



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/Oct/202122/9

DATED: 15/10/2021

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/Oct/202122/9 dated 15/10/2021 of Norms Committee - III for the year 2021-22 was actually held on 21.10.2021 and 29.10.2021 under the Chairmanship of Dr. Amiya Chandra, Additional 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
2	SHAISH KUMAR, Technical Authority	Technical Consultant, DGFT
3	DINESHNARAIN MATHUR, Technical Authority	Technical Consultant, DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	BROOKS LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001339AM21
RA File Number	302404000010 AM21
Licence No and Date	3010105213/02/06/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 2/82-ALC4/2020 dated 10.07.2020, 5/82-ALC4/2020 dated 09.10.2020, followed by Reminder to firm on 23.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	2 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

HQ File Number	018205001344AM21
RA File Number	318304000011 AM21
Licence No and Date	3110067749/03/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Justification for low yield of 54.2% for Phosphorus Oxy Chloride and 56.2% for Ammonia. Justification for use of Iodine as a Catalyst.	

Case No.	3 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001355AM21				
RA File Number	052404000082 AM21				
Licence No and Date	0510414338/05/06/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Azelastine Hydrochloride Nasal Solution (Nasal Spray) 0.1% (137 mcg per	1270000.000 Number	1	Azelastine Hydrochloride	35494.00 gram

	spray) 30ML. (Each spray contains Azelastine Hydrochloride equivalent to 30 mg) (Equivalent to 38100.000 Gram of bulk drug)				
2	Azelastine Hydrochloride Ophthalmic Solution 0.05% W/V 6ML. (Each solution contains Azelastine Hydrochloride equivalent to 3 mg) (Equivalent to 9600.000 Gram of bulk drug) (Total Net Contents 47700.000 Gram)	3200000.000 Number	1	Azelastine Hydrochloride	9792.00 gram

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

Case No.	4 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KUSUMA PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001360AM21
RA File Number	039404000115 AM21
Licence No and Date	0310836572/08/06/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

i. Complete technical details as per Annexure to Appendix 4E.

Justification for wastage claimed.

Case No.	5 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001362AM21
RA File Number	522404000013 AM21
Licence No and Date	5210043424/08/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Justification for low yield of 70% in first stage. ii. Quantity and value of By-Product Acetic Acid generated in production process.	

Case No.	6 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001366AM21
RA File Number	039404000141 AM21
Licence No and Date	0310836585/09/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

- i. **Justification for low yield of 40%.**
- ii. **Authentic Literature to certify the low yield.**
- iii. **Commercial Value of By-Product and their quantity.**
- iv. **Production / Consumption data for last two years duly certified by GST.**

Case No.	7 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	MANGALAM INTERMEDIATES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001372AM21
RA File Number	522104000033 AM21
Licence No and Date	5210043430/10/06/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 2/82-ALC4/2020 dated 10.07.2020, 5/82-ALC4/2020 dated 09.10.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	8 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021																
HQ File Number	018205001374AM21																
RA File Number	052404000100 AM21																
Licence No and Date	0510414377/11/06/2020																
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Ciprofloxacin and Dexamethasone Sterile Otic Suspension 7.5ml (Each ml contains Ciprofloxacin 3mg. & Dexamethasone 1mg (Equivalent to 3375gm Ciprofloxacin and 1125gm Dexamethasone Bulk Drug)</td> <td rowspan="2">150000.000 Number</td> <td>1</td> <td>Ciprofloxacin HCL</td> <td>3933.56 gram</td> </tr> <tr> <td>2</td> <td>Dexamethasone USP (Micronised)</td> <td>1181.25 gram</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Ciprofloxacin and Dexamethasone Sterile Otic Suspension 7.5ml (Each ml contains Ciprofloxacin 3mg. & Dexamethasone 1mg (Equivalent to 3375gm Ciprofloxacin and 1125gm Dexamethasone Bulk Drug)	150000.000 Number	1	Ciprofloxacin HCL	3933.56 gram	2	Dexamethasone USP (Micronised)	1181.25 gram
Export product	Qty.	Sl. No.	Import items	Qty.													
Ciprofloxacin and Dexamethasone Sterile Otic Suspension 7.5ml (Each ml contains Ciprofloxacin 3mg. & Dexamethasone 1mg (Equivalent to 3375gm Ciprofloxacin and 1125gm Dexamethasone Bulk Drug)	150000.000 Number	1	Ciprofloxacin HCL	3933.56 gram													
		2	Dexamethasone USP (Micronised)	1181.25 gram													

Case No.	9 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001375AM21
RA File Number	072404000067 AM21
Licence No and	0710116585/11/06/2020

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 7/82-ALC4/2020 dated 04.12.2020 against advance authorization No. 0710112820 dated 13.02.2018, 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.
ISO NONYL ACETATE	1 kg	1	3,5,5, TRIMETHYL HEXANOL (NONANOL)	0.774 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	10 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001847AM21
RA File Number	052304000050 AM21
Licence No and Date	0510414389/12/06/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	11 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	VANDANA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001378AM21
RA File Number	092404000127 AM21
Licence No and Date	0910068863/12/06/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
CYCLOHEXYL ESTER (CEI)	1 kg	1	GLYOXYLIC ACID-50%	0.726 kg
		2	L(-) MENTHOL	0.663 kg
		3	2,5 DI HYDROXY 1,4 DITHIANE (DIOL)	0.312 kg
		4	CYTOSINE	0.395 kg
		5	HEXAMETHYL DISILAZANE (HMDS)	0.286 kg
		6	METHYLENE CHLORIDE STABILIZED WITH AMYLENE 50 PPM (MDC)	2.63 kg

		7	TRIPHOSGENE	0.400 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	12 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	3AK CHEMIE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001380AM21
RA File Number	092404000129 AM21
Licence No and Date	0910068864/12/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Exact chemical name of export product. ii. If it is blended product, then furnish complete percentage composition of export with COA (Certificate of Analysis). iii. Justification for wastage claimed, if any.	

Case No.	13 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	RA CHEM PHARMA LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

and Date	
HQ File Number	018205001394AM21
RA File Number	092404000169 AM21
Licence No and Date	0910068886/18/06/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 2/82-ALC4/2020 dated 10.07.2020, 5/82-ALC4/2020 dated 09.10.2020, followed by Reminder to firm on 18.09.2020 and 19.11.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	14 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001397AM21
RA File Number	039404000169 AM21
Licence No and Date	0310836740/18/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 3/82-ALC4/2020 dated 07.08.2020 against advance authorization No. 0310831519 dated 13.09.2019, 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.
4-HYDROXYBENZYL ALCOHOL	1 kg	1	4-HYDROXYBENZALDEHYDE OR PARA HYDROXY BENZALDEHYDE	1.20 kg
		2	SODIUM BOROHYDRIDE	0.23 kg

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

Case No.	15 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001399AM21
RA File Number	022404000027 AM21
Licence No and Date	0210209928/18/06/2020
Norms Committee Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to refer the case to Department of Chemical & Petrochemical (D/o C&PC) for obtaining its comments.	

Case No.	16 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred

Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001400AM21
RA File Number	022404000028 AM21
Licence No and Date	0210209929/18/06/2020
Norms Committee Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to refer the case to Department of Chemical & Petrochemical (D/o C&PC) for obtaining its comments.	

Case No.	17 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	BALAJI SPECIALITY CHEMICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001406AM21			
RA File Number	318304000021 AM21			
Licence No and Date	3110067767/22/06/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking 96% yield, 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.
ETHYLENE DIAMINE	1 kg	1	MONOETHANOLAMINE	1.06 kg

		2	AMMONIA ANHYDROUS	0.294 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	18 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001418AM21
RA File Number	022404000031 AM21
Licence No and Date	0210209935/23/06/2020
Norms Committee Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to refer the case to Department of Chemical & Petrochemical (D/o C&PC) for obtaining its comments.	

Case No.	19 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SONGWON SPECIALTY CHEMICALS - INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001415AM21
RA File Number	342404000060 AM21
Licence No and	3410046173/23/06/2020

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Justification of import item No. 2 and 3 together. ii. Percentage yield of each stage of reaction with stiochiometric balance on molar basis. iii. Dimethylformamide and Ethylene Dichloride are used as a solvent and recovery of these solvent. Production / Consumption data for last two years duly certified by GST.	

Case No.	20 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SONGWON SPECIALTY CHEMICALS - INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001416AM21
RA File Number	342404000064 AM21
Licence No and Date	3410046174/23/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: Complete technical details as per Annexure to Appendix 4E.	

Case No.	21 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred

Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001417AM21
RA File Number	022404000030 AM21
Licence No and Date	0210209934/23/06/2020
Norms Committee Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to refer the case to Department of Chemical & Petrochemical (D/o C&PC) for obtaining its comments.	

Case No.	22 / NC/3/MEET/Oct/202122/9													
Case Status	Case Approved													
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021													
HQ File Number	018205001421AM21													
RA File Number	318304000022 AM21													
Licence No and Date	3110067771/24/06/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 6/82-ALC4/2020 dated 13.11.2020 against advance authorization No. 3110067787 dated 07.07.2020 , 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:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Guaiacol</td><td>1 kg</td><td>1</td><td>Phenol</td><td>0.97 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import items	Qty.	Guaiacol	1 kg	1	Phenol	0.97 kg
Export Product	Qty.	Sl. No.	Import items	Qty.										
Guaiacol	1 kg	1	Phenol	0.97 kg										

		2	Methanol	0.38 kg
		3	Hydrogen Peroxide PURITY 60%	0.687 kg
		4	Acetone (Solvent)	0.1 kg

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

Case No.	23 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	RONAK CHEMICALS			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001422AM21			
RA File Number	342404000017 AM21			
Licence No and Date	3410046180/24/06/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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.
BARBITURIC ACID	1 kg	1	DI ETHYL MALONATE	1.38 kg

		2	SODIUM METHOXIDE POWDER	0.467 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	24 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	ZEISS PHARMACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001428AM21			
RA File Number	302204000037 AM21			
Licence No and Date	3010105262/25/06/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
Drug Formulations Injections (vials 30 ML) - CEFPIROME SULPHATE for Injection 1 G Each vial contain Cefpirome sulphate (sterile) (buffered with sodium carbonate)-1.46 Grams equivalent to CEFPIROME SULPHATE for Injection - 1 G)	1 Vial	1	Relevant Bulk Drug - Cefpirome sulphate (sterile) (buffered with sodium carbonate)	1.447 gram

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

Case No.	25 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001431AM21
RA File Number	072404000092 AM21
Licence No and Date	0710116675/29/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Justification for converting Granular Form to Powder Form. ii. Mesh size of Export Product. Production / Consumption data for last two years duly certified by GST.	

Case No.	26 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001436AM21
RA File Number	052404000144 AM21

Licence No and Date	0510414508/30/06/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	27 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001437AM21
RA File Number	039404000210 AM21
Licence No and Date	0310836960/30/06/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	28 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MAHI DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001438AM21
RA File Number	262404000003 AM21
Licence No and Date	2610012912/30/06/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	29 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001447AM21
RA File Number	092404000143 AM21
Licence No and Date	0910068917/30/06/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
Production / Consumption data duly certified by GST.	

Case No.	30 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001440AM21
RA File Number	039404000201 AM21
Licence No and Date	0310836986/01/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	31 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001441AM21
RA File Number	039404000202 AM21
Licence No and Date	0310836987/01/07/2020
Norms Committee Decision:	

The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm.

Hence, the Committee decided to **reject** the case.

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

Case No.	32 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001442AM21
RA File Number	039404000200 AM21
Licence No and Date	0310836988/01/07/2020
Norms Committee Decision:	
The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm.	
Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	33 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected

Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001443AM21
RA File Number	039404000979 AM20
Licence No and Date	0310836990/01/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	34 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001444AM21
RA File Number	039404001071 AM20
Licence No and Date	0310836991/01/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case.	

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

Case No.	35 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001445AM21
RA File Number	052404000149 AM21
Licence No and Date	0510414531/01/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Delta Decalactone Natural (Tetrahydro-6-pentyl-2H pyran-2-One)	935.00 kg	1	Massoia C-10 Lactone Natural (6-Pentyl-5,6-dihydro-2H-pyran-2-One)	970.00 kg

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

Case No.	36 / NC/3/MEET/Oct/202122/9
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Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001446AM21
RA File Number	039404000157 AM21
Licence No and Date	0310837001/01/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	37 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001449AM21
RA File Number	322404000019 AM21
Licence No and Date	3210079591/02/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Justification for having low yield percentage.	

Production / Consumption data for last two years duly certified by GST.

Case No.	38 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001453AM21
RA File Number	039404001083 AM20
Licence No and Date	0310837056/07/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	39 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001455AM21
RA File Number	039504000192 AM21

Licence No and Date	0310837078/08/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	40 / NC/3/MEET/Oct/202122/9		
Case Status	Case Approved		
Party Name	GLENMARK PHARMACEUTICALS LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021		
HQ File Number	018205001456AM21		
RA File Number	039404000227 AM21		
Licence No and Date	0310837081/08/07/2020		
Norms Committee Decision:			
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 6/82-ALC4/2020 dated 13.11.2020 against advance authorization No. 0310838803 dated 08.10.2020 , 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:			

2	Desonide Cream 0.05% 60gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.750 Kgs)	1 Number
3	Desonide Lotion 0.05% 59ml (Net Wt. of Desonide USP Micronised (Sicor) is 0.738 Kgs)	1 Number
4	Desonide Lotion 0.05% 118ml (Net Wt. of Desonide USP Micronised (Sicor) is 1.475 Kgs)	1 Number
5	Desonide Ointment 0.05% 15gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.188 Kgs)	1 Number
6	Desonide Ointment 0.05% 60gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.750 Kgs)	1 Number

SI. No.	Import Items	For the Export of 1 No. Pack					
		0.05% 15 gm pack	0.05% 60 gm pack	0.05% 59 ml pack	0.05% 118 ml pack	0.05% 15 gm pack	0.05% 60 gm pack
1	Desonide USP Micronised (Sicor)	0.00765 gm	0.0306 gm	0.301 gm	0.602 gm	0.00765 gm	0.0306 gm

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

Case No.	41 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001457AM21
RA File Number	318304000020 AM21
Licence No and Date	3110067788/08/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	42 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001458AM21
RA File Number	039404000218 AM21
Licence No and Date	0310837120/09/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Exact chemical name of import and export item. ii. COA and Catalogue of import item from foreign supplier. iii. Composition of Export Product.	

iv. Complete manufacturing process.

Chemical reaction with molecular and structural formula.

Case No.	43 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	LINK PHARMACHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001463AM21
RA File Number	342404000085 AM21
Licence No and Date	3410046202/10/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
1,3 - DICHLORO ACETONE	1 kg	1	1-CHLORO-2,3-EXPOXYPROPANE (EPICHLOROHYDRIN)	0.94 kg
		2	SODIUM DICHLOROMATE	1.55 kg

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

Case No.	44 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001464AM21
RA File Number	072404000102 AM21
Licence No and Date	0710116730/10/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **2/82-ALC4/2018 dated 16.05.2018** against advance authorization No. **0710111644 dated 23.05.2017**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	CALCIUM GLUCONATE (EP FOR INJECTION/JP/USP/POWDER)	1 kg	1	CALCIUM GLUCONATE	1.09 kg
2	CALCIUM BOROGLUCONATE	1 kg	1	CALCIUM GLUCONATE	0.913 kg
3	CALCIUM GLUBIONATE (FOR INJECTION) / CALCIUM GLUBIONATE	1 kg	1	CALCIUM GLUCONATE	0.430 kg

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

Case No.	45 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001471AM21
RA File Number	092404000159 AM21
Licence No and Date	0910068951/10/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	46 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SHARON BIO-MEDICINE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001459AM21
RA File Number	039504000141 AM21
Licence No and Date	0310837129/10/07/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
LOPERAMIDE 2 MG ORAL DISPERSIBLE TABLETS LOPERAMIDE 2 MG FAST MELT TAB 6S EACH TABLETS CONTAINS LOPERAMIDE HYDROCHLORIDE 2 MG AND PHARMABRUST B1 184 KGS FOR 1 BATCH EQUAL TO 1000000 TABLETS 85645 PACKS OF 36S EQUAL TO 3083220 TABLETS	1 Number Tablet	1	PHARMABURST B1	184.00 mg

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

Case No.	47 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001461AM21
RA File Number	052404000168 AM21
Licence No and Date	0510414600/10/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

Copy of DML showing Approved Composition of Export item.

Case No.	48 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001466AM21
RA File Number	072404000105 AM21
Licence No and Date	0710116735/13/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Specification of Pharma Goods of Export as per Pharmacopia. COA of Export and import item stating percentage purity and impurity profile	

Case No.	49 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001468AM21
RA File Number	082404000075 AM21
Licence No and	0810148122/14/07/2020

Date				
Norms Committee Decision: The Committee considered the case as per agenda and 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.
Formulated Amine Curing Agent (containing 50% Diethyl Toluene Diamine, 50% Isophorone Diamine)	80000.000 kg	1	Di Ethyl Toluene Diamine Ethacure 100 Lonzacure DETDA 80 DETDA 80 DETDA	40400.000 kg
		2	Iso Phoron Diamine Vestamine IPD Baxxodur EC 201 Wanamine IPDA	40400.000 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	50 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001473AM21
RA File Number	039404000254 AM21
Licence No and Date	0310837163/14/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

- i. Detailed manufacturing process.
- ii. COA of import item from foreign supplier indicating percentage purity.

Manufacturing process of Export Item No. 2.

Case No.	51 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001474AM21
RA File Number	039404000257 AM21
Licence No and Date	0310837175/14/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **2/82-ALC4/2020 dated 10.07.2020** against advance authorization No. **0310834476 dated 24.01.2020**, 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:

Sl. No.	Export Product	Qty.	Import items	Qty.
1	Clobetasol Propionate Foam 0.05% 50gm (Net. wt. of Net. wt. of Clobetasol Propionate USP (Micronized) is 3.750 Kgs.)	150000.000 Packs	CLOBETASOL PROPIONATE USP (MICRONIZED)	24.65 kg
2	Clobetasol Propionate Foam 0.05% 100gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 7.500 Kgs.)	150000.000 Packs		

3	Clobetasol Propionate Cream USP 0.05% (Pack Size 15gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.750 Kgs)	100000.000 Packs		
4	Clobetasol Propionate Cream USP 0.05% (Pack size 30gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.300 Kgs)	20000.000 Packs		
5	Clobetasol Propionate Cream USP 0.05% (Pack size 45 gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.450 Kgs)	20000.000 Packs		
6	Clobetasol Propionate Cream USP 0.05% (Pack size 60gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs)	20000.000 Packs		
7	Clobetasol Propionate Ointment USP 0.05% (Pack size 15gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.150 Kgs)	20000.000 Packs		
8	Clobetasol Propionate Ointment USP 0.05% (Pack size 30gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.750 Kgs)	50000.000 Packs		
9	Clobetasol Propionate Ointment USP 0.05% (Pack size 45gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs)	40000.000 Packs		
10	Clobetasol Propionate Ointment USP 0.05% (Pack size 60gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs)	20000.000 Packs		
11	Clobetasol Propionate Spray 0.05% (Pack size 59ml) (Net Weight of Clobetasol Propionate USP (Micronized) 1.180 Kgs)	40000.000 Packs		
12	Clobetasol Propionate Spray 0.05% (Pack size 125ml) (Net Weight of Clobetasol Propionate USP (Micronized) 2.500 Kgs)	40000.000 Packs		
13	Clobetasol Prop. Top Sol USP, 0.05% 25ml (Net Weight of Clobetasol Propionate USP (Micronized) 0.625 Kgs)	50000.000 Packs		
14	Clobetasol Prop. Top Sol USP, 0.05% 50ml	40000.000 Packs		

	(Net Weight of Clobetasol Propionate USP (Micronized) 1.000 Kgs)			
15	Clobetasol Pro Shampoo, 0.05 % 118ml (Net Weight of Clobetasol Propionate USP (Micronized) 2.360 Kgs)	40000.000 Packs		
16	Clobetasol Propionate Foam 0.05% 100gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 0.500 Kgs.)	10000.000 Packs		
17	Clobetasol Propionate Foam 0.05% 50gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 0.250 Kgs.)	10000.000 Packs		
RA concerned may take further necessary action as per above decision of NC.				

Case No.	52 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001478AM21
RA File Number	039404000232 AM21
Licence No and Date	0310837216/15/07/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the description of Export Product does not match with the DML. Hence, it was decided to reject the case.	

Case No.	53 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001479AM21
RA File Number	039404000260 AM21
Licence No and Date	0310837228/16/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current, Honey Lemon & Other Flavours. Each Lozenge Contains 12mg Benzocaine. Net content of Benzocaine - 97.015 Kgs.	1 Number	1	Benzocaine	12.24 mg
2	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current and Lime & Lemon and Other Flavours. Each Lozenge contains 10mg Benzocaine. Net content of Benzocaine - 33.52 Kgs.	1 Number	2	Benzocaine	10.20 mg
3	Benzocaine, Cetylpyridinium Chloride And Dextromethorphan Hydrobromide Anaesthetic Throat Lozenges.	1 Number	3	Benzocaine	1.275 mg
	Each Lozenge Contains 1.25mg Benzocaine. Net content of				

4	Benzocaine - 4.695 Kgs.	1 Number	4	Benzocaine	15.30 mg
	Life Brand Sore Throat & Nasal Congestion Relief Extra Strength (Flavours Cherry/Honey & Lemon/Other flavours) Sugar Free Lozenges.Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.		5	Isomalt ST-M	2571.00 mg
5	Personnelle Oral Anesthetic Sore Throat Lozenges Extra Strenght Sugar Free (Flavours Cherry/Honey Lemon/Other flavours) Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number	6	Benzocaine	15.30 mg
			7	Isomalt ST-M	2571.00 mg
6	Option+Oral Lozenges Sore Throat & Nasal Congestion Relief Extra Strenght (Flavours Cherry/Honey Lemon /Other flavours). Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number	8	Benzocaine	15.30 mg
			9	Isomalt ST-M	2571.00 mg
7	Biomedic Oral Anesthetic Lozenges Sore Throat & Nasal Congestion Relief Extra Strength Cherry ST & NC RELEX Lozenges (Flavours Cherry / Honey Lemon/ Other flavours) Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number	10	Benzocaine	15.30 mg
			11	Isomalt ST-M	2571.00 mg
8	Atoma Sore Throat & Nasal Congestion Relief Extra Strength Lozenges Cherry/Honey & Lemon Flavour. Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2700 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number	12	Benzocaine	15.30 mg
			13	Isomalt ST-M	2571.00 mg

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

Case No.	54 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	MEHTA API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001480AM21
RA File Number	039504000231 AM21
Licence No and Date	0310837276/20/07/2020
Norms Committee Decision:	
The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	55 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ASTRAL STERITECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001481AM21
RA File Number	342404000096 AM21

Licence No and Date	3410046228/20/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	56 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001483AM21
RA File Number	092404000174 AM21
Licence No and Date	0910068965/20/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	57 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001494AM21
RA File Number	092404000209 AM21
Licence No and Date	0910068983/21/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Sultamicillin	1 kg	1	6-Aminopenicillanic acid (6-APA)	0.60 kg
		2	Acetonitrile	1.24 kg
		3	Activated Carbon (Carbon Enoanticromos)	0.070 kg
		4	D(-) Alpha Phenyl Glycine Base (PG Base)	0.472 kg
		5	Dimethylformamide	1.00 kg
		6	Iodomethyl sulbactam	0.87 kg
		7	Isopropyl alcohol	2.85 kg

		8	Methanol (Methyl Alcohol)	0.25 kg
		9	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads) or (Immobilized Acylase Enzyme) XInase	0.0014 kg

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

Case No.	58 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001485AM21
RA File Number	052404000176 AM21
Licence No and Date	0510414657/21/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Moxifloxacin HCL and Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml (MILFLOX DM, MILFODOX, MIFLOCO DELTA) (Each ml contain Moxifloxacin Base 5mg. equi. to	26300.000 Number	1	Moxifloxacin Hydrochloride	752.50 gram
		2	Dexamethasone Sodium Phosphate	151.88 gram

Moxifloxacin HCL 5.45mg. & Dexamethasone Phosphate 1mg equi. to Dexamethasone Sodium Phosphate 1.1mg (Equi.to 716.675gm Moxifloxacin HCL and 144.650gm Dexamethasone Sodium Phosphate Bulk Drug)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	59 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ADVANCE PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001486AM21
RA File Number	082404000095 AM21
Licence No and Date	0810148200/21/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	60 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001492AM21
RA File Number	342404000098 AM21
Licence No and Date	3410046235/22/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Diclofenac Sodium Gel 3 % 100g Tube (Net Content of Active Ingredients = 60 kg)	20000.000 Number	1	Diclofenac Sodium USP	61.2 kg

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

Case No.	61 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001496AM21
RA File Number	092404000185 AM21

Licence No and Date	0910068991/22/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Catalogue of import item from foreign supplier indicating the use of item in this type of reaction. Production / Consumption data for last two years duly certified by GST.	

Case No.	62 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	USV PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001489AM21				
RA File Number	039504000240 AM21				
Licence No and Date	0310837311/22/07/2020				
Norms Committee Decision: The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Desipramine Hydrochloride Tablets, USP 25 MG 100 S (24,000 Bottles x 100 Per Bottles = 24,00,000 Tablets) (Net Content Weight = 60.000 Kgs)	2400000.000 Tablets	1	Desipramine HCL	61.20 kg

2	Desipramine Hydrochloride Tablets, USP 50 MG 100 S (12,600 Bottles x 100 Per Bottles = 12,60,000 Tablets) (Net Content Weight = 63.000 Kgs)	1260000.000 Tablets	1	Desipramine HCL	64.26 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	63 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001490AM21
RA File Number	052404000191 AM21
Licence No and Date	0510414685/22/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 3/82-ALC4/2020 dated 07.08.2020, 6/82-ALC4/2020 dated 13.11.2020, followed by Reminder to firm on 18.09.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC	

Case No.	64 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001497AM21				
RA File Number	052404000159 AM21				
Licence No and Date	0510414709/24/07/2020				
Norms Committee Decision: The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Inj. Fentanyl Citrate eqv. to Fentanyl 50mcg/ml, 2ml Ampoule	2290000.000 Number	1	Fentanyl Citrate	395.72 gram
2	Inj. Fentanyl Citrate eqv. to Fentanyl 50mcg/ml, 10ml Ampoule	190000.000 Number	1	Fentanyl Citrate	164.16 gram
RA concerned may take further necessary action as per above decision of NC.					

Case No.	65 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	PHAROSE REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001502AM21

RA File Number	182404000004 AM21			
Licence No and Date	1810004355/24/07/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
Alpha Ketoanalogue+ Essential Amino Acids Film-Coated Tablet - MEDICINE (Each tablet contains L-Histidine 38.0 mg)	1 Number	1	L-HISTIDINE BULK DRUG	38.76 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	66 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001501AM21
RA File Number	072404000118 AM21
Licence No and Date	0710116798/27/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

(i) **Justification for converting Granular Form to Powder Form.**

i. Mesh size of Export Product.

Production / Consumption data for last two years duly certified by GST.

Case No.	67 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001508AM21
RA File Number	092404000160 AM21
Licence No and Date	0910068998/28/07/2020
Norms Committee Decision:	
The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm.	
Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	68 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001509AM21
RA File Number	092404000167 AM21
Licence No and Date	0910069002/28/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
2(R)-(Hydroxy Methyl)-5(S) cytosine-1-YI-1, oxathiolane salicylic acid salt (Lamivudine Salicylate)	3- 1 kg	1	GLYOXALIC ACID 50%	0.746 kg
		2	2,5-DIHYDROXY-1,4-DIATHINE	0.327 kg
		3	SODIUM BOROHYDRIDE	0.26 kg
		4	DI METHYL FORMAMIDE (DMF)	0.26 kg
		5	CYTOSINE	0.434 kg
		6	HEXA METHYL DISILAZANE (HMDS)	0.69 kg
		7	METHYLENE DI CHLORIDE (MDC)	2.63 kg
		8	L-MENTHOL (FRESH / RECOVERY)	0.665 kg
		9	TRI ETHYL AMINE (TEA)	0.233 kg

		10	TRIPHOSGINE	0.40 kg
		11	SALICYLIC ACID	0.30 kg

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

Case No.	69 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SAFECON LIFESCIENCES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001504AM21
RA File Number	062404000092 AM20
Licence No and Date	0610039560/28/07/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	70 / NC/3/MEET/Oct/202122/9
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Case Status	Case Approved										
Party Name	S.M. HERBALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021										
HQ File Number	018205001506AM21										
RA File Number	052404000146 AM21										
Licence No and Date	0510414764/28/07/2020										
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>10-DEACETYLE BACCATIN -III (OTHER VEGETABLE ALKALOID) MADE OF TAXUS WALLICHIANA TWIG & LEAF</td><td>1 kg</td><td>1</td><td>TAXUS WALLICHIANA TWIG & LEAF</td><td>244.68 kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export product	Qty.	Sl. No.	Import items	Qty.	10-DEACETYLE BACCATIN -III (OTHER VEGETABLE ALKALOID) MADE OF TAXUS WALLICHIANA TWIG & LEAF	1 kg	1	TAXUS WALLICHIANA TWIG & LEAF	244.68 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
10-DEACETYLE BACCATIN -III (OTHER VEGETABLE ALKALOID) MADE OF TAXUS WALLICHIANA TWIG & LEAF	1 kg	1	TAXUS WALLICHIANA TWIG & LEAF	244.68 kg							

Case No.	71 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001512AM21
RA File Number	342404000111 AM21
Licence No and	3410046259/29/07/2020

Date					
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jan/202021/4 dated 12.02.2021 against advance authorization No. 3410045217 dated 18.06.2019, 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
Rose Oxide (Tetrahydro-4-Methyl -2-(2-Methyl Propenyl) 2 H Pyron		1 kg	1	Citral Synthetic	3.454 kg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	72 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001513AM21
RA File Number	039504000239 AM21
Licence No and Date	0310837496/30/07/2020
Norms Committee Decision: The Committee considered the case as per agenda and 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:	

Sl. No.	Export product	Qty.
1	Phytosterol Natural Refined Phytosterol 95%	120000.000 kg
2	Natural Mixed Tocopherol 70%	55000.000 kg

Sl. No.	Import items	Qty.
1	Fatty Acid Distillate / Deoderised Distillate	1842500 kg
2	Acetone	88000 kg
3	Heptane-S	188100 kg

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

Case No.	73 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

HQ File Number	018205001524AM21			
RA File Number	092404000239 AM21			
Licence No and Date	0910069013/31/07/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
Ibuclin Cold & Flu Max powder for oral solution - Lemon flavour (Each Sachet contains Paracetamol 750 mg, Phenylephrine Hydrochloride 10 mg and Ascorbic acid 60 mg)	9056250.000 Number	1	Ascorbic Acid THIS LICENCE IS ISSUED WITH PRIOR IMPORT CONDITON AND THE E.O. SHOULD BE COMPLETED WITHIN 12 MONTHS FROM THE DATE OF EACH IMPORT CONSIGNMENT AS PER APPX.4J OF FTP 2015-20, read with PN.No.62, dt.24.03.2017 read with PN.No.62, dt.24.03.2017	554.240 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	74 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	CADILA HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001516AM21
RA File Number	082404000110 AM21
Licence No and	0810148274/04/08/2020

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Aug/202122/7 dated 13.08.2021** against advance authorization No. **0810143923 dated 20.11.2018**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	AZITHROMYCIN ORAL SUSPENSION USP 100MG/5ML (300MG/15ML BOTTLE) (ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP - NET WEIGHT 106.078 KGS.)	1 Number	1	AZITHROMYCIN DIHYDRATE USP (This Licence is issued with condition that import of any Drug against this Licence will be allowed through Registered Sources as per provision laid down in Drug & Cosmetic Act. and as per Para 4.07 of HBP 2015-20 subject to fixation of norms by ALC, New Delhi)	330.12 mg
			2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg
2	AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (600MG/15ML BOTTLE) (ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP - NET WEIGHT 424.315 KGS.)	1 Number	1	AZITHROMYCIN DIHYDRATE USP (This Licence is issued with condition that import of any Drug against this Licence will be allowed through Registered Sources as per provision laid down in Drug & Cosmetic Act. and as per Para 4.07 of HBP 2015-20 subject to fixation of norms by ALC, New Delhi)	660.24 mg
			2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg
3	AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (900MG/22.5ML BOTTLE) (ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP - NET WEIGHT 446.378 KGS.)	1 Number	1	AZITHROMYCIN DIHYDRATE USP (This Licence is issued with condition that import of any Drug against this Licence will be allowed through Registered Sources as per provision laid down in Drug & Cosmetic Act. and as per Para 4.07 of HBP 2015-20 subject to fixation of norms by ALC, New Delhi)	990.36 mg
			2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	17424.00 mg

4	AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (1200MG/30ML BOTTLE) (ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP - NET WEIGHT 463.958 KGS.)	1 Number	1	AZITHROMYCIN DIHYDRATE USP (This Licence is issued with condition that import of any Drug against this Licence will be allowed through Registered Sources as per provision laid down in Drug & Cosmetic Act. and as per Para 4.07 of HBP 2015-20 subject to fixation of norms by ALC, New Delhi)	1320.48 mg
			2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	23232.00 mg

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

Case No.	75 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ORTIN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001532AM21
RA File Number	092404000197 AM21
Licence No and Date	0910069018/05/08/2020
Norms Committee Decision: Deferred for comments of TE.	

Case No.	76 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SHARON BIO-MEDICINE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021													
HQ File Number	018205001518AM21													
RA File Number	039504000269 AM21													
Licence No and Date	0310837562/07/08/2020													
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Diarrhoea Relief Instant 2 mg Orodispersible Tablets Loperamide 2 mg Fast Melt Tablets each Tablet contains Pharmaburst 188.6 mg 108790 packs 36s equal to 3946152 Tablets</td> <td>1 Number Tablet</td> <td>1</td> <td>PHARMABURST B1</td> <td>184.00 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Diarrhoea Relief Instant 2 mg Orodispersible Tablets Loperamide 2 mg Fast Melt Tablets each Tablet contains Pharmaburst 188.6 mg 108790 packs 36s equal to 3946152 Tablets	1 Number Tablet	1	PHARMABURST B1	184.00 mg
Export product	Qty.	Sl. No.	Import items	Qty.										
Diarrhoea Relief Instant 2 mg Orodispersible Tablets Loperamide 2 mg Fast Melt Tablets each Tablet contains Pharmaburst 188.6 mg 108790 packs 36s equal to 3946152 Tablets	1 Number Tablet	1	PHARMABURST B1	184.00 mg										

Case No.	77 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	AVIEUM LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001521AM21
RA File Number	318304000035 AM21
Licence No and Date	3110067807/07/08/2020
Norms Committee Decision:	

The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm.

Hence, the Committee decided to **reject** the case.

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

Case No.	78 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SHIVA BIOCHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001522AM21
RA File Number	502404000009 AM21
Licence No and Date	5010002703/07/08/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. COA of import item from foreign supplier indicating percentage moisture content.	
ii. Complete specification of export item.	
Process of manufacturing indicating wastage at each stage of manufacturing.	

Case No.	79 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected

Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001526AM21
RA File Number	072404000129 AM21
Licence No and Date	0710116853/10/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	80 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001528AM21
RA File Number	039404000306 AM21
Licence No and Date	0310837580/10/08/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Complete chemical reaction with molecular and structural formula and molecular weights alongwith stagewise percentage yield on molar basis. ii. Stoichiometric balance details for the entire manufacturing process.	

Production / Consumption data for last two years duly certified by Central Excise / GST.

Case No.	81 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001529AM21
RA File Number	039404000310 AM21
Licence No and Date	0310837582/10/08/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Ciprofloxacin and Dexamethasone Otic Suspension USP (0.3% - 0.1%) 7.5ml Bottle. (Each ml Contains: CIPROFLOXACIN HCL Equivalent to CIPROFLOXACIN BASE 3mg & DEXAMETHASONE 1mg) per bottle of 7.5ml) (Each 7.5 ml Cont.: Ciprofloxacin 22.5mg & Dexamethasone 7.5 mg) Nt.wt Ciprofloxacin HCL 27 kgs & Dexamethasone 9 kgs.	12,00,000 Number	1	Ciprofloxacin HCL	31.05 kg
		2	Dexamethasone	9.45 kg
		3	Ear Drop Bottle	Relevant as per packing policy
		4	Ear Drop Caps	Relevant as per packing policy
		5	Ear Drop Insert	Relevant as per packing policy

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

Case No.	82 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001539AM21
RA File Number	052404000223 AM21
Licence No and Date	0510414876/11/08/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Inj. Norepinephrine Bitartrate 2mg eq. to Norepinephrine 1mg/ml, 4ml Ampoule	1 Number	1	Noradrenaline Bitartrate (Norepinephrine Bitartrate)	8.80 mg

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

Case No.	83 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001568AM21
RA File Number	092404000262 AM21
Licence No and Date	0910069046/17/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	84 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001569AM21
RA File Number	092404000263 AM21
Licence No and Date	0910069049/18/08/2020
Norms Committee Decision:	

The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm.

Hence, the Committee decided to **reject** the case.

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

Case No.	85 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	NITIKA PHARMACEUTICAL SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001546AM21
RA File Number	502404000011 AM21
Licence No and Date	5010002710/18/08/2020
Norms Committee Decision:	
The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm.	
Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	86 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected

Party Name	AURA LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001558AM21
RA File Number	342404000133 AM21
Licence No and Date	3410046298/18/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	87 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001563AM21
RA File Number	052404000225 AM21
Licence No and Date	0510414951/20/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case.	

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

Case No.	88 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	PIRAMAL ENTERPRISES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001565AM21
RA File Number	039504000288 AM21
Licence No and Date	0310837797/20/08/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **0310835077 dated 26.02.2020**, 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:

Sl. No.	Export Product	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
2	Atorvastatin Calcium Tablets USP 10mg (Pack Size 1000 tabs) (Net 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.)	1 Number Tablet
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

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
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
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

Sl. No.	Import Item	For export of 1 Number Tablet (All Qty. in mg)			
		10 mg	20 mg	40 mg	80 mg
1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.241	22.483	44.965	89.931
2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	61.038	122.508	244.170	488.340
3	Calcium Acetate	17.333	34.770	69.336	138.672
4	Plastic Bottles 75CC white HDPE Round 38mm	Relevant as per packing policy			
5	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)				
6	Plastic Bottles 120CC white HDPE Round 38mm				

7	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	
8	CR38400APJT865 BLUE PP465 1400 (Plastics Caps/Closures PP 38MM-400 Blue CR)	
9	Blue 53mm Pp Cap Lp-E & Triseal F217hy (Plastics Caps/Closures PP 53MM-400 Blue PP)	
10	CC8940AFS837 WHITE PP551 CT 89 400SP (Plastics Caps/Closures PP 89MM-400 White Plain)	

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

Case No.	89 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001567AM21
RA File Number	039404000362 AM21
Licence No and Date	0310837815/20/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm.	

Hence, the Committee decided to **reject** the case.

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

Case No.	90 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001571AM21
RA File Number	092404000264 AM21
Licence No and Date	0910069070/20/08/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Valaciclovir Hydrochloride	1 kg	1	Acyclovir	0.758 kg
		2	N,N-Dicyclohexyl Carbodimide (DCC)	1.061 kg
		3	Dimethyl Formamide (DMF)	3.515 kg
		4	CBZ L-Valine	1.112 kg

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

Case No.	91 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	THERAPIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001572AM21
RA File Number	092404000250 AM21
Licence No and Date	0910069090/24/08/2020
Norms Committee Decision:	
The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC	

Case No.	92 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001573AM21

RA File Number	039404000344 AM21
Licence No and Date	0310837840/24/08/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Complete technical details as per Annexure to Appendix 4E. Whether BPPA is indigenous or to be imported, as it is shown indigenous under Appendix 4E.	

Case No.	93 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	BRAWN LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001574AM21			
RA File Number	052304000115 AM21			
Licence No and Date	0510414997/25/08/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
SOMATOSTATIN FOR INJECTION 3MG VIAL (WHITE LYOPHILIZED POWDER/CAKE FILLED IN A CLEAR GLASS TUBULAR VIALS)	1 Vial	1	SOMATOSTATIN BP (WHITE OR ALMOST WHITE,	3.30 mg

			HYGROSCOPIC, AMORPHOUS POWDER)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	94 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001575AM21
RA File Number	092404000047 AM21
Licence No and Date	0910069097/25/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	95 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001576AM21
RA File Number	092404000042 AM21
Licence No and Date	0910069098/25/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	96 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	MEDREICH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001578AM21			
RA File Number	072404000144 AM21			
Licence No and Date	0710116931/26/08/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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:				

Sustained Release Capsules of Ferrous Sulphate with Folic Acid [FEFOL 270mg/0.3mg] [11820000 NO] Each spansule capsule contains Dried Ferrous Sulphate BP 270mg [in time release form] Folic Acid 0.3mg] [Iron 270mg/Folic Acid 0.3mg Capsules]	1 Number	1	Ferrous Sulphate Pellets 18/25	324.00 mg
		2	Folic Acid Pellets 18/25	90.00 mg

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

Case No.	97 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001584AM21
RA File Number	318304000048 AM21
Licence No and Date	3110067835/27/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC	

Case No.	98 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001585AM21
RA File Number	092404000253 AM21
Licence No and Date	0910069107/27/08/2020
Norms Committee Decision: Deferred for comments of Department of Biotechnology (DBT).	

Case No.	99 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001589AM21
RA File Number	072404000145 AM21
Licence No and Date	0710116940/28/08/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Mesh size of Export Product. Production / Consumption data for last one year duly certified by GST.	

Case No.	100 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001586AM21
RA File Number	039504000299 AM21
Licence No and Date	0310837947/28/08/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	101 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001588AM21
RA File Number	072404000146 AM21
Licence No and Date	0710116939/28/08/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
Complete technical details as per Annexure to Appendix 4E.	

Case No.	102 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001603AM21
RA File Number	039404000388 AM21
Licence No and Date	0310838005/31/08/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	103 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001604AM21
RA File Number	052304000157 AM21
Licence No and Date	0510415066/31/08/2020
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	104 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	CADILA HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001605AM21
RA File Number	082404000157 AM21
Licence No and Date	0810148453/01/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 15 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 399.975 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 53330)	53330.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	407.975 gram
			3	AL TUBE FOR CLOBETASOL PROPIONATE	Relevant as per packing policy

				OINTMENT USP 0.05%, 15 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	
2	CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 30 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 2999.520 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 199968)	199968.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	3059.510 gram
			4	AL TUBE FOR CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 30 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
3	CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 45 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 799.785 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 35546)	35546.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	815.780 gram
			5	AL TUBE FOR CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 45 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
4	CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 60 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL	86648.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION	2651.43 gram

	PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 2599.440 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 86648)			THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	
			6	AL TUBE FOR CLOBETASOL PROPIONATE OINTMENT USP 0.05%, 60 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
5	CLOBETASOL PROPIONATE CREAM USP 0.05%, 15 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 1999.875 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 266650)	266650.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	2040.00 gram
			7	AL TUBE FOR CLOBETASOL PROPIONATE CREAM USP 0.05%, 15 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
6	CLOBETASOL PROPIONATE CREAM USP 0.05%, 30 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 1199.760 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 79984)	79984.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF	1223.76 gram

				NORMS BY ALC, NEW DELHI)	
			8	AL TUBE FOR CLOBETASOL PROPIONATE CREAM USP 0.05%, 30 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
7	CLOBETASOL PROPIONATE CREAM USP 0.05%, 45 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 599.805 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 26658)	26658.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	611.80 gram
			9	AL TUBE FOR CLOBETASOL PROPIONATE CREAM USP 0.05%, 45 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
8	CLOBETASOL PROPIONATE CREAM USP 0.05%, 60 GM (EACH GRAM CONTAIN 0.5 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 6198.840 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 206628)	206628.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	6322.82 gram
			10	AL TUBE FOR CLOBETASOL PROPIONATE	Relevant as per packing policy

				CREAM USP 0.05%, 60 GM (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	
9	CLOBETASOL PROPIONATE LOTION 0.05%, 59 ML (EACH ML CONTAIN 0.415 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 912.654 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 37274)	37274.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	930.907 gram
			11	BOTTLE 60ML HDPE FLAT & WHITE COLOR (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
			13	WHITE DISCTOP CAP 20MM-410 WITH INDLINER (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
10	CLOBETASOL PROPIONATE LOTION 0.05%, 118 ML (EACH ML CONTAIN 0.415 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 1326.499 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 27088)	27088.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	1353.03 gram
			12	BOTTLE 120ML HDPE FLAT & WHITE COLOR	Relevant as per packing policy

				(AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	
			13	WHITE DISCTOP CAP 20MM-410 WITH INDLINER (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
11	CLOBETASOL PROPIONATE SPRAY 0.05%, 59 ML (EACH ML CONTAIN 0.415 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 801.835 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 32748)	32748.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	817.88 gram
			2	UNDECYLENIC ACID USP	4811.00 gram
			14	PUMP+ACTUATOR FOR 75ML BOTTLE (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy
12	CLOBETASOL PROPIONATE SPRAY 0.05%, 125 ML (EACH ML CONTAIN 0.415 MG OF CLOBETASOL PROPIONATE USP) (ACTIVE INGREDIENT: CLOBETASOL PROPIONATE USP - NET WT. 601.335 GMS. & RELEVANT PACKING MATERIAL IN FINISHED FORM - NET NOS. 11592)	11592.000 Number	1	CLOBETASOL PROPIONATE USP (THIS LICENCE IS ISSUED WITH CONDITION THAT IMPORT OF ANY DRUG AGAINST THIS LICENSE WILL BE ALLOWED THROUGH REGISTERED SOURCES AS PER PROVISION LAID DOWN IN DRUG & COSMETIC ACT AND AS PER PARA 4.07 OF HBP 2015-20 SUBJECT TO FIXATION OF NORMS BY ALC, NEW DELHI)	613.36 gram

			2	UNDECYLENIC ACID USP	3608.00 gram
			15	PUMP+ACTUATOR FOR 125ML BOTTLE (AS PER GENERAL POLICY FOR PACKING MATERIAL, WASTAGE ALLOWED @ 1% ON NET QUANTITY)	Relevant as per packing policy

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

Case No.	105 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001608AM21
RA File Number	052404000258 AM21
Licence No and Date	0510415088/02/09/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	106 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	SHARP MINT LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001609AM21
RA File Number	052404000265 AM21
Licence No and Date	0510415091/02/09/2020
Norms Committee Decision: The Committee considered the case as per agenda in the presence of technical experts and it was noted that the firm still has not furnished the 4.07 application asked for by NC-3 in its Meeting No. 4/82-ALC4/2020 dated 18.09.2020, 7/82-ALC4/2020 dated 04.12.2020, followed by Reminder to firm on 16.10.2020. Reply still awaited from the firm. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	107 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SHITAL CHEMICAL INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001610AM21
RA File Number	342404000140 AM21
Licence No and Date	3410046347/02/09/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
CHLORO ACETYL CHLORIDE	1 kg	1	MONOCHLORO ACETIC ACID	0.884 kg

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

Case No.	108 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001614AM21
RA File Number	082404000395 AM20
Licence No and Date	0810148478/03/09/2020
Norms Committee Decision: Deferred for comments of TE.	

Case No.	109 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved

Party Name	VENOR PHARMA LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021																						
HQ File Number	018205001613AM21																						
RA File Number	052404000255 AM21																						
Licence No and Date	0510415104/03/09/2020																						
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Sl. No.</th> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Inj. Labetalol HCL 5mg/ml, 20 ml Ampoule</td> <td>1 Number</td> <td>2</td> <td>Labetalol HCL (For Inj. Use)</td> <td>105 mg / Ampoule</td> </tr> <tr> <td>2</td> <td>Tab. Labetalol HCL 100 mg</td> <td>1 Number</td> <td>1</td> <td>Labetalol HCL</td> <td>102 mg / Tablet</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.						Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.	1	Inj. Labetalol HCL 5mg/ml, 20 ml Ampoule	1 Number	2	Labetalol HCL (For Inj. Use)	105 mg / Ampoule	2	Tab. Labetalol HCL 100 mg	1 Number	1	Labetalol HCL	102 mg / Tablet
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.																		
1	Inj. Labetalol HCL 5mg/ml, 20 ml Ampoule	1 Number	2	Labetalol HCL (For Inj. Use)	105 mg / Ampoule																		
2	Tab. Labetalol HCL 100 mg	1 Number	1	Labetalol HCL	102 mg / Tablet																		

Case No.	110 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001617AM21

RA File Number	052404000248 AM21				
Licence No and Date	0510415116/04/09/2020				
Norms Committee Decision: The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Inj. Hydromorphone HCL2mg/ml, 1 ml Ampoule	500000.000 Number	1	Hydromorphone HCL	1.10 kg
2	Inj. Hydromorphone HCL1mg/ml, 1 ml Ampoule	100000.000 Number	1	Hydromorphone HCL	0.11 kg
3	Inj. Hydromorphone HCL4mg/ml, 1 ml Ampoule	10000.000 Number	1	Hydromorphone HCL	0.044 kg
4	Tab. Hydromorphone HCL2mg	500000.000 Number	1	Hydromorphone HCL	1.02 kg
5	Tab. Hydromorphone HCL4mg	500000.000 Number	1	Hydromorphone HCL	2.04 kg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	111 / NC/3/MEET/Oct/202122/9
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Case Status	Case Approved																			
Party Name	YASHO INDUSTRIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021																			
HQ File Number	018205001618AM21																			
RA File Number	039504000350 AM21																			
Licence No and Date	0310838091/04/09/2020																			
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">YALUB PA 135(3,5-DI-TERTIARY-BUTYL-4-HYDROXYHYDROCINNAMIC ACID)</td> <td rowspan="3">1 kg</td> <td>1</td> <td>2,6-DI-TERTIARY-BUTYL PHENOL</td> <td>0.825 kg</td> </tr> <tr> <td>2</td> <td>METHYL ACRYLATE</td> <td>0.349 kg</td> </tr> <tr> <td>3</td> <td>EXXAL 8(ISO OCTANOL)</td> <td>0.366 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	YALUB PA 135(3,5-DI-TERTIARY-BUTYL-4-HYDROXYHYDROCINNAMIC ACID)	1 kg	1	2,6-DI-TERTIARY-BUTYL PHENOL	0.825 kg	2	METHYL ACRYLATE	0.349 kg	3	EXXAL 8(ISO OCTANOL)	0.366 kg
Export product	Qty.	Sl. No.	Import items	Qty.																
YALUB PA 135(3,5-DI-TERTIARY-BUTYL-4-HYDROXYHYDROCINNAMIC ACID)	1 kg	1	2,6-DI-TERTIARY-BUTYL PHENOL	0.825 kg																
		2	METHYL ACRYLATE	0.349 kg																
		3	EXXAL 8(ISO OCTANOL)	0.366 kg																

Case No.	112 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

HQ File Number	018205001685AM21													
RA File Number	039504000328 AM21													
Licence No and Date	0310838112/07/09/2020													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 7/82-ALC4/2020 dated 04.12.2020 against advance authorization No. 0310835403 dated 16.03.2020, 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>NAS-5 (2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT)</td> <td>1 kg</td> <td>1</td> <td>TOBIAS ACID (PURITY MIN. 97%)</td> <td>1.618 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	NAS-5 (2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT)	1 kg	1	TOBIAS ACID (PURITY MIN. 97%)	1.618 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
NAS-5 (2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT)	1 kg	1	TOBIAS ACID (PURITY MIN. 97%)	1.618 kg										

Case No.	113 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ZIM LABORATORIES LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001619AM21
RA File Number	039504000310 AM21
Licence No and Date	0310838114/07/09/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
Prolonged-release Indapamide Granules 0.77% for Direct Compression	2000.000 kg	1	Indapamide EP	15.538 kg

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

Case No.	114 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001620AM21
RA File Number	072404000154 AM21
Licence No and Date	0710116964/07/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. **Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.**
- ii. **Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.**

Case No.	115 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	CHIRAG ENTERPRISE
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001621AM21
RA File Number	242404000040 AM21
Licence No and Date	2410043228/07/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Percentage wastage at each stage of manufacturing. Production / Consumption data for last two years duly certified by Central Excise / GST.	

Case No.	116 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001624AM21
RA File Number	318304000060 AM21
Licence No and Date	3110067848/08/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Sep/202122/8 dated 24.09.2021 against	

advance authorization No. **3110067681 dated 11.02.2020**, 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.
GAMMA BUTYROLACTONE	1 kg	1	1,4 BUTANEDIOL	1.16 kg
		2	GBL CATAYLYST	0.001 kg

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

Case No.	117 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AMINES AND PLASTICIZERS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001625AM21
RA File Number	039404000370 AM21
Licence No and Date	0310838163/08/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. **Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.**
- ii. **Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.**

Case No.	118 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001622AM21
RA File Number	072404000153 AM21
Licence No and Date	0710116971/08/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E. ii. Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.	

Case No.	119 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001623AM21
RA File Number	318304000061 AM21
Licence No and Date	3110067847/08/09/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **3110067616 dated 02.12.2019**, 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.
N-METHYL-2-PYRROLIDONE	1 kg	1	METHANOL	0.370 kg
		2	AMMONIA ANHYDROUS	0.160 kg
		3	GAMMA BUTYROLACTONE	0.885 kg

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

Case No.	120 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001626AM21
RA File Number	052404000277 AM21
Licence No and Date	0510415162/09/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.

Case No.	121 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001627AM21
RA File Number	039504000327 AM21
Licence No and Date	0310838181/09/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	
ii. Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.	

Case No.	122 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001636AM21
RA File Number	039404000422 AM21

Licence No and Date	0310838206/10/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	123 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	GLENMARK PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001628AM21			
RA File Number	039404000341 AM21			
Licence No and Date	0310838186/10/09/2020			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 2/82-ALC4/2020 dated 10.07.2020 against advance authorization No. 0310834275 dated 17.01.2020, 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:				
Sl. No.	Export Product	Qty.	Import items	Qty.
1	Alclometasone Dipropionate USP Cream 0.05% 15gm (Pack Size 15gm) (Net Wt. of Alclometasone Dipropionate USP is 0.675 Kgs.)	90000.000 Packs	Alclometasone Dipropionate USP	5.036 kg

2	Alclometasone Dipropionate USP Cream 0.05% 45gm (Pack Size 45gm) (Net Wt. of Alclometasone Dipropionate USP is 1.058 Kgs.)	47000.000 Packs		
3	Alclometasone Dipropionate USP Cream 0.05% 60gm (Pack Size 60gm) (Net Wt. of Alclometasone Dipropionate USP is 1.440 Kgs.)	48000.000 Packs		
4	Alclometasone Dipropionate Ointment 0.05% 15gm (Pack Size 15gm) (Net Wt. of Alclometasone Dipropionate USP is 0.360 Kgs.)	48000.000 Packs		
5	Alclometasone Dipropionate Ointment 0.05% 45gm (Pack Size 45gm) (Net Wt. of Alclometasone Dipropionate USP is 0.799 Kgs.)	35500.000 Packs		
6	Alclometasone Dipropionate Ointment 0.05% 60gm (Pack Size 60gm) (Net Wt. of Alclometasone Dipropionate USP is 0.600 Kgs.)	20000.000 Packs		
RA concerned may take further necessary action as per above decision of NC.				

Case No.	124 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	SRIAM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001651AM21
RA File Number	097104000084 AM21
Licence No and Date	0910069160/10/09/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
(R)-2-(Diphenylmethyl) pyrrolidine hydrochloride (RDPH-II)	1 kg	1	D-Proline/R-Proline	1.167 kg

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

Case No.	125 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ANUPAM RASAYAN INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001629AM21
RA File Number	522404000043 AM21
Licence No and Date	5210043532/10/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
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2,6-DIFLUOROBENZAMIDE	100000.000 kg	1	2,6-Dichlorobenzonitrile	140000.000 kg
		2	Potassium Fluoride	105000.000 kg
		3	Sulfolane (Anhydrous)	90000.000 kg

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

Case No.	126 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001630AM21				
RA File Number	039404000407 AM21				
Licence No and Date	0310838188/10/09/2020				
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Aug/202122/7 dated 13.08.2021 against advance authorization No. 0310832013 dated 04.10.2019, 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Nifedipine Extended-Release Tablets 30mg.(Each tablet	1 Number	1	Sentry Polyox WSR Coagulant NF	56.8 mg

	contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg (ii) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 33.12 mg (iii) SENTRY POLYOX WSR N80 FP NF - 118.40 mg. Net content (i) 432 Kgs (ii) 251.90 Kgs (iii) 900.51 Kgs)		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg
			3	SENTRY POLYOX WSR N80 FP NF	118.40 mg
2	Nifedipine Extended-Release Tablets 60mg.(Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg (ii) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 42.32 mg (iii) SENTRY POLYOX WSR N80 FP NF - 236.80 mg. Net content (i) 203 Kgs (ii) 75.62 Kgs (iii) 423.16 Kg)	1 Number	4	Sentry Polyox WSR Coagulant NF	113.60 mg
			5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg
			6	SENTRY POLYOX WSR N80 FP NF	236.80 mg

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

Case No.	127 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	STRATECHEM (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001631AM21
RA File Number	039504000359 AM21
Licence No and Date	0310838204/10/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

ii. Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.

Case No.	128 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	GLENMARK PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001632AM21				
RA File Number	039404000340 AM21				
Licence No and Date	0310838214/11/09/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jan/202021/4 dated 12.02.2021 against advance authorization No. 0310835905 dated 25.04.2020 , 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 25gm)((Net Wt. of Import Item Sr. No. 1 is 82.50 Kgs. & Sr. No. 2 is 412.50 Kgs.))	1 Number Pack	1	Clindamycin Phosphate USP	262.50 mg / pack
			2	HYDROUS BENZOYL PEROXIDE USP	1312.50 mg / pack
2	Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 35gm)((Net Wt. of Import Item Sr. No. 1 is 115.50 Kgs. & Sr. No. 2 is 577.50 Kgs.))	1 Number Pack	1	Clindamycin Phosphate USP	367.50 mg / pack
			2	HYDROUS BENZOYL PEROXIDE USP	1837.50 mg / pack
3	Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size	1 Number Pack	1	Clindamycin Phosphate USP	525.00 mg / pack

4	50gm)((Net Wt. of Import Item Sr. No. 1 is 150.00 Kgs. & Sr. No. 2 is 750.00 Kgs.))		2	HYDROUS BENZOYL PEROXIDE USP	2625.00 mg / pack
	Adapalene & Benzoyl Peroxide Gel 0.1%/2.5% (Pack Size 45gm)((Net Wt. of Import Item Sr. No. 2 is 45.00 Kgs.))	1 Number Pack	2	HYDROUS BENZOYL PEROXIDE USP	1181.25 mg / pack

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

Case No.	129 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001634AM21
RA File Number	039404000406 AM21
Licence No and Date	0310838227/11/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Complete name of Export Product. ii. Complete and Balanced chemical reactions showing molecular weight and percentage yield on molar basis.	

Case No.	130 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001635AM21
RA File Number	039404000408 AM21
Licence No and Date	0310838219/11/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (for 1 Number Lozenges)
1	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current, Honey Lemon & Other Flavours. Each Lozenge Contains 12mg Benzocaine. Net content of Benzocaine - 97.015 Kgs.	1 Number Lozenges	1	Benzocaine	12.24 mg
2	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current and Lime & Lemon and Other Flavours. Each Lozenge contains 10mg Benzocaine. Net content of Benzocaine - 33.52 Kgs.	1 Number Lozenges	2	Benzocaine	10.20 mg
3	Benzocaine, Cetylpyridinium Chloride And Dextromethorphan Hydrobromide Anaesthetic Throat Lozenges. Each Lozenge Contains 1.25mg Benzocaine. Net content of Benzocaine - 4.695 Kgs.	1 Number Lozenges	3	Benzocaine	1.275 mg
			4	Benzocaine	15.30 mg

4	Life Brand Sore Throat & Nasal Congestion Relief Extra Strength (Flavours Cherry/Honey & Lemon/Other flavours) Sugar Free Lozenges.Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number Lozenges	5	Isomalt ST-M	2571.00 mg
5	Personnelle Oral Anesthetic Sore Throat Lozenges Extra Strenght Sugar Free (Flavours Cherry/Honey Lemon/Other flavours) Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number Lozenges	6	Benzocaine	15.30 mg
			7	Isomalt ST-M	2571.00 mg
6	Option+Oral Lozenges Sore Throat & Nasal Congestion Relief Extra Strenght (Flavours Cherry/Honey Lemon /Other flavours). Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number Lozenges	8	Benzocaine	15.30 mg
			9	Isomalt ST-M	2571.00 mg
7	Biomedic Oral Anesthetic Lozenges Sore Throat & Nasal Congestion Relief Extra Strength Cherry ST & NC RELEX Lozenges (Flavours Cherry / Honey Lemon/ Other flavours) Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number Lozenges	10	Benzocaine	15.30 mg
			11	Isomalt ST-M	2571.00 mg
8	Atoma Sore Throat & Nasal Congestion Relief Extra Strength Lozenges Cherry/Honey & Lemon Flavour. Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2700 Mg. Net Content Benzocaine 13.333 Kgs and Isomalt ST-M - 2285.352 Kgs.	1 Number Lozenges	12	Benzocaine	15.30 mg
			13	Isomalt ST-M	2571.00 mg

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

Case No.	131 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ALPA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001661AM21
RA File Number	562404000020 AM21
Licence No and Date	5610005946/11/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Ciprofloxacin Hydrochloride Tablets BP 500 mg. (EACH FILM COATED TABLET ONTAINS:CIPROFLOXACIN HYDROCHLORIDE BP EQ. TO CIPROFLOXACIN 500 MG.)	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE IP/BP/USP	555.00 mg

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

Case No.	132 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001656AM21
RA File Number	092404000317 AM21
Licence No and Date	0910069173/14/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
CARVEDILOL	1 kg	1	4-Hydroxy-9H-Carbazole	1.06 kg
		2	Activated Carbon (Carbon Enoanticromos)	0.100 kg
		3	Epichlorohydrin	0.95 kg
		4	Methanol (Methyl Alcohol)	1.00 kg
		5	Isopropyl Alcohol	1.00 kg

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

Case No.	133 / NC/3/MEET/Oct/202122/9													
Case Status	Case Approved													
Party Name	KRITI NUTRIENTS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021													
HQ File Number	018205001662AM21													
RA File Number	562404000021 AM21													
Licence No and Date	5610005948/14/09/2020													
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Non GMO Soya Lecithin Liquid Food Grade (Acid value upto 25)</td> <td>148 MT</td> <td>1</td> <td>Soya Lecithin Liquid (Acid value more than 25)</td> <td>149.18 MT</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Non GMO Soya Lecithin Liquid Food Grade (Acid value upto 25)	148 MT	1	Soya Lecithin Liquid (Acid value more than 25)	149.18 MT
Export product	Qty.	Sl. No.	Import items	Qty.										
Non GMO Soya Lecithin Liquid Food Grade (Acid value upto 25)	148 MT	1	Soya Lecithin Liquid (Acid value more than 25)	149.18 MT										

Case No.	134 / NC/3/MEET/Oct/202122/9			
Case Status	Case Deferred			
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001663AM21
RA File Number	072404000163 AM21
Licence No and Date	0710117014/15/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	135 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001664AM21
RA File Number	092404000274 AM21
Licence No and Date	0910069187/15/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: Copy of DML.	

Case No.	136 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001666AM21
RA File Number	039404000395 AM21
Licence No and Date	0310838311/16/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E. Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.	

Case No.	137 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	VPL CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001667AM21
RA File Number	072404000158 AM21
Licence No and Date	0710117023/17/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

- i. Complete and balanced chemical reactions with molecular weight.
- ii. Percentage yield on molar basis.

Whether the export item is Minoxidil or Monidil Sulphate.

Case No.	138 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	HIMALAYAN PRODUCTS AND INDUSTRIES CORPN PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001668AM21
RA File Number	052404000283 AM21
Licence No and Date	0510415240/17/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	139 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001675AM21
RA File Number	342404000171 AM21

Licence No and Date	3410046407/18/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Technical literature in support of low yield at step II and III alongwith By-Product recovery and use. ii. Production / Consumption data duly certified by GST.	

Case No.	140 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001669AM21
RA File Number	042404000098 AM21
Licence No and Date	0410167074/18/09/2020
Norms Committee Decision: Deferred for comments of TE.	

Case No.	141 / NC/3/MEET/Oct/202122/9
Case Status	Case Rejected
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001673AM21

RA File Number	039404000430 AM21
Licence No and Date	0310838379/21/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm has applied both raw materials and the intermediates made out of it. Hence, it was decided to reject the case.	

Case No.	142 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001674AM21
RA File Number	052404000295 AM21
Licence No and Date	0510415273/21/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	143 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

HQ File Number	018205001676AM21
RA File Number	092404000306 AM21
Licence No and Date	0910069226/21/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	144 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001671AM21
RA File Number	039404000421 AM21
Licence No and Date	0310838377/21/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	145 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved

Party Name	GLENMARK LIFE SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001672AM21			
RA File Number	039404000431 AM21			
Licence No and Date	0310838378/21/09/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
GLIMEPIRIDE	1 kg	1	4-[2-(3-ETHYL-4-METHYL-2-OXO-3-PYRROLINE-1-CARBOXAMIDO)-ETHYL]BENZENE SULFONAMIDE	0.80 kg
		2	TRANS-4-METHYL CYCLOHEXYL ISOCYANATE	0.39 kg
		3	METHANOL	4.56 kg
		4	TOLUENE	1.24 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	146 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SIDMAK LABORATORIES (INDIA) PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001682AM21
RA File Number	522404000047 AM21
Licence No and Date	5210043542/22/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	147 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001683AM21
RA File Number	092404000282 AM21
Licence No and Date	0910069242/22/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of DML for each export item.	

Case No.	148 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001677AM21
RA File Number	318304000058 AM21
Licence No and Date	3110067866/22/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Acetyl Anisole (4 Methoxy Acetophenone)	1 kg	1	Phenol	0.74 kg
		2	Methanol	0.276 kg
		3	Acetic Anhydride PURITY 99%	0.755 kg

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

Case No.	149 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

and Date																	
HQ File Number	018205001678AM21																
RA File Number	039504000378 AM21																
Licence No and Date	0310838408/22/09/2020																
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">ZINC DIMETHACRYLATE(ZDMA)</td> <td rowspan="2">1 kg</td> <td>1</td> <td>METHACRYLIC ACID</td> <td>0.769 kg</td> </tr> <tr> <td>2</td> <td>ZINC OXIDE</td> <td>0.364 kg</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	ZINC DIMETHACRYLATE(ZDMA)	1 kg	1	METHACRYLIC ACID	0.769 kg	2	ZINC OXIDE	0.364 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
ZINC DIMETHACRYLATE(ZDMA)	1 kg	1	METHACRYLIC ACID	0.769 kg													
		2	ZINC OXIDE	0.364 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	150 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001695AM21
RA File Number	092404000305 AM21
Licence No and Date	0910069254/23/09/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. **Copy of DML for the export item.**
- ii. **COA of import item from foreign supplier.**

Case No.	151 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001686AM21
RA File Number	052404000299 AM21
Licence No and Date	0510415286/23/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	152 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001687AM21

RA File Number	052404000300 AM21
Licence No and Date	0510415287/23/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	153 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	SRIAM LABS PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001848AM21				
RA File Number	092404000346 AM21				
Licence No and Date	0910069251/23/09/2020				
Norms Committee Decision: The Committee considered the case as per agenda and 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.
1,3-Dimethoxy-5-[(E)-2-(4-methoxy phenyl)-1-ethenyl] benzene (BRVT-1)		1 kg	1	3,5- Dihydroxy benzoic acid	0.99 kg
			2	Sodium Boro Hydride	0.628 kg

		3	Triethylphosphite	1.384 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	154 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001688AM21
RA File Number	052404000308 AM21
Licence No and Date	0510415295/23/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: Copy of DML showing Approved Composition of Export item.	

Case No.	155 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	MAHARSHI PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001680AM21

RA File Number	082404000186 AM21			
Licence No and Date	0810148644/23/09/2020			
Norms Committee Decision: The Committee considered the case as per agenda and 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.
TRIAMCINOLONE ACETONIDE	1 kg	1	(3TR) 1,4,9(11), 16-PREGNATETRAEN-21-OL-3,20-DIONE-21-ACETATE	1.00 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	156 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001689AM21
RA File Number	092404000344 AM21
Licence No and Date	0910069243/23/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and 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.
CINACALCET HYDROCHLORIDE	1 kg	1	3-(Trifluoromethyl)Cinnamic Acid	1.16 kg
		2	Triethylamine	0.57 kg
		3	Ethyl Chloroformate	0.70 kg
		4	Sodium Borohydride	0.19 kg
		5	2,3-Dichloro-5,6-Dicyano-1,4-Benzoquinone (DDQ)	1.29 kg
		6	Tetrahydrofuran	4.70 kg
		7	R-(+)-1-(1-Naphthyl)Ethylamine	0.65 kg
		8	Activated Carbon (Carbon Enoanticromos)	0.100 kg

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

Case No.	157 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	MAHARSHI PHARMA CHEM PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

and Date														
HQ File Number	018205001681AM21													
RA File Number	082404000187 AM21													
Licence No and Date	0810148645/23/09/2020													
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>BETAMETHASONE DIPROPIONATE BP93/USP 23</td> <td>1 kg</td> <td>1</td> <td>17ALPHA 21-DIHYDROXY-16-BETA METHYL-9-BETA-11-BETA-EPOXY PREGNA-1, 4-DIENE-3, 20-DIONE (DB-XI)</td> <td>1.10 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	BETAMETHASONE DIPROPIONATE BP93/USP 23	1 kg	1	17ALPHA 21-DIHYDROXY-16-BETA METHYL-9-BETA-11-BETA-EPOXY PREGNA-1, 4-DIENE-3, 20-DIONE (DB-XI)	1.10 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
BETAMETHASONE DIPROPIONATE BP93/USP 23	1 kg	1	17ALPHA 21-DIHYDROXY-16-BETA METHYL-9-BETA-11-BETA-EPOXY PREGNA-1, 4-DIENE-3, 20-DIONE (DB-XI)	1.10 kg										

Case No.	158 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001693AM21
RA File Number	039404000283 AM21
Licence No and Date	0310838453/24/09/2020
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	159 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001696AM21
RA File Number	092404000318 AM21
Licence No and Date	0910069256/24/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Rocuronium Bromide	1 kg	1	Rocuronium Bromide Diol Condition Pre import condition is imposed in case this is unregistered and export obligation should be completed within 12 months from the date of import of each consignment as per Appendix 4J of FTP 2015 20	1.05 kg

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

Case No.	160 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001692AM21
RA File Number	052404000274 AM21
Licence No and Date	0510415306/24/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Tab. Morphine Sulphate (NR/PR) 10mg content per tablet	3800000.000 Number	1	Morphine Sulphate	38.76 kg
2	Tab. Morphine Sulphate 30 mg (NR/PR)	700000.000 Number	1	Morphine Sulphate	21.42 kg
3	Tab. Morphine Sulphate 60 mg (NR/PR)	50000.000 Number	1	Morphine Sulphate	3.06 kg
4	Inj. Morphine Sulphate 10 mg	1000000.000 Number	1	Morphine Sulphate	11.00 kg
5	Inj. Morphine Sulphate 15 mg	880000.000 Number	1	Morphine Sulphate	14.52 kg

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

Case No.	161 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001735AM21
RA File Number	039504000361 AM21
Licence No and Date	0310838514/28/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **7/82-ALC4/2020 dated 04.12.2020** against advance authorization No. **0310835403 dated 16.03.2020**, 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.
NAS-5 (2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT)	1 kg	1	TOBIAS ACID (PURITY MIN. 97%)	1.618 kg

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

Case No.	162 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001701AM21
RA File Number	092404000275 AM21
Licence No and Date	0910069265/28/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. End-use of the export item (Name the API). ii. Technical justification with catalogue for the requirement of import item No. 4, 5 and 6. Production / Consumption data duly certified by GST Authorities.	

Case No.	163 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001703AM21
RA File Number	052304000197 AM21
Licence No and Date	0510415370/30/09/2020
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	164 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001704AM21
RA File Number	039404000467 AM21
Licence No and Date	0310838594/30/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. COA of import item indicating percentage purity from foreign supplier for entire quantity of import.	
Percentage purity of export item.	

Case No.	165 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001710AM21
RA File Number	092404000362 AM21
Licence No and	0910069287/30/09/2020

Date	
Norms Committee Decision: Deferred for comments of TE.	

Case No.	166 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001713AM21
RA File Number	039404000468 AM21
Licence No and Date	0310838628/01/10/2020
Norms Committee Decision: Deferred for comments of TE.	

Case No.	167 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001724AM21
RA File Number	022404000087 AM21
Licence No and Date	0210210144/06/10/2020
Norms Committee Decision:	

The Committee considered case as per agenda in the presence of the technical experts and it was decided to refer the case to Department of Chemical & Petrochemical (D/o C&PC) for obtaining its comments.

Case No.	168 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001736AM21
RA File Number	039404000490 AM21
Licence No and Date	0310838813/09/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export Product	Qty.
1	Clobetasol Propionate Foam 0.05% 50gm (Net. wt. of Net. wt. of Clobetasol Propionate USP (Micronized) is 5.00 Kgs.)	200000.000 Number
2	Clobetasol Propionate Foam 0.05% 100gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 10.00 Kgs.)	200000.000 Number
3	Clobetasol Propionate Cream USP 0.05% (Pack Size 15gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.15 Kgs)	20000.000 Number

4	Clobetasol Propionate Cream USP 0.05% (Pack size 30gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.300 Kgs)	20000.000 Number
5	Clobetasol Propionate Cream USP 0.05% (Pack size 45 gm) (Net Weight of Clobetasol Propionate USP (Micronized) 1.125 Kgs)	50000.000 Number
6	Clobetasol Propionate Cream USP 0.05% (Pack size 60gm) (Net Weight of Clobetasol Propionate USP (Micronized) 1.500 Kgs)	50000.000 Number
7	Clobetasol Propionate Ointment USP 0.05% (Pack size 15gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.375 Kgs)	50000.000 Number
8	Clobetasol Propionate Ointment USP 0.05% (Pack size 30gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.750 Kgs)	50000.000 Number
9	Clobetasol Propionate Ointment USP 0.05% (Pack size 45gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs)	40000.000 Number
10	Clobetasol Propionate Ointment USP 0.05% (Pack size 60gm) (Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs)	20000.000 Number
11	Clobetasol Propionate Spray 0.05% (Pack size 59ml) (Net Weight of Clobetasol Propionate USP (Micronized) 1.180 Kgs)	40000.000 Number
12	Clobetasol Propionate Spray 0.05% (Pack size 125ml) (Net Weight of Clobetasol Propionate USP (Micronized) 2.500 Kgs)	40000.000 Number
13	Clobetasol Prop. Top Sol USP, 0.05% 25ml (Net Weight of Clobetasol Propionate USP (Micronized) 0.625 Kgs)	50000.000 Number
14	Clobetasol Prop. Top Sol USP, 0.05% 50ml (Net Weight of Clobetasol Propionate USP (Micronized) 1.000 Kgs)	40000.000 Number

15	Clobetasol Pro Shampoo, 0.05 % 118ml (Net Weight of Clobetasol Propionate USP (Micronized) 2.360 Kgs)	40000.000 Number
16	Clobetasol Propionate Foam 0.05% 100gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 0.500 Kgs.)	10000.000 Number
17	Clobetasol Propionate Foam 0.05% 50gm (Net. wt. of Clobetasol Propionate USP (Micronized) is 0.250 Kgs.)	10000.000 Number

Sl. No.	Import Item	Qty.
1	CLOBETASOL PROPIONATE USP (MICRONIZED)	29.70 kg

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

Case No.	169 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001738AM21
RA File Number	039404000504 AM21
Licence No and Date	0310838842/13/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. **Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.**
- ii. **Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.**

Case No.	170 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001741AM21
RA File Number	039404000536 AM21
Licence No and Date	0310838904/15/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. **Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.**

Case No.	171 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021

HQ File Number	018205001749AM21
RA File Number	039404001019 AM20
Licence No and Date	0310838949/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	172 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001750AM21
RA File Number	039404000978 AM20
Licence No and Date	0310838950/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	173 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred

Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001751AM21
RA File Number	039404000297 AM21
Licence No and Date	0310838951/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	174 / NC/3/MEET/Oct/202122/9			
Case Status	Case Approved			
Party Name	BENZO CHEM INDUSTRIES PVT LTD			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021			
HQ File Number	018205001752AM21			
RA File Number	039404000523 AM21			
Licence No and Date	0310838952/16/10/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 6/82-ALC4/2020 dated 13.11.2020 against advance authorization No. 0310832317 dated 18.10.2019 , 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:				

4-HYDROXYBENZYL ALCOHOL	1 kg	1	4-HYDROXYBENZALDEHYDE OR PARA HYDROXY BENZALDEHYDE	1.20 kg
		2	SODIUM BOROHYDRIDE	0.23 kg

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

Case No.	175 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001753AM21
RA File Number	039404000524 AM21
Licence No and Date	0310838953/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	176 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001745AM21
RA File Number	039404000392 AM21
Licence No and Date	0310838931/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	177 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001754AM21
RA File Number	039404000531 AM21
Licence No and Date	0310838954/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and 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.
BUDESONIDE MICRONIZED IP / EP / BP /USP	1 kg	1	16 ALPHA-HYDROXYPREDNISOLONE (16-HPN)	0.972 kg

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

Case No.	178 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001746AM21
RA File Number	039404000516 AM21
Licence No and Date	0310838932/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	179 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001755AM21
RA File Number	039404000184 AM21
Licence No and Date	0310838958/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	180 / NC/3/MEET/Oct/202122/9				
Case Status	Case Approved				
Party Name	BENZO CHEM INDUSTRIES PVT LTD				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021				
HQ File Number	018205001748AM21				
RA File Number	039404000514 AM21				
Licence No and Date	0310838947/16/10/2020				
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Sep/202122/8 dated 24.09.2021 against advance authorization No. 0310834862 dated 13.02.2020, 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.

2-DIMETHYLAMINO-2-PHENYLBUTAN-1-OL (DAFOL)	1 kg	1	PROPIOPHENONE	1.408 kg
		2	SODIUM CYANIDE	0.599 kg
		3	PARA FORMALDEHYDE	0.528 kg
		4	SODIUM BOROHYDRIDE	0.528 kg
		5	TETRA HYDRO FURAN (THF)	1.00 kg

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

Case No.	181 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001756AM21
RA File Number	039404000825 AM20
Licence No and Date	0310838959/16/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	182 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	NEON LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001757AM21
RA File Number	039504000409 AM21
Licence No and Date	0310838968/19/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	183 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001758AM21
RA File Number	039404000525 AM21
Licence No and Date	0310838974/19/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.

Case No.	184 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001759AM21
RA File Number	039404000528 AM21
Licence No and Date	0310838975/19/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	185 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001771AM21
RA File Number	022404000094 AM21
Licence No and	0210210167/20/10/2020

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	186 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001764AM21
RA File Number	039404000414 AM21
Licence No and Date	0310838998/20/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Erythromycin Phosphate BP/EP/USP/IP	1 kg	1	Erythromycin Thiocyanate	0.779 kg
				Activity

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

Case No.	187 / NC/3/MEET/Oct/202122/9																		
Case Status	Case Approved																		
Party Name	ANUH PHARMA LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021																		
HQ File Number	018205001765AM21																		
RA File Number	039404000415 AM21																		
Licence No and Date	0310838999/20/10/2020																		
Norms Committee Decision: The Committee considered the case as per agenda and 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Erythromycin Propionate BP/EP/USP/IP</td> <td>1 kg</td> <td>1</td> <td>Erythromycin Thiocyanate</td> <td>0.90 kg</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>Activity</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Erythromycin Propionate BP/EP/USP/IP	1 kg	1	Erythromycin Thiocyanate	0.90 kg					Activity
Export product	Qty.	Sl. No.	Import items	Qty.															
Erythromycin Propionate BP/EP/USP/IP	1 kg	1	Erythromycin Thiocyanate	0.90 kg															
				Activity															

Case No.	188 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001766AM21
RA File Number	039404000548 AM21
Licence No and Date	0310839000/20/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	189 / NC/3/MEET/Oct/202122/9	
Case Status	Case Approved	
Party Name	GLENMARK PHARMACEUTICALS LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021	
HQ File Number	018205001850AM21	
RA File Number	039404000550 AM21	
Licence No and Date	0310839024/20/10/2020	
Norms Committee Decision: The Committee considered the case as per agenda and 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:		
Sl. No.	Export Product	Qty.

1	Drospirenone and Ethinyl Estradiol Tablets (YASMIN) 3 mg / 0.03 mg (Pack 3 x 28s) (Net wt of Drospirenone USP (Micronized) is 92.610 Kgs)	490000.000 Number
2	Drospirenone and Ethinyl Estradiol Tablets (YAZ) 3 mg / 0.02 mg (Pack 3 x 28s) (Net wt of Drospirenone USP (Micronized) is 103.68 Kgs)	480000.000 Number

Sl. No.	Import Item	Qty.
1	Drospirenone USP (Micronized)	200.22 kg

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

Case No.	190 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001767AM21
RA File Number	039404000526 AM21
Licence No and Date	0310839001/20/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	

i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.

Case No.	191 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001769AM21
RA File Number	039404000527 AM21
Licence No and Date	0310839017/20/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	192 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	TRANSPEK INDUSTRY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001776AM21
RA File Number	342404000196 AM21
Licence No and	3410046491/22/10/2020

Date				
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 3/82-ALC4/2020 dated 07.08.2020 and 7/AM21 dated 24.12.2020 against advance authorization No. 3410045473 dated 20.09.2019, 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.
N-OCTANOYL CHLORIDE	1 kg	1	CAPRYLIC ACID	0.904 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	193 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	TRANSPEK INDUSTRY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001777AM21
RA File Number	342404000197 AM21
Licence No and Date	3410046492/22/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and 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.
N-VALERYL CHLORIDE	1 kg	1	PENTANOIC ACID	0.894 kg

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

Case No.	194 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001778AM21
RA File Number	039404000412 AM21
Licence No and Date	0310839084/23/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	195 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001779AM21
RA File Number	039404000411 AM21
Licence No and Date	0310839085/23/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	196 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001783AM21
RA File Number	039404000571 AM21
Licence No and Date	0310839148/27/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	197 / NC/3/MEET/Oct/202122/9
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001790AM21
RA File Number	039404000569 AM21
Licence No and Date	0310839187/28/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **0310836099 dated 05.05.2020**, 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:

Sl. No.	Export Product	Qty.
1	GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG. Each tablet contains (i) Glipizide USP- 10 mg (ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 29.70 mg (iii) Sentry Polyox WSR N80 FP NF- 178.10 mg (iv) Sentry Polyox WSR 303 NF- 100 mg. Net content (i) 150.44 Kgs (ii) 446.81 Kgs (iii) 2679.37 Kgs (iv) 1504.42 Kgs.	1 Number
2	GLIPIZIDE EXTENDED RELEASE TABLETS 5 MG. Each tablet contains (i) Glipizide USP- 5 mg (ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 58.70 Kgs (ii) 239.48 Kgs (iii) 1045.37 Kgs (iv) 586.96 Kgs.	1 Number
3	GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG. Each tablet contains (i) Glipizide USP- 2.5 mg (ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 11.06 Kgs (ii) 90.27 Kgs (iii) 394.03 Kgs (iv) 221.24 Kgs.	1 Number

Sl. No.	Import Items	For export of 1 Number of Tablet
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		2.5 mg	5.0 mg	10.0 mg
1	GLIPIZIDE USP	2.55 mg	5.10 mg	10.20 mg
2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg	20.40 mg	29.70 mg
3	SENTRY POLYOX WSR N80 FP NF	89.05 mg	89.05 mg	178.10 mg
4	SENTRY POLYOX WSR 303 NF	50.00 mg	50.00 mg	100.00 mg

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

Case No.	198 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001793AM21
RA File Number	052404000372 AM21
Licence No and Date	0510415667/28/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that both the import and export are the same API and the firm has not differentiated the Particle size of import and export. Hence, it was decided to call for following information from the firm: i. COA of import item from foreign supplier showing particle size.	

COA of Export item showing particle size.

Case No.	199 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001788AM21
RA File Number	039404000410 AM21
Licence No and Date	0310839173/28/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	

Case No.	200 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001789AM21
RA File Number	039404000346 AM21
Licence No and Date	0310839184/28/10/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to call for following information from the firm:

- i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.**

Case No.	201 / NC/3/MEET/Oct/202122/9
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202122/ 9 and 15/10/2021
HQ File Number	018205001806AM21
RA File Number	318304000085 AM21
Licence No and Date	3110067911/29/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Copy of 4.07 application having complete technical details as per Annexure to Appendix 4E.	