-III 01/82/050/02535/AM19/DES-III 01/82/050/00210/AM20/DES-III 01/82/050/00018/AM20/DES-III 01/82/050/00019/AM20/DES-III
RLA F. No.	17/24/040/00153/AM17 17/24/040/00051/AM18 03/95/040/00183/AM20 03/95/040/00800/AM20 17/24/040/00002/AM18 17/24/040/00046/AM18 03/95/040/00573/AM20 17/24/040/00036/AM18 17/24/040/00012/AM18 03/95/040/00182/AM20 03/95/040/01239/AM19 03/95/040/01240/AM19
Advance Authorization No. and Date	1710006583 dated 07.03.2017 1710006669 dated 02.11.2017 0310829293 dated 28.05.2019 0310832786 dated 14.11.2019 1710006602 dated 17.04.2017 1710006662 dated 05.09.2017 0310832202 dated 14.10.2019 1710006650 dated 17.07.2017 1710006710 dated 12.06.2018 0310829291 dated 28.05.2019 0310828109 dated 02.04.2019 0310828110 dated 02.04.2019
Subject	Request of M/s Vergo Pharma Research Laboratories Pvt. Ltd. for reconsideration of adhoc norms fixed against 12 Advance Authorizations 1710006583 dated 07.03.2017, 1710006669 dated 02.11.2017, 0310829293 dated 28.05.2019, 0310832786 dated 14.11.2019, 1710006602 dated 17.04.2017, 1710006662 dated 05.09.2017, 0310832202 dated 14.10.2019, 1710006650 dated 17.07.2017, 1710006710 dated 12.06.2018, 0310829291 dated 28.05.2019, 0310828109 dated 02.04.2019 and 0310828110 dated 02.04.2019
Decision: Shri Sanjeev Kumar, Vice President – Technical Operation attended the Personal Hearing on 13.04.2022 through Video Conferencing and explained its case. The Committee noted that the firm is registered with the Drug Authorities of UK for these export items and the process employed is by wet granulation. The Committee took note of wastage claimed during the wet granulation process and potency compensation, and decided to revise adhoc norms as under:	

Advance Authorization No. 1710006583 dated 07.03.2017

Export Product	Qty.	Sl. No.	Import items	Qty.
Colchicine 500MCG Tablets	1 Number	1	Colchicine	562.50 mcg/ 500mcg tablet

Advance Authorization No. 1710006669 dated 02.11.2017

Export Product	Qty.	Sl. No.	Import items	Qty.
Colchicine 500MCG Tablets	1 Number	1	Colchicine Ph.Eur	562.50 mcg/ 500mcg tablet

Advance Authorization No. 0310829293 dated 28.05.2019

Export Product	Qty.	Sl. No.	Import items	Qty.
Colchicine 500MCG Tablets	1 Number	1	Colchicine Ph.Eur	562.50 mcg/ 500mcg tablet

Advance Authorization No. 0310832786 dated 14.11.2019

Export Product	Qty.	Sl. No.	Import items	Qty.
Colchicine 500MCG Tablets	1 Number	1	Colchicine Ph.Eur	562.50 mcg/ 500mcg tablet

Advance Authorization No. 1710006602 dated 17.04.2017

Export product	Qty.	Import items	Qty.
LIOTHYRONINE SODIUM 20MCG TABLET	1 Number	LIOTHYRONINE SODIUM	24 mcg/20 mcg tablet

Advance Authorization No. 1710006662 dated 05.09.2017

Export product	Qty.	Import items	Qty.
LIOTHYRONINE SODIUM 20MCG TABLET	1 Number	LIOTHYRONINE SODIUM	24 mcg/20 mcg tablet

Advance Authorization No. 0310832202 dated 14.10.2019

Export product	Qty.	Sl. No.	Import items	Qty.
LIOTHYRONINE SODIUM 5 MCG TABLETS	1 Number	1	LIOTHYRONINE SODIUM	6 MCG / 5 MCG TABLET
LIOTHYRONINE SODIUM 10 MCG TABLETS	1 Number	1	LIOTHYRONINE SODIUM	12 MCG / 10 MCG TABLET
LIOTHYRONINE SODIUM 20 MCG TABLETS	1 Number	1	LIOTHYRONINE SODIUM	24 MCG / 20 MCG TABLET

Advance Authorization No. 1710006650 dated 17.07.2017

Export Product	Qty.	Sl. No.	Import items	Qty.
CARBIMAZOLE 5mg Tabs	1 Number	1	Carbimazole (Carbimazole Ph.Eur+In-House) - RA000518	5.20 mg/tablet
CARBIMAZOLE 10mg Tabs	1 Number	1	Carbimazole (Carbimazole Ph.Eur+In-House) - RA000518	10.40 mg/tablet
CARBIMAZOLE 20mg Tabs	1 Number	1	Carbimazole (Carbimazole Ph.Eur+In-House) - RA000518	20.80 mg/tablet

Advance Authorization No. 1710006710 dated 12.06.2018

Export product	Qty.	Sl. No.	Import Item	Qty.
Amantadine HCL capsules 100mg	1capsule	1	Amantadine Hydrochloride EP	104 mg/ capsule

Advance Authorization No. 0310829291 dated 28.05.2019

Export product	Qty.	Sl. No.	Import Item	Qty.
Amantadine HCL capsules 100 mg	1capsule	1	Amantadine Hydrochloride	104 mg/ capsule

Advance Authorization No. 0310828109 dated 02.04.2019

Export product	Qty.	Sl. No.	Import items	Qty.
Alverine Citrate 60mg Hard Capsules	1 Number	1	Alverine Citrate	62.4 mg / 60 mg tablet
Alverine Citrate 120mg Hard Capsules	1 Number	1	Alverine Citrate	124.8 mg / 120 mg tablet

Advance Authorization No. 0310828110 dated 02.04.2019

Export product	Qty.	Sl. No.	Import items	Qty.
Mebeverine Tablets 135mg	1 Number	1	Mebeverine HCL	138.375 mg/ 135 mg tablet

Note: Above revised norms are for regularization and closure purpose only. No repeat licence will be issued on the basis of above decision.

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

Case No.	Out of Agenda
Meeting No.	NC/3/MEET/Mar/202122/16
Date	08/04/2022
Firm's Name	M/s Zentiva Private Limited
HQ F. No.	HQRNORMAPPLY00048038AM21
RLA F. No.	03AA04014240AM21
Advance Authorization No. and Date	0311000408 dated 28.12.2020
Subject	Correction in the adhoc norms fixed against Advance Authorization No. 0311000408 dated 28.12.2020 by Norms Committee – 3 in its Meeting No. NC/3/MEET/Oct/202122/10 dated 12.11.2021

Decision: Further, the Committee took one more case (out of agenda) in which it was observed that earlier the norms for this Advance Authorization were wrongly worked out on the basis of 125 mg and 250 mg of Hydrochlorothiazide per Tablet with 2% wastage as per SION A-412. However, it is now observed that as per DML, the content of Hydrochlorothiazide is 12.5 mg in Export item No. 1 and 2 and 25 mg per Tablet in Export item No. 3. Accordingly, it was decided to revise the adhoc norms as under::

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Ramilich /Ramilich Comp /Ramipril HCTZT/ZTV 5- 12.5mg DE/FR(Net Wt.Hydrochlorothiazide125.000KGS) (NA)	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
2	Ramilich / Ramilich Comp /Ramipril HCT ZT/ZTV 2.5- 12.5mg DE/IT (Net Wt. Hydrochlorothiazide 118.825KGS)(NA)	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
3	Ramilich /Ramilich Comp /Ramipril HCTZT/ZTV 5- 25mg DE/IT/HU (Net Wt. Hydrochlorothiazide 267.500 KGS) (NA)	1 Number	1	Hydrochlorothiazide	25.50 mg / Tablet

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

Meeting ended with thanks to Chair and participants
