



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Feb/202223/19**DATED:** 07/02/2023Please 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/Feb/202223/19 dated 07/02/2023 of Norms Committee - III for the year 2022-23 was held on 07/02/2023 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	DGFT(HQ)
2	NAND Lal,Technical Consultant	DPIIT
3	SHAISH KUMAR,Technical Consultant	DGFT
4	DINESHNARAIN MATHUR,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	BIO-GEN EXTRACTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00003010AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Shri Jai Shankar R, Director Operations had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representative of the firm decided to call for following information / documents from the firm: i. Fresh COA for import item from Foreign Supplier to show that import item is non- dispersible in cold water as claimed by the firm.	

Case No.	2 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	BIO-GEN EXTRACTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00003011AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Shri Jai Shankar R, Director Operations had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representative of the firm decided to call for following information / documents from the firm: i. Fresh COA for import item from Foreign Supplier to show that import item is non- dispersible in cold water as claimed by the firm.	

Case No.	3 / NC/3/MEET/Feb/202223/19
Case Status	Case Rejected
Party Name	BIO-GEN EXTRACTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00003012AM23

RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Shri Jai Shankar R, Director Operations had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representative of the firm observed that the firm has now changed the import description from Natural Lycopene Beadlet 10% CWS-S to Lycopene 10% Powder. Such changes will affect the entire case details including COA from foreign supplier. In view of above, the present case under Para 4.06 is rejected. The firm is advised to apply afresh , if required with all necessary documents.	

Case No.	4 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00004919AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Shri Tripathy, Sr. Export & Import, Manager, Shri Vinay Khetan, Advisor and Shri Amit Ravetakar, Technical had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm: i. Approved Composition of Export Product from FDA. ii. Flow Chart with material balance. iii. Step – wise wastage. iv. Calculation Sheet to arrive at the quantity asked for.	

Case No.	5 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00004920AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	

Shri Tripathy, Sr. Export & Import, Manager, Shri Vinay Khetan, Advisor and Shri Amit Ravetakar, Technical had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm:

- i. **Approved Composition of Export Product from FDA.**
- ii. **Flow Chart with material balance.**
- iii. **Step – wise wastage.**
- iv. **Calculation Sheet to arrive at the quantity asked for.**

Case No.	6 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00004921AM23
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

Shri Tripathy, Sr. Export & Import, Manager, Shri Vinay Khetan, Advisor and Shri Amit Ravetakar, Technical had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm:

- i. **Approved Composition of Export Product from FDA.**
- ii. **Flow Chart with material balance.**
- iii. **Step – wise wastage.**
- iv. **Calculation Sheet to arrive at the quantity asked for.**

Case No.	7 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00003343AM23
RA File Number	039404000911 AM18
Licence No and Date	0310819230/19/02/2018

Norms Committee Decision:

Shri Shivanand Prabhu, Manager and Shri Harshal Uttarwar, Site Head had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm:

- i. Width of import items or Area (Packing material) wherever unit is given in Meter.
 ii. Justification for wastage of 5%, 12% and 20% wastage on packing material.

Detailed specification of packing material.

Case No.	8 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00006029AM23
RA File Number	039404000198 AM19
Licence No and Date	0310822656/27/07/2018

Norms Committee Decision:

Dr. Asif Musharaaf, Sr. Technical and Shri Sanjay Dhayalkar, Logistics Manager had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to change the description of Export Product from 'Atorvastatin Calcium' to "ATS-8: (4-R-CIS)-1-1-DIMETHYL-6-CYANOMETHYL-2-2-DIMETHYL-1,3 DIOXANE-4-ACETATE" with the following conditions:

- i. 1000 kg of Atorvastatin Calcium will be equivalent to 708 kg of ATS-8. Export Obligation will accordingly be amended for the export of ATS-8.
- ii. Import quantity entitlement will be worked out for import item No. 1 to 9 on pro-rata basis with respect to the norms fixed by NC-3 in its Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against Advance Authorization No. 0310824086 dated 01.10.2018, 0310824121 dated 01.10.2018 and 0310824101 dated 01.10.2018 on repeat basis.
- iii. Firm will pay custom duty and interest as per policy for import item No. 10 - Fluoro Benzene in total (as the same is not allowed) and for any excess import on import item No. 1 to 9.

Following adhoc norms for ATS-8 will be applicable on repeat basis as per Para (ii) above:

Export product	Qty.	Sl. No.	Import items	Qty.
(4-R-CIS)-1,1-DIMETHYL-6-CYANOMETHYL-2,2-DIMETHYL-1,3-DIOXANE-4-ACETATE (ATS-8)	1 kg	1	Ethyl-4-Chloro aceto acetate	1.060 kg
		2	Lithium metal	0.100 kg
		3	Tert Butyl Acetate	2.110 kg
		4	Lyophilised Enzyme Powder CDX-403	0.0102 kg

		5	IEP OX 58 Spray Dried Enzyme Powder	0.0160 kg
		6	IEP OX 56 Spray Dried Enzyme Powder	0.117 kg
		7	(B-NAD) B-Nicotinamide-adenine dinucleotide (Coenzyme-1)	0.00132 kg
		8	2,2-Dimethoxy propane	0.950 kg
		9	Ethyl Acetate	3.60 kg
		10	Fluoro Benzene	Not allowed
Note: Above revised norms are for regularization and closure purpose only.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	9 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00006028AM23
RA File Number	039404000197 AM19
Licence No and Date	0310822657/27/07/2018

Norms Committee Decision:

Dr. Asif Musharaaf, Sr. Technical and Shri Sanjay Dhayalkar, Logistics Manager had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to change the description of Export Product from 'Atorvastatin Calcium' to "ATS-8: (4-R-CIS)-1-1-DIMETHYL-6-CYANOMETHYL-2-2-DIMETHYL-1,3 DIOXANE-4-ACETATE" with the following conditions:

- i. 1000 kg of Atorvastatin Calcium will be equivalent to 708 kg of ATS-8. Export Obligation will accordingly be amended for the export of ATS-8.
- ii. Import quantity entitlement will be worked out for import item No. 1 to 8 on pro-rata basis with respect to the norms fixed by NC-3 in its Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against Advance Authorization No. 0310822731 dated 31/07/2018 on repeat basis.
- iii. Firm will pay custom duty and interest as per policy for import item No. 9 – Methylene Di Chloride and 10 - Fluoro Benzene in total (as the same is not allowed) and for any excess import on import item No. 1 to 8.

Following adhoc norms for ATS-8 will be applicable on repeat basis as per Para (ii) above:

Export Product	Qty	Sl. No.	Import Items	Qty
(4-R-CIS)-1-1-DIMETHYL-6-CYANOMETHYL-2-2-DIMETHYL-1,3-DIOXANE-4-ACETATE (ATS-8)	1 kg	1	ETHYL-4-CHLORO ACETO ACETATE	1.06 kg
		2	LITHIUM METAL	0.100 kg
		3	TERT BUTYL ACETATE	2.11 kg
		4	OPTIMIZED ENZYME CDX-041, LYOPHIZED POWDER	0.019 kg
		5	LYOPHILISED ENZYME POWDER CDX-901	0.00555 kg
		6	LYOPHILISED ENZYME POWDER CDX-403	0.0031 kg
		7	NADP-SP-B-NICOTINAMIDE-ADENINE DINUCLEOTIDE PHOSPHATE OXIDIZED FORM, MONOSODIUM SALT (B-NADP+,B-TPN+,COENZYME-II)	0.0005 kg
		8	2,2-DIMETHOXY PROPANE	0.95 kg
		9	Methylene Di Chloride	Not allowed
		10	Fluoro Benzene	Not allowed

Note: Above revised norms are for regularization and closure purpose only.

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

Case No.	10 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00006030AM23
RA File Number	039404000392 AM19
Licence No and Date	0310822799/02/08/2018

Norms Committee Decision:

Dr. Asif Musharaaf, Sr. Technical and Shri Sanjay Dhayalkar, Logistics Manager had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to change the description of Export Product from 'Atorvastatin Calcium' to "ATS-8: (4-R-CIS)-1-1-DIMETHYL-6-CYANOMETHYL-2-2-DIMETHYL-1,3 DIOXANE-4-ACETATE" with the following conditions:

- i. 1000 kg of Atorvastatin Calcium will be equivalent to 708 kg of ATS-8. Export Obligation will accordingly be amended for the export of ATS-8.
- ii. Import quantity entitlement will be worked out for import item No. 1 to 9 on pro-rata basis with respect to the norms fixed by NC-3 in its Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against Advance Authorization No. 0310824086 dated 01.10.2018, 0310824121 dated 01.10.2018 and 0310824101 dated 01.10.2018 on repeat basis.
- iii. Firm will pay custom duty and interest as per policy for import item No. 10 - Fluoro Benzene in total (as the same is not allowed) and for any excess import on import item No. 1 to 9.

Following adhoc norms for ATS-8 will be applicable on repeat basis as per Para (ii) above:

Export product	Qty.	Sl. No.	Import items	Qty.
(4-R-CIS)-1,1-DIMETHYL-6-CYANOMETHYL-2,2-DIMETHYL-1,3-DIOXANE-4-ACETATE (ATS-8)	1 kg	1	Ethyl-4-Chloro aceto acetate	1.060 kg
		2	Lithium metal	0.100 kg
		3	Tert Butyl Acetate	2.110 kg
		4	Lyophilised Enzyme Powder CDX-403	0.0102 kg
		5	IEP OX 58 Spray Dried Enzyme Powder	0.0160 kg
		6	IEP OX 56 Spray Dried Enzyme Powder	0.117 kg
		7	(B-NAD) B-Nicotinamide-adenine dinucleotide (Coenzyme-1)	0.00132 kg

		8	2,2-Dimethoxy propane	0.950 kg
		9	Ethyl Acetate	3.60 kg
		10	Fluoro Benzene	Not allowed
Note: Above revised norms are for regularization and closure purpose only.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	11 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00006031AM23
RA File Number	039404000574 AM19
Licence No and Date	0310824112/01/10/2018

Norms Committee Decision:

Dr. Asif Musharaaf, Sr. Technical and Shri Sanjay Dhayalkar, Logistics Manager had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to change the description of Export Product from 'Atorvastatin Calcium' to "ATS-8: (4-R-CIS)-1-1-DIMETHYL-6-CYANOMETHYL-2-2-DIMETHYL-1,3 DIOXANE-4-ACETATE" with the following conditions:

- i. 1000 kg of Atorvastatin Calcium will be equivalent to 708 kg of ATS-8. Export Obligation will accordingly be amended for the export of ATS-8.
- ii. Import quantity entitlement will be worked out for import item No. 1 to 9 on pro-rata basis with respect to the norms fixed by NC-3 in its Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against Advance Authorization No. 0310824086 dated 01.10.2018, 0310824121 dated 01.10.2018 and 0310824101 dated 01.10.2018 on repeat basis.
- iii. Firm will pay custom duty and interest as per policy for import item No. 10 - Fluoro Benzene in total (as the same is not allowed) and for any excess import on import item No. 1 to 9.

Following adhoc norms for ATS-8 will be applicable on repeat basis as per Para (ii) above:

Export product	Qty.	Sl. No.	Import items	Qty.
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(4-R-CIS)-1,1-DIMETHYL-6-CYANOMETHYL-2,2-DIMETHYL-1,3-DIOXANE-4-ACETATE (ATS-8)	1 kg	1	Ethyl-4-Chloro aceto acetate	1.060 kg
		2	Lithium metal	0.100 kg
		3	Tert Butyl Acetate	2.110 kg
		4	Lyophilised Enzyme Powder CDX-403	0.0102 kg
		5	IEP OX 58 Spray Dried Enzyme Powder	0.0160 kg
		6	IEP OX 56 Spray Dried Enzyme Powder	0.117 kg
		7	(B-NAD) B-Nicotinamide-adenine dinucleotide (Coenzyme-1)	0.00132 kg
		8	2,2-Dimethoxy propane	0.950 kg
		9	Ethyl Acetate	3.60 kg
		10	Fluoro Benzene	Not allowed
Note: Above revised norms are for regularization and closure purpose only.				

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

Case No.	12 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00006032AM23
RA File Number	039404000573 AM19
Licence No and Date	0310824116/01/10/2018
Norms Committee Decision:	
Dr. Asif Musharaaf, Sr. Technical and Shri Sanjay Dhayalkar, Logistics Manager had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to change the description of Export Product from 'Atorvastatin Calcium' to "ATS-8: (4-R-CIS)-1-1-DIMETHYL-6-	

CYANOMETHYL-2-2-DIMETHYL-1,3 DIOXANE-4-ACETATE” with the following conditions:

- i. 1000 kg of Atorvastatin Calcium will be equivalent to 708 kg of ATS-8. Export Obligation will accordingly be amended for the export of ATS-8.
- ii. Import quantity entitlement will be worked out for import item No. 1 to 9 on pro-rata basis with respect to the norms fixed by NC-3 in its Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against Advance Authorization No. 0310824086 dated 01.10.2018, 0310824121 dated 01.10.2018 and 0310824101 dated 01.10.2018 on repeat basis.
- iii. Firm will pay custom duty and interest as per policy for import item No. 10 - Fluoro Benzene in total (as the same is not allowed) and for any excess import on import item No. 1 to 9.

Following adhoc norms for ATS-8 will be applicable on repeat basis as per Para (ii) above:

Export product	Qty.	Sl. No.	Import items	Qty.
(4-R-CIS)-1,1-DIMETHYL-6-CYANOMETHYL-2,2-DIMETHYL-1,3-DIOXANE-4-ACETATE (ATS-8)	1 kg	1	Ethyl-4-Chloro aceto acetate	1.060 kg
		2	Lithium metal	0.100 kg
		3	Tert Butyl Acetate	2.110 kg
		4	Lyophilised Enzyme Powder CDX-403	0.0102 kg
		5	IEP OX 58 Spray Dried Enzyme Powder	0.0160 kg
		6	IEP OX 56 Spray Dried Enzyme Powder	0.117 kg
		7	(B-NAD) B-Nicotinamide-adenine dinucleotide (Coenzyme-1)	0.00132 kg
		8	2,2-Dimethoxy propane	0.950 kg
		9	Ethyl Acetate	3.60 kg
		10	Fluoro Benzene	Not allowed

Note: Above revised norms are for regularization and closure purpose only.

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

Case No.	13 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00002622AM23
RA File Number	042404000143 AM19
Licence No and Date	0410164962/10/12/2018
Norms Committee Decision: Shri V. Krishnakumar, CEO and Dr. R. Sarvanan Sr. Scientist had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm: Production / Consumption data for the licensing period duly certified by GST.	

Case No.	14 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM REVIW00001752AM23
RA File Number	042404000218 AM19
Licence No and Date	0410165065/04/01/2019
Norms Committee Decision: Shri V. Krishnakumar, CEO and Dr. R. Sarvanan Sr. Scientist had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm: Production / Consumption data for the licensing period duly certified by GST.	

Case No.	15 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023

and Date	
HQ File Number	HQRNORM REVIW00001751AM23
RA File Number	042404000089 AM20
Licence No and Date	0410166026/29/08/2019
Norms Committee Decision: Shri V. Krishnakumar, CEO and Dr. R. Sarvanan Sr. Scientist had attended the Personal Hearing and explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm: Production / Consumption data for the licensing period duly certified by GST.	

Case No.	16 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00109628AM22
RA File Number	03AA04019238 AM22
Licence No and Date	0311004420/08/06/2021
Norms Committee Decision: Shri Shivanand Prabhu, Manager and Shri Harshal Uttarwar, Site Head had attended the Personal Hearing and informed that they have surrendered the subject Advance Authorization in RA and the same has also been redeemed. In view of above, the Committee decided to withdraw the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	17 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00212058AM22
RA File Number	03AA040109332 AM22
Licence No and Date	0311007711/14/10/2021
Norms Committee Decision: Shri Shivanand Prabhu, Manager and Shri Harshal Uttarwar, Site Head had attended the Personal Hearing and	

explained firm's case. The Committee after hearing explanation of Representatives of the firm decided to call for following information / documents from the firm:

- i. **Width of import items or Area (Packing material) wherever unit is given in Meter.**
- ii. **Justification for wastage of 5%, 12% and 20% wastage on packing material.**

Detailed specification of packing material.

Case No.	18 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	HAFFKINE BIO PHARMACEUTICAL CORPORATION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00301796AM22
RA File Number	03AX04000434 AM22
Licence No and Date	0311009905/30/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology vide D.O. Letter No. PID-13011(15)/1/2021-PPB-DBT dated 23.01.2023, it was decided to call for following information / documents from the firm:

- i. **Technical process flow diagram of manufacturing of Bivalent (Type I & Type III) Oral Poliomyelitis Vaccine and wastage involved at each step.**
- ii. **DML (Drug Manufacturing License).**

Case No.	19 / NC/3/MEET/Feb/202223/19
Case Status	Case Rejected
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00345204AM22
RA File Number	03AX04001106 AM22
Licence No and Date	0311011140/06/02/2022

Norms Committee Decision:

The firm was called for attending Personal Hearing before Norms Committee-3 to explain its case. However, the firm vide e-mail dated 02.02.2023 has furnished Revised Manufacturing Process and has requested to condone the Personal Hearing.

The Committee considered the reply furnished by the firm and it was observed that the chemistry given by the firm is not legible and it was also noted that the firm did not attend the Personal Hearing. Hence, it was decided to **reject**

the case.

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

Case No.	20 / NC/3/MEET/Feb/202223/19
Case Status	Case Deferred
Party Name	ARKRAY HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00347493AM22
RA File Number	52AX04000059 AM22
Licence No and Date	5211001995/08/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology vide D.O. Letter No. PID-13011(15)/1/2021-PPB-DBT dated 23.01.2023, it was decided to call for following information / documents from the firm: i. Technical process flow diagram of manufacturing of Parahit-F Device Test Kit involving imported items and wastage involved at each step. ii. Batch manufacturing record and material issued and material reconciliation sheet for production of a batch, duly signed by dealing QA/ Executive / Manager. iii. DML (Drug Manufacturing License).	

Case No.	21 / NC/3/MEET/Feb/202223/19
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202223/ 19 and 07/02/2023
HQ File Number	HQRNORM APPLY 00000901AM23
RA File Number	30AX04000049 AM23
Licence No and Date	3011002146/20/05/2022
Norms Committee Decision: The firm has filed its request on DGFT Portal vide HQRCOMMSUB00008385AM23 and has requested to withdraw its request for fixation of adhoc norms. The Committee considered the request of firm and decided to withdraw the case. RA concerned may take further necessary action as per above decision of NC.	

