Office of Directorate General of Foreign Trade
New Delhi -0

Para 4.7 Decision

Minutes of the Norms Committee – 3 Meeting No. 12/82-ALC4/2019 dated 17.01.2020 (actually held on 21.01.2020) for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2015-20 pertaining to Chemical and Allied products falling under Chapter 29 and 30, held under the Chairmanship of Shri Satyan Sharda, Addl. DGFT in Room No.11, Udyog Bhawan, New Delhi.

Following members were present:-

(i) Shri Nirmal Kumar, Dy. Director General of Foreign Trade
(ii) Shri Ajay Kumar, Assistant Director
(iii) Consultant, Technical Expert Pharmaceuticals
(iv) Consultant, Technical Expert Chemicals

The committee went through the minutes of earlier meeting No. 11/82-ALC4/2019 dated 03.01.2020

ONLINE CASES

1

Case No.:59/10/82-ALC4/2013	Party Name:MYLAN LABORATORIES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/00242/AM14/	RLA File :09/24/040/00585/AM13/	Lic.No/Date:0910055390 14.03.2013	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
LAMIVUDINE (NI)-EU ROUTE	1 kg	1	(1R,2S,5R)-MENTHYL-5R-ACETOXY-1,3-OXATHIOLANE-2R-CARBOXYLATE (MAC)	2.19 kg
		2	CYTOSINE	0.955 kg
		3	HEXA METHYL DISILAZANE (HMDS)	1.89 kg
		4	TRIMETHYL SILYL IODIDE (TMSI)	1.37 kg
		5	METHANE SULPHONIC ACID	0.0207 kg
		6	TOLUENE	4.65 kg
		7	TRIETHYLAMINE	2.00 kg
		8	METHYLENE DI CHLORIDE	3.68 kg
		9	HEXANES	1.20 kg
		10	DIPOTASSIUM HYDROGEN ORTHOPHOSPHATE	1.9849 kg
		11	SODIUM BOROHYDRIDE	0.48 kg
		12	3-HYDROXY-2-NAPHTHOICACID	0.76 kg
		13	METHANOL	2.33 kg
		14	ISOPROPYL ALCOHOL	6.58 kg
		15	NORIT CARBON	0.100 kg

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

2	**Case No.:46/5/82-ALC4/2014**	Party Name:KOPRAN LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00363/AM15/	RLA File :03/94/040/01172/AM14/	Lic.No/Date:0310776367 28.03.2014	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Pregabalin	1 kg	1	Isovaleraldehyde	2.72 kg
		2	Diethyl Malonate	5.81 kg
		3	Acetyl Chloride	5.71 kg
		4	Ethyl Cyanoacetate	3.57 kg

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

3	**Case No.:2/6/82-ALC4/2014**	Party Name:SOFTGEL HEALTH CARE PVT. LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00404/AM15/	RLA File :04/24/040/00031/AM15/	Lic.No/Date:0410159058 22.07.2014	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
SOFT GELATIN CAPSULES DOCOSAHEXAENOIC ACID 200 MG	2505000.000 Number	1	DHA OIL 40% FROM ALGAE	1533.060 kg
SOFT GELATIN CAPSULES - DOCOSAHEXAENOIC ACID 200 MG (FORATALEX PRENATAL)	501000.000 Number			

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

Case No.:948/15/82-ALC4/2018	Party Name:ADCOCK INGRAM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/02405/AM19/	RLA File :07/24/040/00043/AM16/	Lic.No/Date:0710108280 27.05.2015	

4

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 15/82-ALC4/2018, dated 22.03.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
SYNDOL TABS - (Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Colour Yellow 14037-1.632MG Tablets) (Para - 9000.000+Caff -600.000+ Doxy-100.000+Codeine - 200.000 Colour Yellow 14037-32640 KGS) (No. of Tablets 20000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	1.632 kg
ADCO DOL TABS -(Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg+Colour Yellow Lake-4.56mg Colour Yellow WS-2.43mg Tablets (Para -33750.000 +Codeine - 750.000 + Caff - 3375.000+ Doxy-375.000 Colour Yellow Lake-342.000 Colour Yellow WS-182.250 KGS) (No. of Tablets 75000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	2.43 kg
		5.	COLOUR QUINOLINE YELLOW WS (SPECTRACOL)	4.56 kg
BETAPYN TABS - (Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Colour Yellow 14037-1.848MG Codeine Phosphate 10mg Tablets (Para -2250.000+ Caff -250.000 Doxy-25.000+Colour Yellow 14037-9.240 Codeine -50.00 KGS (No. of Tablets 5000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	Do not match with MBF
PYNSTOP TABS - (Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets (Para - 2250.000+ Caff -225.000+ Doxy-25.000+Codeine - 50.000 Kgs) (No. of Tablets 5000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg

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

Case No.:950/15/82-ALC4/2018	Party Name:ADCOCK INGRAM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/02407/AM19/	RLA File :07/24/040/00065/AM16/	Lic.No/Date:0710108316 04.06.2015	

5

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 15/82-ALC4/2018, dated 22.03.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
SYNDOL TABS - (Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Colour Yellow 14037-1.632MG Tablets (Para - 4500.000+Caff - 300.000+ Doxy-50.000+Codeine - 100.000 Colour Yellow 14037-16.320 KGS) (No. of Tablets 10000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / Tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	1.632 kg
ADCO DOL TABS -(Paracetamol 450mg + Codeine Phosphate 10mg + Caffeine 45mg + Doxylamine Succinate 5mg+Colour Yellow Lake-4.56mg Colour Yellow WS-2.43mg Tablets (Para - 9000.000 +Codeine - 200.000 + Caff - 900.000+ Doxy-100.000 Colour Yellow Lake-91.200 Colour Yellow WS-48.600 KGS) (No. of Tablets 20000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / Tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	2.43 kg
		5.	COLOUR QUINOLINE YELLOW WS (SPECTRACOL)	4.56 kg
BETAPYN TABS - (Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Colour Yellow 14037-1.848MG Codeine Phosphate 10mg Tablets (Para -2250.000+ Caff -250.000 Doxy-25.000+Colour Yellow 14037-9.240 Codeine -50.00 KGS (No. of Tablets 5000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / Tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		4.	COLOUR YELLOW 14037 IH	Do not match with MBF
PYNSTOP TABS - (Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets (Para - 2250.000+ Caff - 225.000+ Doxy-25.000+Codeine - 50.000 Kgs) (No. of Tablets 5000000)	1 million tablets	1.	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	459 mg / Tablet
		2.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		3.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg

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

Case No.:81/13/82-ALC4/2015	Party Name:PAB ORGANICS	Meet No/Date:12/82-	**Status:**

		PVT.LTD,	ALC4/2019 17.01.2020	**Approved**
	HQ File :01/82/050/01044/AM16/	RLA File :34/24/040/00083/AM16/	Lic.No/Date:3410041361 07.07.2015	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
2, 3 DICHLORO BENZOYL CYANIDE (2,3 DICHLORO BENZOYL NITRILE)	1 kg	1	2, 3 DICHLORO BENZOYL CHLORIDE	1.297 kg

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

7	**Case No.:969/15/82-ALC4/2018**	Party Name:SOMU SOLVENTS PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02426/AM19/	RLA File :07/24/040/00175/AM16/	Lic.No/Date:0710108673 02.09.2015	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

8	**Case No.:405/15/82-ALC4/2018**	Party Name:SHIVA PHARMACHEM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01862/AM19/	RLA File :34/24/040/00139/AM16/	Lic.No/Date:3410041522 16.09.2015	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

9	**Case No.:259/15/82-ALC4/2018**	Party Name:CADILA PHARMACEUTICALS LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01716/AM19/	RLA File :08/24/040/00222/AM16/	Lic.No/Date:0810136251 12.10.2015	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

10	**Case No.:322/15/82-ALC4/2018**	Party Name:HESTER BIOSCIENCES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01779/AM19/	RLA File :08/24/040/00270/AM16/	Lic.No/Date:0810136418 02.11.2015	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

11	**Case No.:1030/15/82-ALC4/2018**	Party Name:SWATI MENTHOL & ALLIED CHEMICALS LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02487/AM19/	RLA File :29/21/040/00029/AM16/	Lic.No/Date:2910025235 21.12.2015	Defer Date:
	Decision: The Committee considered the case as per online agenda in the presence of technical experts and it was noted that the firm still has not furnished the following information asked for by NC-3 in its Meeting No. **7/82-ALC4/2019 dated 06.09.2019**, followed by Reminder on **31.10.2019**: **(i) Complete 4E with all technical details chemistry, molecular weight, stoichiometric reaction and % of yield at every stage.** **(ii) Central Excise or GST Certificate.** In view of above, the Committee decided to issue **Final Reminder** to firm to furnish its reply, failing which the case will be rejected.			

12	**Case No.:494/15/82-ALC4/2018**	Party Name:BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01951/AM19/	RLA File :03/94/040/00818/AM16/	Lic.No/Date:0310801693 11.01.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Ademetionine Tablets 400mg (Pack of 20 Tablets)	1 Number	1	Ademetionine 1,4-butane disulfonate (SD4)	743.22 mg / tablet

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

13	**Case No.:260/15/82-ALC4/2018**	Party Name:VINNY HEALTHCARE PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01717/AM19/	RLA File :08/24/040/00386/AM16/	Lic.No/Date:0810137198 12.02.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

14	**Case No.:996/15/82-ALC4/2018**	Party Name:RECKITT BENCKISER (INDIA) LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02453/AM19/	RLA File :07/24/040/00374/AM16/	Lic.No/Date:0710109433 23.02.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

15	**Case No.:1006/15/82-ALC4/2018**	Party Name:STELLENCE PHARMSCIENCE PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02463/AM19/	RLA File :07/24/040/00420/AM16/	Lic.No/Date:0710109590 29.03.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
4 METHYL 5 HYDROXY METHYL IMIDAZOLE	1 kg	1	4 METHYL IMIDAZOLE	1.085 kg

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

16	**Case No.:221/15/82-ALC4/2018**	Party Name:GOPINATH CHEM-TECH LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01678/AM19/	RLA File :08/24/040/00469/AM16/	Lic.No/Date:0810137649 11.04.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

17	**Case No.:274/15/82-ALC4/2018**	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01731/AM19/	RLA File :07/24/040/00034/AM17/	Lic.No/Date:0710109729 27.04.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

18	**Case No.:222/15/82-ALC4/2018**	Party Name:ADCOCK INGRAM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01679/AM19/	RLA File :07/24/040/00015/AM17/	Lic.No/Date:0710109746 02.05.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

Case No.:223/15/82-ALC4/2018	Party Name:ADCOCK INGRAM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/01680/AM19/	RLA File :07/24/040/00018/AM17/	Lic.No/Date:0710109744 02.05.2016	

19

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 15/82-ALC4/2018, dated 22.03.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
SYNDOL TABS - (Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Colour Yellow 14037-1.632MG Tablets) (Para - 9000.000+Caff -600.000+ Doxy-100.000+Codeine - 200.000 Colour Yellow 14037-32.640 KGS) (No. of Tablets 20000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	1.632 kg
ADCO DOL TABS -(Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg+Colour Yellow Lake-4.56mg Colour Yellow WS-2.43mg Tablets (Para - 33750.000 +Codeine - 750.000 + Caff - 3375.000+ Doxy-375.000 Colour Yellow Lake-342.000 Colour Yellow WS-182.250 KGS) (No. of Tablets 75000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	2.43 kg
		4.	COLOUR QUINOLINE YELLOW WS (SPECTRACOL)	4.56 kg
BETAPYN TABS -(Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Colour Yellow 14037-1.848mg Codeine Phosphate 10mg Tablets (Para - 2250.000+ Caff -250.000 Doxy-25.000+Colour Yellow 14037-9.240 Codeine -50.00 KGS (No. of Tablets 5000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	Do not match with MBF
PYNSTOP TABS - (Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets (Para - 2250.000+ Caff -225.000+ Doxy-25.000+Codeine - 50.000 Kgs) (No. of Tablets 5000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg

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

20	**Case No.:224/15/82-ALC4/2018**	Party Name:ADCOCK INGRAM LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01681/AM19/	RLA File :07/24/040/00019/AM17/	Lic.No/Date:0710109754 03.05.2016	

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 15/82-ALC4/2018, dated 22.03.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
SYNDOL TABS - (Paracetamol 450mg + Caffeine 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Colour Yellow 14037-1.632MG Tablets) (Para - 9000.000+Caff -600.000+ Doxy-100.000+Codeine - 200.000 Colour Yellow 14037-32.640 KGS) (No. of Tablets 20000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	1.632 kg
ADCO DOL TABS - (Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mg+ Colour Yellow Lake-4.56mg Colour Yellow WS-2.43mg Tablets (Para -31500.000 +Codeine - 700.000 + Caff - 3150.000+ Doxy-350.000 Colour Yellow Lake-319.200 Colour Yellow WS-170.100 KGS) (No. of Tablets 70000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	2.43 kg
		4.	COLOUR QUINOLINE YELLOW WS (SPECTRACOL)	4.56 kg
BETAPYN TABS -(Paracetamol 450mg + Caffeine 50mg + Doxylamine Succinate 5mg + Colour Yellow 14037-1.848mg Codeine Phosphate 10mg Tablets (Para -2250.000+ Caff -250.000 Doxy-25.000+Colour Yellow 14037-9.240 Codeine -50.00 KGS (No. of Tablets 5000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg
		3.	COLOUR YELLOW 14037 IH	Do not match with MBF
PYNSTOP TABS - (Paracetamol 450mg + Caffeine 45mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets (Para - 2250.000+ Caff -225.000+ Doxy-25.000+Codeine - 50.000 Kgs) (No. of Tablets 5000000)	1 million tablets	1.	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg
		2.	CODIENE PHOSPHATE BP / EP / USP / PH.EUR	10.2 kg

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

21	**Case No.:286/15/82-ALC4/2018**	Party Name:MOREPEN LABORATORIES LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01743/AM19/	RLA File :05/24/040/00060/AM17/	Lic.No/Date:0510398453 11.05.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

22	**Case No.:225/15/82-ALC4/2018**	Party Name:VIVIMED LABS (ALATHUR) PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/01682/AM19/	RLA File :04/24/040/00012/AM17/	Lic.No/Date:0410161928 12.05.2016	
	Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not furnished the information on following deficiencies raised by NC-3 in its Meeting No. **15/82-ALC4/2018 dated 22.03.2019**, followed by Reminder on **01.07.2019** and Final Reminder on **01.08.2019**: **(i) Drug Manufacturing License (DML) of the export product.** **(ii) Master Batch Formula (MBF) of the export product.** Hence, the Committee decided to **reject** the case. RA concerned may take further necessary action as per above decision of NC.			

23	**Case No.:230/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01687/AM19/	RLA File :07/24/040/00083/AM17/	Lic.No/Date:0710109922 08.06.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

24	**Case No.:231/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01688/AM19/	RLA File :07/24/040/00082/AM17/	Lic.No/Date:0710109921 08.06.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

25	**Case No.:501/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01958/AM19/	RLA File :07/24/040/00081/AM17/	Lic.No/Date:0710109926 09.06.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

26	**Case No.:234/15/82-ALC4/2018**	Party Name:R L FINE CHEM	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01691/AM19/	RLA File :07/24/040/00057/AM17/	Lic.No/Date:0710109991 23.06.2016	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

27	**Case No.:270/15/82-ALC4/2018**	Party Name:ARKRAY HEALTHCARE PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01727/AM19/	RLA File :52/24/040/00025/AM17/	Lic.No/Date:5210041960 14.07.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of written comments furnished by Department of Biotechnology vide its OM No. BT/IL/05/004/2010-PID, dated 13.11.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PARAHIT -F DEVICE TEST KIT (1 KIT OF 50 TESTS OR 25 TESTS OR 10 TESTS (RAPID DIAGNOSTICS TEST KIT)	22500 Test Kits	1	ANTI MOUSE IgG (GOAT)	0.01965 gm
		2	MAB TO P.FALCIPARUM FOR NCM	0.0068 gm
		3	MAB FOR P.FALCIPARUM COLLOIDAL GOLD REAGENT	0.00311 gm
		4	MOUSE IgG (PURIFIED)	0.00156 gm

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

28	**Case No.:477/15/82-ALC4/2018**	Party Name:STELLENCE PHARMSCIENCE PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01934/AM19/	RLA File :07/24/040/00143/AM17/	Lic.No/Date:0710110111 15.07.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
4 METHYL 5 HYDROXY METHYL IMIDAZOLE	1 kg	1	4 METHYL IMIDAZOLE	1.085 kg

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

29	**Case No.:516/15/82-ALC4/2018**	Party Name:BELOOR BAYIR BIOTECH LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01973/AM19/	RLA File :07/24/040/00182/AM17/	Lic.No/Date:0710110335 30.08.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
CIRCALIFE CAPSULES 30S WT 13.23 KGS	1 Number	1	MELATONIN BP	3.06 mg / capsule
MELATONINA 3MG 30S WT 29.4KGS	1 Number	1	MELATONIN BP	3.06 mg / capsule

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

30	**Case No.:6/11/85-ALC3/2016**	Party Name:GELTEC PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/85/050/00103/AM17/	RLA File :03/94/040/00502/AM17/	Lic.No/Date:0310807611 06.09.2016	Defer Date:

Decision: The Committee considered the case as per agenda in the presence of technical experts and it was observed that:

(i) Export Products are in Brand Name.
(ii) Composition is not approved by any Competent Authority.

In view of above deficiencies, norms cannot be fixed. Hence, the Committee decided to call the firm to attend **Personal Hearing** before Norms Committee

31	**Case No.:335/12/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00962/AM19/	RLA File :07/24/040/00216/AM17/	Lic.No/Date:0710110453 23.09.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AMOXICILLIN & POTASSIUM CLAVULANATE FOR ORAL SUSPENSION 457MG/5ML, 70 ml bottles [EXP.QTY: 952.476 + 295.189 = 1247.665 KG]	1 bottle of 70 ml	1	AMOXICILLIN TRIHYDRATE	5880.00 mg
		2	POTASSIUM CLAVULANATE + SYLOID AL 1:1 BP/PH.EUR	1979.87 mg

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

32	**Case No.:646/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02103/AM19/	RLA File :07/24/040/00251/AM17/	Lic.No/Date:0710110596 28.10.2016	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

33	**Case No.:679/15/82-ALC4/2018**	Party Name:BELOOR BAYIR BIOTECH LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02136/AM19/	RLA File :07/24/040/00273/AM17/	Lic.No/Date:0710110770 09.12.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
CIRCALIFE 3MG CAPS 30 S. NT.WT 6.60 KGS	1 Number	1	MELATONIN	3.06 mg / capsule
CIRCALIFE 3MG CAPS 30 S NT.WT 6.60 KGS	1 Number			
MELATONINA CAPS 30 S NT.WT 16.50 KGS	1 Number			
MELATONINA CAPS 30 S NT.WT 16.50 KGS	1 Number			

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

34	**Case No.:271/15/82-ALC4/2018**	Party Name:ARKRAY HEALTHCARE PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01728/AM19/	RLA File :52/24/040/00052/AM17/	Lic.No/Date:5210042097 14.12.2016	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of written comments furnished by Department of Biotechnology vide its OM No. BT/IL/05/004/2010-PID, dated 13.11.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PARAHIT -F DEVICE TEST KIT (1 KIT OF 50 TESTS OR 25 TESTS OR 10 TESTS (RAPID DIAGNOSTICS TEST KIT).	22500 Test Kits	1	ANTI MOUSE IgG (GOAT)	0.01965 gm
		2	MAB TO P.FALCIPARUM FOR NCM	0.0068 gm
		3	MAB FOR P.FALCIPARUM COLLOIDAL GOLD REAGENT	0.00311 gm
		4	MOUSE IgG (PURIFIED)	0.00156 gm

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

35	**Case No.:680/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02137/AM19/	RLA File :07/24/040/00282/AM17/	Lic.No/Date:0710110805 16.12.2016	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

36	**Case No.:265/15/82-ALC4/2018**	Party Name:ATUL LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01722/AM19/	RLA File :08/24/040/00374/AM17/	Lic.No/Date:0810139395 28.12.2016	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

37	**Case No.:992/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02449/AM19/	RLA File :07/24/040/00353/AM17/	Lic.No/Date:0710111032 27.01.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

38	**Case No.:374/15/82-ALC4/2018**	Party Name:GLAND PHARMA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01831/AM19/	RLA File :09/24/040/00594/AM17/	Lic.No/Date:0910064653 07.02.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty. (for 1 Number PFS)
Nadroparin Calcium Injection (Low Molecular Weight Heparin) 2850 IU/0.3ml PFS	1 Number	1	Nadroparin Calcium	26.125 mg
		2	Barrel Syringes	Relevant as per packing policy (Net +1% wastage)
		3	Needle Shield	
		4	Plunger Stoppers	
		5	Plunger Rods	
		6	Preventis	
		7	Medical Grade Paper	Not admissible
		8	Tubing	Not admissible
Nadroparin Calcium Injection (Low Molecular Weight Heparin) 5700 IU/0.6ml PFS	1 Number	1	Nadroparin Calcium	52.25 mg
		2	Barrel Syringes	Relevant as per packing policy (Net +1% wastage)
		3	Needle Shield	
		4	Plunger Stoppers	
		5	Plunger Rods	
		6	Preventis	
		7	Medical Grade Paper	Not admissible
		8	Tubing	Not admissible

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

39	**Case No.:995/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02452/AM19/	RLA File :07/24/040/00362/AM17/	Lic.No/Date:0710111117 10.02.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

40	**Case No.:1001/15/82-ALC4/2018**	Party Name:BELOOR BAYIR BIOTECH LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02458/AM19/	RLA File :07/24/040/00374/AM17/	Lic.No/Date:0710111126 14.02.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
MELATONINA CAPS 30 S NT.WT.97.02 KGS	1 Number	1	MELATONIN BP	3.06 mg / capsule
CIRCALIFE 3MG CAPS 30 S NET WT 6.93 KGS	1 Number	1	MELATONIN BP	3.06 mg / capsule

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

41	**Case No.:1002/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02459/AM19/	RLA File :07/24/040/00365/AM17/	Lic.No/Date:0710111160 21.02.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

42	**Case No.:276/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01733/AM19/	RLA File :05/23/040/00561/AM17/	Lic.No/Date:0510401758 22.02.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

43	**Case No.:277/15/82-ALC4/2018**	Party Name:ARKRAY HEALTHCARE PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01734/AM19/	RLA File :52/24/040/00079/AM17/	Lic.No/Date:5210042190 01.03.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of written comments furnished by Department of Biotechnology vide its OM No. BT/IL/05/004/2010-PID, dated 13.11.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PARAHIT -F DEVICE TEST KIT (1 KIT OF 50 TESTS OR 25 TESTS OR 10 TESTS (RAPID DIAGNOSTICS TEST KIT).	22500 Test Kits	1	ANTI MOUSE IgG (GOAT)	0.01965 gm
		2	MAB TO P.FALCIPARUM FOR NCM	0.0068 gm
		3	MAB FOR P.FALCIPARUM COLLOIDAL GOLD REAGENT	0.00311 gm
		4	MOUSE IgG (PURIFIED)	0.00156 gm

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

44	**Case No.:1007/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02464/AM19/	RLA File :07/24/040/00396/AM17/	Lic.No/Date:0710111261 09.03.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
METFORMIN HYDROCHLORIDE 500MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	320 mg / 500 mg PR Tablet
METFORMIN HYDROCHLORIDE 750MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	240 mg / 750 mg PR Tablet
METFORMIN HYDROCHLORIDE 1000MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	320 mg / 1000 mg PR Tablet

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

45	**Case No.:293/15/82-ALC4/2018**	Party Name:ARKRAY HEALTHCARE PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01750/AM19/	RLA File :52/24/040/00002/AM18/	Lic.No/Date:5210042239 25.04.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of written comments furnished by Department of Biotechnology vide its OM No. BT/IL/05/004/2010-PID, dated 13.11.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PARAHIT -F DEVICE TEST KIT (1 KIT OF 50 TESTS OR 25 TESTS OR 10 TESTS (RAPID DIAGNOSTICS TEST KIT).	22500 Test Kits	1	ANTI MOUSE IgG (GOAT)	0.01965 gm
		2	MAB TO P.FALCIPARUM FOR NCM	0.0068 gm
		3	MAB FOR P.FALCIPARUM COLLOIDAL GOLD REAGENT	0.00311 gm
		4	MOUSE IgG (PURIFIED)	0.00156 gm

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

46	**Case No.:294/15/82-ALC4/2018**	Party Name:SUPREET CHEMICALS PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01751/AM19/	RLA File :52/24/040/00006/AM18/	Lic.No/Date:5210042249 02.05.2017	Defer Date:

Decision: The Committee considered the request of firm and it was decided to call for following information from the firm:

(i) Recovery of By-Product i.e. Para Amino Phenol and its commercial value.

47	**Case No.:282/15/82-ALC4/2018**	Party Name:MSN PHARMACHEM PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01739/AM19/	RLA File :09/24/040/00067/AM18/	Lic.No/Date:0910065021 11.05.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

48	**Case No.:289/15/82-ALC4/2018**	Party Name:ATUL LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01746/AM19/	RLA File :08/24/040/00043/AM18/	Lic.No/Date:0810140311 18.05.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

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

(i) Complete 4E with all technical details i.e chemistry, molecular weight, stoichiometric reaction and % of yield on molar basis at every stage.

49	**Case No.:392/15/82-ALC4/2018**	Party Name:ALEMBIC PHARMACEUTICALS LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01849/AM19/	RLA File :34/24/040/00034/AM18/	Lic.No/Date:3410043214 22.05.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AZITHROMYCIN STEP 4	1 kg activity	1	ERYTHROMYCIN BASE USP	1.58 kg
		2	HYDROXYLAMINE HYDROCHLORIDE	0.71 kg
		3	METHANOL	2.24 kg
		4	METHANE SULFONYL CHLORIDE	0.47 kg
		5	ACETONE	6.45 kg
		6	ETHYL ALCOHOL	2.81 Litre
		7	PLATINUM METAL	0.100 gram
AZITHROMYCIN STEP 3	1 kg activity	1	ERYTHROMYCIN BASE USP	1.506 kg
		2	HYDROXYLAMINE HYDROCHLORIDE	0.68 kg
		3	METHANOL	1.09 kg
		4	METHANE SULFONYL CHLORIDE	0.45 kg
		5	ACETONE	1.27 kg
		6	ETHYL ALCOHOL	2.61 Litre
		7	PLATINUM METAL	0.100 gram

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

50	**Case No.:290/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01747/AM19/	RLA File :07/24/040/00052/AM18/	Lic.No/Date:0710111636 23.05.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

51	**Case No.:291/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01748/AM19/	RLA File :07/24/040/00056/AM18/	Lic.No/Date:0710111650 24.05.2017	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

52	**Case No.:296/15/82-ALC4/2018**	Party Name:MICRO LABS LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Withdrawn**
	HQ File :01/82/050/01753/AM19/	RLA File :07/24/040/00082/AM18/	Lic.No/Date:0710111725 08.06.2017	
	Decision: The Committee considered the case as per agenda in the presence of technical experts and it was observed that the norms for the subject Advance Authorization have already been ratified by NC-3 in its Meeting No. **10/82-ALC4/2019 dated 29.11.2019**. In view of above, the Committee decided to **withdraw** the case.			

53	**Case No.:525/4/82-ALC4/2017**	Party Name:CIPLA LIMITED.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00533/AM18/	RLA File :03/94/040/00211/AM18/	Lic.No/Date:0310813980 14.06.2017	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

54

Case No.:300/15/82-ALC4/2018	Party Name:SRIAM LABS PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/01757/AM19/	RLA File :09/24/040/00145/AM18/	Lic.No/Date:0910065229 29.06.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
(1S, 4R)-Amino-2-cyclopentene-1-methanol D (-) tartarate (CAP-II)	1 kg	1	2-Azabicylo [2.2.1] hept-5-en-3-one (Vincelactam)	1.337 kg
		2	Sodium boro hydride	0.214 kg
		3	L(+) Tartaric acid	0.90 kg

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

55	**Case No.:109/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01064/AM18/	RLA File :09/24/040/00181/AM18/	Lic.No/Date:0910065247 06.07.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

56	**Case No.:571/15/82-ALC4/2018**	Party Name:SRIAM LABS PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02028/AM19/	RLA File :09/24/040/00158/AM18/	Lic.No/Date:0910065242 06.07.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
ABACAVIR SULFATE	1 kg	1	2-Azabicylo [2.2.1] hept-5-en-3-one (Vincelactam)	2.50 kg
		2	Sodium borohydride (SBH)	0.48 kg
		3	L(+) Tartaric Acid	1.251 kg
		4	N-(2-amino-4,6-dichloro-5-pyrimidinyl) Formamide (FADCP)0.19 kg	1.042 kg
		5	Cyclopropylamine	0.19 kg

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

57	**Case No.:309/15/82-ALC4/2018**	Party Name:DISCOVERY INTERMEDIATES PVT LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01766/AM19/	RLA File :09/24/040/00157/AM18/	Lic.No/Date:0910065252 07.07.2017	Defer Date:
	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 and % of yield on molar basis.** **(ii) Recovery of By – Products and its value.** **(iii) End – use of export product.**			

58	**Case No.:301/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01758/AM19/	RLA File :07/24/040/00111/AM18/	Lic.No/Date:0710111877 13.07.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS 1125MG [1600000 No.] [1840 + 481.65 Kgs = 2321.65 Kgs] Each tab contains Amoxicillin Trihydrate 1150mg equivalent to Amoxicillin 1000mg & Clav.Potassium as Clavulanic Acid 125mg]	1 No. Tablet	1	AMOXICILLIN TRIHYDRATE BP COMP	1170.56 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	303.773 mg
AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS 1000MG [4061106 No.] [4086.488 + 1221.288 Kgs = 5307.776 Kgs] Each tab contains Amoxicillin Trihydrate 1006.25mg equivalent to Amoxicillin 875mg & Clav.Potassium as Clavulanic Acid 125mg]	1 No. Tablet	1	AMOXICILLIN TRIHYDRATE BP COMP	1024.238 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	303.773 mg
AMOXICILLIN & CLAVULANATE POTASSIUM 625MG TABLETS [3220000 No.] [1851.500 + 968.344 Kgs = 2819.844 Kgs] Each tab contains Amoxicillin Trihydrate 575mg equivalent to Amoxicillin 500mg & Clav.Potassium as Clavulanic Acid 125mg]	1 No. Tablet	1	AMOXICILLIN TRIHYDRATE BP COMP	585.28 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	303.773 mg
AMOXICILLIN & CLAVULANATE POTASSIUM 562.5MG TABLETS [3200000 No.] [1840 + 481.165 Kgs = 2321.165 Kgs] Each tab contains Amoxicillin Trihydrate 575mg equivalent to Amoxicillin 500mg & Clav.Potassium as Clavulanic Acid 62.5mg]	1 No. Tablet	1	AMOXICILLIN TRIHYDRATE BP COMP	585.28 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	151.88 mg

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

59	**Case No.:305/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01762/AM19/	RLA File :07/24/040/00115/AM18/	Lic.No/Date:0710111888 18.07.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 457MG/5ML [70ML / 140ML PACK SIZE] [2672194 NO./1229.209 + 380.953 = 1610.163 KG] [460MG of Amoxicillin Trihydrate is equivalent to Amoxicillin 400mg] [PTASSIUM CLAVULANATE & SYLOID AL -142.562MG]	1 bottle of 70 ml	1	AMOXICILLIN TRIHYDRATE BP	5880.00 mg
		2	POTASSIUM CLAVULANATE + SYLOID AL 1:1 BP/PH.EUR	1979.87 mg

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

60	**Case No.:306/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01763/AM19/	RLA File :07/24/040/00116/AM18/	Lic.No/Date:0710111889 18.07.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 228.5MG/5ML,70ML [5355000 NO.] Each 5ml after reconstitution contains Amoxicillin Trihydrate 230mg equivalent to Amoxicillin 200mg + Pot.Clav BP equivalent to Clav.Acid 28.5mg] [1231.650+381.715 = 1613.365 Kgs]	5355000 Number	1	AMOXICILLIN TRIHYDRATE BP	1293.232 kg
		2	POTASSIUM CLAVULANATE + SYLOID 1:1 [POT.CLAVULANATE + SILICON DIOXIDE (1:1)]	400.801 kg
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 562.5MG/5ML,60ML [360000 No.] [Each 5ml after reconstitution contains Amoxicillin Trihydrate 575mg equivalent to Amoxicillin 500mg + Pot.Clavulanate equivalent to Clav.Acid 62.5mg] [207 + 56.274 = 263.274 Kgs]	360000 Number	1	AMOXICILLIN TRIHYDRATE BP	217.350 kg
		2	POTASSIUM CLAVULANATE + SYLOID 1:1 [POT.CLAVULANATE + SILICON DIOXIDE (1:1)]	59.088 kg
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 281.25MG/5ML,60ML [180000 No.][Each 5ml after reconstitution contains Amoxicillin Trihydrate 287.5mg equivalent to Amoxicillin 250mg + Pot.Clav equivalent to Clav. Acid 31.25mg] [51.75 + 13.639 = 65.389 Kgs]	180000 Number	1	AMOXICILLIN TRIHYDRATE BP	54.338 kg
		2	POTASSIUM CLAVULANATE + SYLOID 1:1 [POT.CLAVULANATE + SILICON DIOXIDE (1:1)]	14.321 kg

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

61	**Case No.:311/15/82-ALC4/2018**	Party Name:ASSOCIATED DYESTUFF PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01768/AM19/	RLA File :08/24/040/00123/AM18/	Lic.No/Date:0810140725 26.07.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

62	**Case No.:297/12/82-ALC4/2018**	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00924/AM19/	RLA File :07/24/040/00129/AM18/	Lic.No/Date:0710111984 08.08.2017	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

63	**Case No.:314/15/82-ALC4/2018**	Party Name:WEXFORD LABORATORIES PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/01771/AM19/	RLA File :07/24/040/00120/AM18/	Lic.No/Date:0710111992 09.08.2017	
	Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not given complete information as asked for in DL. Hence, no norms can be recommended in its proposed format. Hence, the Committee decided to **reject** the case. RA concerned may take further necessary action as per above decision of NC.			

64	**Case No.:315/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01772/AM19/	RLA File :07/24/040/00105/AM18/	Lic.No/Date:0710111997 09.08.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Amoxicillin & Potassium Clavulanate Tablets 625mg [8605640 No.] [Each film coated tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500mg Potassium Clavulanate BP (as diluted Potassium Clavulanate BP) equivalent to Clavulanic Acid 125mg] [Exp.Qty: 4948.243 + 2587.957 = 7536.200 Kgs]	1 Number	1	AMOXICILLIN TRIHYDRATE BP COMP	585.28 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	303.773 mg
Amoxicillin & Potassium Clavulanate Tablets 625mg[5380180 No.] [Each film coated tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500mg Potassium Clavulanate BP (as diluted Potassium Clavulanate BP) equivalent to Clavulanic Acid 125mg] [Exp.Qty: 3093.604 + 1617.971 = 4711.575 Kgs]	1 Number	1	AMOXICILLIN TRIHYDRATE BP COMP	585.28 mg
		2	POTASSIUM CLAVULANATE + MCC BLEND (1:1)	303.773 mg

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

65	**Case No.:116/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01071/AM18/	RLA File :09/24/040/00234/AM18/	Lic.No/Date:0910065373 23.08.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

66	**Case No.:134/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01089/AM18/	RLA File :09/24/040/00233/AM18/	Lic.No/Date:0910065372 23.08.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

67

Case No.:318/15/82-ALC4/2018	Party Name:MYLAN LABORATORIES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/01775/AM19/	RLA File :09/24/040/00259/AM18/	Lic.No/Date:0910065385 24.08.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PALBOCICLIB	1 kg	1	6-Bromo-2-chloro-8-cyclopentyl-5-methyl-8H-pyrido[2,3-d]pyrimidin-7-one	1.54 kg
		2	4-(6-amino-pyridin-3-yl)-piperazine-1-carboxylic acid tertiary butyl ester	1.85 kg
		3	Tetrahydrofuran	5.60 kg
		4	Butyl vinyl ether	0.85 kg
		5	Bis[2-(diphenylphosphino)phenyl] Ether	0.10 kg
		6	n-Heptane	14.84 kg
		7	1,2- Diaminopropane	1.50 kg

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

68	**Case No.:131/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01086/AM18/	RLA File :09/24/040/00238/AM18/	Lic.No/Date:0910065396 28.08.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

69	**Case No.:132/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01087/AM18/	RLA File :09/24/040/00235/AM18/	Lic.No/Date:0910065398 28.08.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

70	**Case No.:141/12/82-ALC4/2017**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01096/AM18/	RLA File :09/24/040/00236/AM18/	Lic.No/Date:0910065397 28.08.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

71	**Case No.:321/15/82-ALC4/2018**	Party Name:AASHA BIOCHEM	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01778/AM19/	RLA File :10/24/040/00018/AM18/	Lic.No/Date:1010059805 31.08.2017	Defer Date:
	Decision: The Representative of the firm attended the Personal Hearing before Norms Committee and explained its case. The Committee after deliberation decided to call for following information / documents from the firm: **(i) Drug Manufacturing License (DML).** **(ii) Certificate of Analysis (COA) from the foreign supplier.** **(iii) Certificate of Analysis (COA) for the export product.** **(iv) Cost of Finished Product.** **(v) Stepwise loss in each stage.** **(vi) Whether it comes under IP, BP, USP and if so give details.** **(vii) HSN Code international on documentary support under ITC HS Code 29012990.** **(viii) Documentary evidence to put under ITC HS Code 29012990.**			

72	**Case No.:483/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01940/AM19/	RLA File :07/24/040/00157/AM18/	Lic.No/Date:0710112113 07.09.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Amoxicillin Oral Suspension 250mg/5ml, 100ml [200000 Bottles] [Each 5ml Contains Amoxicillin Trihydrate 287.5mg equivalent to 250mg]	200000 Bottles	1	Amoxicillin Trihydrate BP Comp	1207.500 kg
Amoxicillin Oral Suspension 125mg/5ml,100ml [160000 Bottles] [Each 5ml Contains Amoxicillin Trihydrate 143.75mg equivalent to 125mg]	160000 Bottles	1	Amoxicillin Trihydrate BP Comp	483.000 kg
Amoxicillin & Potassium Clavulanate Oral Suspension 281.25mg/5ml,60ml [100000 Bottles] [Each 5ml Contains Amoxicillin Trihydrate 287.5mg equivalent to 250mg & Pot.Clav + Syloid 1:1 - 37.887mg equivalent to 31.25mg of Clav.Acid]]	100000 Bottles	1	Amoxicillin Trihydrate BP Comp	362.250 kg
		2	Potassium Clavulanate + Syloid 1:1	157.50 kg
Amoxicillin & Potassium Clavulanate Oral Suspension 228.5mg/5ml, 100ml [110000 Bottles] [Each 5ml Contains Amoxicillin Trihydrate 230mg equivalent to 200mg & Pot.Clav + Syloid 1:1 - 35.641mg equivalent to 28.5mg of Clav.Acid]	110000 Bottles	1	Amoxicillin Trihydrate BP Comp	462.00 kg
		2	Potassium Clavulanate + Syloid 1:1	155.56 kg
Amoxicillin & Potassium Clavulanate Oral Suspension 457mg/5ml, 100ml [52000 Bottles] [Each 5ml Contains Amoxicillin Trihydrate 460mg equivalent to 400mg & Pot.Clav + Syloid 1:1 71.281mg equivalent to 57mg of Clav.Acid]]	52000 Bottles	1	Amoxicillin Trihydrate BP Comp	436.80 kg
		2	Potassium Clavulanate + Syloid 1:1	147.08 kg

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

73	**Case No.:177/12/82-ALC4/2017**	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01132/AM18/	RLA File :09/24/040/00273/AM18/	Lic.No/Date:0910065450 11.09.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of past recommendations of Department of Pharma dated 15.11.2017 for 400/57 mg and 600/42.9 mg, pro rata for 200/28.5 mg, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Norms for export product: **Amoxicillin + Clavulanate Oral Suspension 200/28.5 mg, in 50 ml, 125 ml and 200 ml bottles**

Raw materials to be imported for 1000 bottles (each 5 ml contains Amoxicillin Trihydrate equivalent to 200 mg Amoxicillin + Potassium Clavulanate equivalent to 28.5 mg Clavulanic Acid)				
Sl. No.	Description	Quantity recommended for 1000 bottles		
		50 ml	75 ml	100 ml
1.	6-APA	1192.80 gm	1789.2 gm	2385.6 gm
2.	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	707.00 gm	1060.50 gm	1414.00 gm

Norms for export product: **Amoxicillin + Clavulanate Oral Suspension 400/57 mg, in 50 ml, 75 ml and 100 ml bottles**

Raw materials to be imported for 1000 bottles (each 5 ml contains Amoxicillin Trihydrate equivalent to 400 mg Amoxicillin + Potassium Clavulanate equivalent to 57 mg Clavulanic Acid)				
Sl. No.	Description	Quantity recommended for 1000 bottles		
		50 ml	75 ml	100 ml
1.	6-APA	2385.60 gm	3578.40 gm	4771.20 gm
2.	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1414.0 gm	2121.00 gm	2828.00 gm

Norms for export product: **Amoxicillin + Clavulanate Oral Suspension 600/42.9 mg, in 50 ml, 125 ml and 200 ml bottles**

Raw materials to be imported for 1000 bottles (each 5 ml contains Amoxicillin Trihydrate equivalent to 600 mg Amoxicillin + Potassium Clavulanate equivalent to 42.9 mg Clavulanic Acid)				
Sl. No.	Description	Quantity recommended for 1000 bottles		
		75 ml	125 ml	200 ml
1.	6-APA	5367.60 gm	8946.00 gm	14313.6 gm
2.	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1596.54 gm	2660.91 gm	4257.46 gm

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

74	**Case No.:198/4/82-ALC4/2018**	Party Name:SAPTAGIR CAMPHOR LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00198/AM19/	RLA File :09/24/040/00293/AM18/	Lic.No/Date:0910065468 15.09.2017	Defer Date:
	Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: **(i) Quantity and value of By-Product i.e. Dipentene obtained.**			

75	**Case No.:506/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01963/AM19/	RLA File :07/24/040/00170/AM18/	Lic.No/Date:0710112139 15.09.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
METFORMIN HYDROCHLORIDE 500MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	320 mg / 500 mg PR Tablet
METFORMIN HYDROCHLORIDE 750MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	240 mg / 750 mg PR Tablet
METFORMIN HYDROCHLORIDE 1000MG PROLONGED RELEASE TABLETS	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K-200 MphCR]	320 mg / 1000 mg PR Tablet
Note: RA will ascertain the export quantity in number of tablets.				

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

76	**Case No.:515/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01972/AM19/	RLA File :07/24/040/00179/AM18/	Lic.No/Date:0710112226 04.10.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Metformin Hydrochloride 500mg Prolonged Release Tablets	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K 200 M PH CR]	320 mg / 500 mg PR Tablet
Metformin Hydrochloride 750mg Prolonged Release Tablets	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K 200 M PH CR]	240 mg / 750 mg PR Tablet
Metformin Hydrochloride 1000mg Prolonged Release Tablets	1 Number	1	HYPROMELLOSE BP/PH.EUR [BENECEL K 200 M PH CR]	320 mg / 1000 mg PR Tablet
Note: RA will ascertain the export quantity in number of tablets.				

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

77	**Case No.:327/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01784/AM19/	RLA File :05/23/040/00268/AM18/	Lic.No/Date:0510404290 13.10.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

78	**Case No.:328/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01785/AM19/	RLA File :05/23/040/00266/AM18/	Lic.No/Date:0510404285 13.10.2017	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

79	**Case No.:329/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01786/AM19/	RLA File :05/23/040/00267/AM18/	Lic.No/Date:0510404287 13.10.2017	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

80	**Case No.:79/12/82-ALC4/2017**	Party Name:CIPLA LIMITED.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01034/AM18/	RLA File :03/94/040/00496/AM18/	Lic.No/Date:0310816778 02.11.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Testosterone Topical Solution Pack Size 110ml, 63 MTD Each Actuation delivers : Testosterone USP 30mg Also contains Alcohol USP Approx. 49.55% w/v (QS to 100% w/v)	100000.000 Number	1	Testosterone USP	192.78 kg
		2	Alcohol (Ethanol 95% v/v)	5450.00 kg

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

81	**Case No.:550/15/82-ALC4/2018**	Party Name:TADIMETY AROMATICS PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02007/AM19/	RLA File :07/24/040/00202/AM18/	Lic.No/Date:0710112366 08.11.2017	Defer Date:

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

(i) Complete set of 4.07 application of subject advance authorization.
(ii) Complete 4E with all technical details i.e chemistry, molecular weight, stoichiometric reaction and % of yield on molar basis at every stage.

82	**Case No.:583/15/82-ALC4/2018**	Party Name:MEDREICH LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02040/AM19/	RLA File :07/24/040/00224/AM18/	Lic.No/Date:0710112429 20.11.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 562.5MG/5ML, 60ML [139000 Bottles] [Exp.Qty: 959.100+250.807=1209.907 Kgs] [Each 5ml contains 575mg of Amox.Trihydrate equivalent to Amoxicillin 500mg & Pot.Clav+Syloid Al 1:1 150.364mg equivalent to Clav.Acid 62.5mg]	139000 Bottles	1	AMOXICILLIN TRIHYDRATE BP / PH. EUR	875.70 kg
		2	POTASSIUM CLAVULANATE + SYLOID (1:1)	258.65 kg
AMOXICILLIN & POTASSIUM CLAVULANATE ORAL SUSPENSION 457MG/5ML, [140ML/70ML] [105000 Bottles] [Exp.Qty: 1352.400+419.132=1771.532 Kgs] [Each 5ml contains 460mg of Amox.Trihydrate equivalent to Amoxicillin 400mg & Pot.Clav+Syloid Al 1:1 142.562mg equivalent to Clav.Acid 57mg]	105000 Bottles	1	AMOXICILLIN TRIHYDRATE BP/PH.EUR	617.40 kg
		2	POTASSIUM CLAVULANATE + SYLOID (1:1)	207.88 kg

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

83	**Case No.:234/4/82-ALC4/2018**	Party Name:VIVIMED LIFE SCIENCES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/00234/AM19/	RLA File :09/24/040/00396/AM18/	Lic.No/Date:0910065686 24.11.2017	

Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not furnished the information on following deficiencies raised by NC-3 in its Meeting No. **14/82-ALC4/2018 dated 14.02.2019**, followed by Final Reminder on **05.09.2019**:

(i) Copy of valid DML for each export product.
(ii) Master Batch Formula for each export product.
(iii) Imports applied for each export items viz – 2.5 mg, 5mg and 10 mg tablets separately.

Hence, the Committee decided to **reject** the case.
RA concerned may take further necessary action as per above decision of NC.

84	**Case No.:236/4/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00236/AM19/	RLA File :09/24/040/00403/AM18/	Lic.No/Date:0910065688 24.11.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

85	**Case No.:243/4/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00243/AM19/	RLA File :09/24/040/00404/AM18/	Lic.No/Date:0910065687 24.11.2017	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

86	**Case No.:769/15/82-ALC4/2018**	Party Name:DORF-KETAL CHEMICALS INDIA PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02226/AM19/	RLA File :03/94/040/00657/AM18/	Lic.No/Date:0310817294 24.11.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Chemical Name: Polymer Additives - Bis (N-Alkylaminocycohexyl) methane Trade Name: Clearlink 1000	1 kg	1	PACM -2M (4,4 - Methylenebi Scyclo Hexanamine), Synonym : Bis (para-aminocyclohexyl) Brand Name : AMICURE-PACM CURING AGENT	0.665 kg
		2	Methyl Ethyl Ketone / MEK	0.798 kg
		3	Catalyst: 3% Platinum on carbon powder (on dry basis) 3% PLATINUM CATALYST #2020 CARBON SULFIDED / 3% PT/CP RW S DOPED 43515	0.00022 kg

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

87	**Case No.:723/15/82-ALC4/2018**	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02180/AM19/	RLA File :09/24/040/00414/AM18/	Lic.No/Date:0910065719 30.11.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
DORIPENEM STERILE / DORIPENEM MONOHYDRATE STERILE Condition: The firm should account for 60 No. of Input at Sl.No.1 of Import List (packing material) while exporting the manufacturing product that should be relfected in SBs.	1 kg	1	1- Beta-Methyl Vinyl Phosphate (MAP)	2.50 kg
		2	10% Palladium on Charcoal (Type: RD9210)	0.100 kg
		3	Doripenem side chain	2.463 kg
		4	Activated Carbon (Carbon Enoanticromos)	0.100 kg
		5	Dimethylformamide (DMF)	3.30 kg
		6	Isopropyl alcohol (IPA)	4.70 kg
		7	Methanol	2.00 kg
		8	Methylene chloride (MDC)	4.00 kg
		9	Tetrahydrofuran (THF)	4.00 kg
		10	Aluminium Canisters / Bottles with Chloro Butyl Plug / Inner & Outer Lid and Gasket / Alu Caps 14 Ltrs (5Kg Cap)]	Relevant as per packing policy with accountability

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

88	**Case No.:240/12/82-ALC4/2017**	Party Name:HERBOCHEM INDUSTRIES	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/01195/AM18/	RLA File :06/24/040/00041/AM18/	Lic.No/Date:0610038759 14.12.2017	

Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not furnished the information on following deficiencies raised by NC-3 in its Meeting No. **4/82-ALC4/2019 dated 19.07.2019**, followed by Reminder dated **04.09.2019** and Final Reminder on **01.11.2019**:

(i) CoA of import item indicating percentage composition of Mentha Arvensis Oil.

Hence, the Committee decided to **reject** the case.
RA concerned may take further necessary action as per above decision of NC.

89	**Case No.:340/15/82-ALC4/2018**	Party Name:AETHER INDUSTRIES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01797/AM19/	RLA File :52/24/040/00051/AM18/	Lic.No/Date:5210042456 15.12.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
THIOPHENE-2-ETHANOL	1 kg	1	THIOPHENE	1.325 kg
		2	MAGNESIUM TURNINGS	0.42 kg
		3	ETHYLENE OXIDE	0.64 kg

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

90	**Case No.:751/15/82-ALC4/2018**	Party Name:CADILA HEALTHCARE LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/02208/AM19/	RLA File :08/24/040/00266/AM18/	Lic.No/Date:0810141617 27.12.2017	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	DIVALPROEX SODIUM SPRINKLE CAPS USP 125MG (134.50MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 125MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 2406.25 KGS)	19250000.000 Number	1	DIVALPROEX SODIUM USP	2591.50 kg
			2	HYPROMELLOSE 3 CPS, 2910 USP	244.24 kg
			3	MICROCRYSTALLINE CELLULOSE NF SPHERES (CELPHERE CP305)	1726.10 kg
			4	METHACRYLIC ACID COPOLY DISPER NF	3582.13 kg
			5	TRIETHYL CITRATE NF	107.50 kg
2	DIVALPROEX SODIUM DELAYED RELEASE TABS USP 125MG (134.50MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 125MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 1043.75 KGS)	8350000.000 Number	1	DIVALPROEX SODIUM USP	1124.12 kg
			4	METHACRYLIC ACID COPOLY DISPER NF	390.36 kg
			5	TRIETHYL CITRATE NF	11.48 kg
			6	POVIDONE USP (K-30)	79.32 kg
			7	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH101)	442.05 kg
			8	MAGNESIUM STEARATE PH.E/NF/JP	19.78 kg

3	DIVALPROEX SODIUM DELAYED RELEASE TABS USP 250MG (269MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 250MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 1975.00 KGS)	7900000.000 Number	1	DIVALPROEX SODIUM USP	2127.08 kg
			4	METHACRYLIC ACID COPOLY DISPER NF	632.00 kg
			5	TRIETHYL CITRATE NF	18.96 kg
			6	POVIDONE USP (K-30)	150.10 kg
			7	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH101)	836.37 kg
			8	MAGNESIUM STEARATE PH.E/NF/JP	37.52 kg
4	DIVALPROEX SODIUM DELAYED RELEASE TABS USP 500MG (538MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 500MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 2950.00 KGS)	5900000.000 Number	1	DIVALPROEX SODIUM USP	3177.15 kg
			4	METHACRYLIC ACID COPOLY DISPER NF	944.00 kg
			5	TRIETHYL CITRATE NF	28.32 kg
			6	POVIDONE USP (K-30)	224.20 kg
			7	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH101)	1249.32 kg
			8	MAGNESIUM STEARATE PH.E/NF/JP	56.05 kg
5	DIVALPROEX SODIUM EXTENDED RELEASE TABS USP 250MG (269MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 250MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 4025.00 KGS)	16100000.000 Number	1	DIVALPROEX SODIUM USP	4334.92 kg
			8	MAGNESIUM STEARATE PH.E/NF/JP	149.00 kg
			9	HYPROMELLOSE 15000 CPS, 2208 USP	3670.80 kg
			10	HYPROMELLOSE 5 CPS, 2910 USP	676.20 kg
			11	HYDROXYPROPYL CELLULOSE NF (KLUCEL HXF)	1304.10 kg
			12	HYDROXYPROPYL CELLULOSE NF (KLUCEL EXF)	531.30 kg
6	DIVALPROEX SODIUM EXTENDED RELEASE TABS USP 500MG (538MG OF DIVALPROEX SODIUM IS EQUIVALENT TO 500MG OF VALPORIC ACID) (ACTIVE INGREDIENT : DIVALPROEX SODIUM USP - NET WT. 6250.00 KGS)	12500000.000 Number	1	DIVALPROEX SODIUM USP	6731.25 kg
			8	MAGNESIUM STEARATE PH.E/NF/JP	231.38 kg
			9	HYPROMELLOSE 15000 CPS, 2208 USP	5700.00 kg
			10	HYPROMELLOSE 5 CPS, 2910 USP	1050.00 kg
			11	HYDROXYPROPYL CELLULOSE NF (KLUCEL HXF)	2025.00 kg
			12	HYDROXYPROPYL CELLULOSE NF (KLUCEL EXF)	825.00 kg

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

91	**Case No.:348/15/82-ALC4/2018**	Party Name:ARKRAY HEALTHCARE PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01805/AM19/	RLA File :52/24/040/00053/AM18/	Lic.No/Date:5210042478 04.01.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and on the basis of written comments furnished by Department of Biotechnology vide its OM No. BT/IL/05/004/2010-PID, dated 13.11.2019, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
PARAHIT -F DEVICE TEST KIT (1 KIT OF 50 TESTS OR 25 TESTS OR 10 TESTS (RAPID DIAGNOSTICS TEST KIT).	22500 Test Kits	1	ANTI MOUSE IgG (GOAT)	0.01965 gm
		2	MAB TO P.FALCIPARUM FOR NCM	0.0068 gm
		3	MAB FOR P.FALCIPARUM COLLOIDAL GOLD REAGENT	0.00311 gm
		4	MOUSE IgG (PURIFIED)	0.00156 gm

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

92	**Case No.:241/12/82-ALC4/2017**	Party Name:HERBOCHEM INDUSTRIES	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/01196/AM18/	RLA File :06/24/040/00044/AM18/	Lic.No/Date:0610038783 10.01.2018	

Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not furnished the information on following deficiencies raised by NC-3 in its Meeting No. **4/82-ALC4/2019 dated 19.07.2019**, followed by Reminder dated **04.09.2019** and Final Reminder on **01.11.2019**:

(i) CoA of import item indicating percentage composition of Mentha Arvensis Oil.

Hence, the Committee decided to **reject** the case.
RA concerned may take further necessary action as per above decision of NC.

93	**Case No.:1021/15/82-ALC4/2018**	Party Name:ANLON HEALTHCARE PRIVATELIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02478/AM19/	RLA File :24/24/040/00039/AM18/	Lic.No/Date:2410042334 12.01.2018	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

94	**Case No.:12/4/82-ALC4/2018**	Party Name:MELOG SPECIALITY CHEMICALS PVT. LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00012/AM19/	RLA File :03/95/040/00810/AM18/	Lic.No/Date:0310818490 15.01.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 07.11.2019 has furnished its reply. Deferred for comments of TE.			

95	**Case No.:165/10/82-ALC4/2018**	Party Name:AURORE LIFE SCIENCES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00452/AM19/	RLA File :09/24/040/00438/AM18/	Lic.No/Date:0910065915 20.01.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: **(i) Percentage of yield on molar basis for each step.**			

96	**Case No.:187/10/82-ALC4/2018**	Party Name:NISARG BIOSCIENCES PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00474/AM19/	RLA File :09/24/040/00497/AM18/	Lic.No/Date:0910065945 31.01.2018	Defer Date:
	Decision: The Committee considered the case as per online agenda in the presence of technical experts and it was noted that the firm still has not furnished the following information asked for by NC-3 in its Meeting No. **8/82-ALC4/2019 dated 20.09.2019**, followed by Reminder on **31.10.2019**: **(i) Exact chemical name of the export product.** In view of above, the Committee decided to issue **<u>Final Reminder</u>** to firm to furnish its reply, failing which the case will be rejected.			

97	**Case No.:132/10/82-ALC4/2018**	Party Name:AURORE LIFE SCIENCES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00419/AM19/	RLA File :09/24/040/00516/AM18/	Lic.No/Date:0910065954 01.02.2018	Defer Date:
	Decision: Deferred for comments of TE.			

98	**Case No.:131/10/82-ALC4/2018**	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00418/AM19/	RLA File :09/24/040/00561/AM18/	Lic.No/Date:0910065961 02.02.2018	Defer Date:
	Decision: Deferred for comments of TE.			

99	**Case No.:135/10/82-ALC4/2018**	Party Name:NISARG BIOSCIENCES PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00422/AM19/	RLA File :09/24/040/00498/AM18/	Lic.No/Date:0910065963 02.02.2018	Defer Date:
	Decision: The Committee considered the case as per online agenda in the presence of technical experts and it was noted that the firm still has not furnished the following information asked for by NC-3 in its Meeting No. **8/82-ALC4/2019 dated 20.09.2019**, followed by Reminder on **31.10.2019**: **(ii) Percentage yield on molar basis at every stage.** **(iii) Exact chemical name of the export product.** In view of above, the Committee decided to issue **<u>Final Reminder</u>** to firm to furnish its reply, failing which the case will be rejected.			

100	**Case No.:140/10/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00427/AM19/	RLA File :09/24/040/00527/AM18/	Lic.No/Date:0910065968 06.02.2018	Defer Date:
	Decision: Deferred for comments of TE.			

101	**Case No.:142/4/82-ALC4/2018**	Party Name:HERBOCHEM INDUSTRIES	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00142/AM19/	RLA File :06/24/040/00047/AM18/	Lic.No/Date: 0610038810 07.02.2018	Defer Date:
	Decision: The Committee considered the case as per online agenda in the presence of technical experts and it was noted that the firm still has not furnished the following information asked for by NC-3 in its Meeting No. **9/82-ALC4/2019 dated 18.10.2019**, followed by Reminder on **09.12.2019**: **(i) Production-Consumption data of each export product individually duly certified by Quality Control Incharge.** **(ii) Commercial sale value of by products.** In view of above, the Committee decided to issue **<u>Final Reminder</u>** to firm to furnish its reply, failing which the case will be rejected.			

102	**Case No.:166/10/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00453/AM19/	RLA File :09/24/040/00528/AM18/	Lic.No/Date:0910065973 07.02.2018	Defer Date:
	Decision: Deferred for comments of TE.			

103	**Case No.:819/15/82-ALC4/2018**	Party Name:DHANUKA LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02276/AM19/	RLA File :05/23/040/00440/AM18/	Lic.No/Date:0510405609 09.02.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

104	**Case No.:1009/15/82-ALC4/2018**	Party Name:TADIMETY AROMATICS PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02466/AM19/	RLA File :07/24/040/00305/AM18/	Lic.No/Date:0710112820 13.02.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 16.11.2019 has furnished its reply. Deferred for comments of TE.			

105	**Case No.:82/10/82-ALC4/2018**	Party Name:FRESENIUS KABI INDIA PRIVATE LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00369/AM19/	RLA File :03/94/040/00911/AM18/	Lic.No/Date:0310819230 19.02.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 14.10.2019 has furnished its reply to the query raised during PH on 20.09.2019.			

106	**Case No.:93/10/82-ALC4/2018**	Party Name:YASHO INDUSTRIES PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00380/AM19/	RLA File :03/95/040/01007/AM18/	Lic.No/Date:0310819263 20.02.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its letter dated 24.10.2019 has furnished its reply. Deferred for comments of TE.			

107	**Case No.:47/13/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01025/AM19/	RLA File :09/24/040/00587/AM18/	Lic.No/Date:0910066003 20.02.2018	Defer Date:
	Decision: Deferred for comments of TE.			

108	**Case No.:186/13/82-ALC4/2018**	Party Name:SONGWON SPECIALTY CHEMICALS INDIA PVT. LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01164/AM19/	RLA File :34/24/040/00341/AM18/	Lic.No/Date:3410043908 22.02.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 01.11.2019. Deferred for comments of TE.			

109	**Case No.:286/4/82-ALC4/2018**	Party Name:SURVIVAL TECHNOLOGIES PVT.LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00286/AM19/	RLA File :03/95/040/00993/AM18/	Lic.No/Date:0310819412 26.02.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 20.06.2019. Deferred for comments of TE.			

110	**Case No.:125/13/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01103/AM19/	RLA File :09/24/040/00611/AM18/	Lic.No/Date:0910066054 12.03.2018	Defer Date:
	Decision: Deferred for comments of TE.			

111

Case No.:18/15/82-ALC4/2018	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/01475/AM19/	RLA File :09/24/040/00635/AM18/	Lic.No/Date:0910066053 12.03.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
CEFALEXIN MONOHYDRATE	1 kg	1	7-Amino Des-Acetoxy Cephalosporanic Acid (7-ADCA)	0.655 kg
		2	Methylene Chloride (MDC)	0.232 kg
		3	Acetone	0.348 kg
		4	Activated Carbon (Carbon Enoanticromos)	0.019 kg
		5	Immobilized Acylase Enzyme (Xinase) - for Cephalexin	0.0065 kg
		6	Isopropyl Alcohol (IPA)	0.046 kg
		7	D(-) Alpha Phenyl Glycine Base	0.529 kg
		8	Toluene	0.346 kg
		9	Methanol (Methyl Alcohol)	0.832 kg

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

112	**Case No.:358/15/82-ALC4/2018**	Party Name:BIOLOGICAL E LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01815/AM19/	RLA File :09/24/040/00600/AM18/	Lic.No/Date:0910066050 12.03.2018	

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 11/82-ALC4/2019 , dated 03.01.2020, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty. [Allowed for the export product of 20 million doses / vials (each vial contains 0.5 ml)]
ADSORBED TETANUS BP/TETANUS TOXOID VACCINE ADSORBED 0.5ML (SINGLE DOSE)	2000000 vials	1	L-CYSTINE	9.38 kg
		2	THIOMERSAL	1.05 kg
		3	N Z CASE TT (CASEIN PEPTONE PLUS)	69.4 kg
		4	L-TYROSINE	1.87 kg
		5	ALUMINIUM CHLORIDE 6 HYDRATE EXTRA	84.00 kg
		6	SILICON EMULSION	8.60 kg
		7	TRISODIUM ORTHO PHOSPHATE	131.25 kg
		8	GLASS VIALS	21000000 Number
		9	RUBBER STOPPERS	21000000 Number
		10	ALUMINIUM CAPS/SEALS	21000000 Number
		11	SHIPPING INDICATORS (Q TAG2 PLUS/VAX ALERTS/TEMPERATURE MONITORING DEVICES/DATA LOGGERS)	10000 Number
		12	V V M LABELS (HEATMARKER VACCINE VIAL MONITOR LABELS)	20200000 Number
		13	FILTERS & FILTER AIDS	1000 Number

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

113	**Case No.:359/15/82-ALC4/2018**	Party Name:BIOLOGICAL E LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01816/AM19/	RLA File :09/24/040/00586/AM18/	Lic.No/Date:0910066051 12.03.2018	

Decision: The Committee considered the case as per agenda in the presence of Technical Experts and in the light of earlier decision taken by NC in its Meeting No. 11/82-ALC4/2019 , dated 03.01.2020, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP Vol. I as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty. [Allowed for the export product of 30 million doses / vials (each vial contains 0.5 ml)]
ADSORBED TETANUS BP/TETANUS TOXOID VACCINE ADSORBED 0.5ML (SINGLE DOSE)	3000000 vials	1	L-CYSTINE	14.07 kg
		2	THIOMERSAL	1.575 kg
		3	N Z CASE TT (CASEIN PEPTONE PLUS)	104.1 kg
		4	L-TYROSINE	2.805 kg
		5	ALUMINIUM CHLORIDE 6 HYDRATE EXTRA	126.0 kg
		6	SILICON EMULSION	12.9 kg
		7	TRISODIUM ORTHO PHOSPHATE	196.875 kg
		8	GLASS VIALS	31500000 Number
		9	RUBBER STOPPERS	31500000 Number
		10	ALUMINIUM CAPS/SEALS	31500000 Number
		11	SHIPPING INDICATORS (Q TAG2 PLUS/VAX ALERTS/TEMPERATURE MONITORING DEVICES/DATA LOGGERS)	15000 Number
		12	V V M LABELS (HEATMARKER VACCINE VIAL MONITOR LABELS)	30300000 Number
		13	FILTERS & FILTER AIDS	1500 Number

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

114	**Case No.:33/13/82-ALC4/2018**	Party Name:VISWAAT CHEMICALS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01011/AM19/	RLA File :03/95/040/01027/AM18/	Lic.No/Date:0310819857 16.03.2018	Defer Date:
	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 following information asked for by NC-3 in its Meeting No. **9/82-ALC4/2019 dated 18.10.2019**, followed by reminder on **09.12.2019**: **(i) Indigenous input and their quantity.** In view of above, the Committee decided to issue **Final Reminder** to firm giving 15 days time to furnish its reply, failing which the case will be rejected.			

115	**Case No.:127/13/82-ALC4/2018**	Party Name:SPANSULES FORMULATIONS	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01105/AM19/	RLA File :09/24/040/00619/AM18/	Lic.No/Date:0910066066 20.03.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 03.09.2019 has furnished its reply. Deferred for comments of TE.			

116	**Case No.:258/12/82-ALC4/2018**	Party Name:SYNTHO CHIRALS PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00885/AM19/	RLA File :09/24/040/00669/AM18/	Lic.No/Date:0910066087 26.03.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: **(i) Exact use and function of the import item – KRED RVT-901 in the manufacturing process.** **(ii) Catalogue of import item – KRED RVT-901 and** **(iii) Duly certified Production Consumption data for the relevant period.**			

117	**Case No.:126/13/82-ALC4/2018**	Party Name:OPTRIX LABORATORIES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01104/AM19/	RLA File :09/24/040/00639/AM18/	Lic.No/Date:0910066086 26.03.2018	Defer Date:
	Decision: Deferred for comments of TE.			

118	**Case No.:67/15/82-ALC4/2018**	Party Name:BIOLOGICAL E LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Withdrawn**
	HQ File :01/82/050/01524/AM19/	RLA File :09/24/040/00637/AM18/	Lic.No/Date:0910066088 26.03.2018	

Decision: The Committee considered the case as per agenda in the presence of technical experts and it was observed that the norms for the subject Advance Authorization have already been ratified by NC-3 in its Meeting No. **11/82-ALC4/2019 dated 03.01.2020**.

In view of above, the Committee decided to **withdraw** the case.

119	**Case No.:320/10/82-ALC4/2018**	Party Name:HETERO LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00607/AM19/	RLA File :09/24/040/00666/AM18/	Lic.No/Date:0910066105 28.03.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Abacavir Sulfate	1 kg	1	Vincelactam	2.50 kg
		2	Di.tert.butyl dicarbonate	5.00 kg
		3	Dimethyl Formamide	7.00 kg
		4	Sodium Borohydride	0.946 kg
		5	N-(2-Amino-4,6-dichloro pyrimidin-5-yl) formamide	1.042 kg
		6	Triethyl orthoformate	1.50 kg
		7	Tetrahydrofuran	4.15 kg
		8	Cyclopropylamine	0.19 kg
		9	Glutaric Acid	1.00 kg

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

120	**Case No.:5/10/82-ALC4/2018**	Party Name:DCM SHRIRAM INDUSTRIES LTD,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00292/AM19/	RLA File :05/23/040/00515/AM18/	Lic.No/Date:0510406067 09.04.2018	Defer Date:

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 following information asked for by NC-3 in its Meeting No. 8/82-ALC4/2019 dated 20.09.2019, followed by reminder on 31.10.2019:

(i) Complete 4E with all technical details chemistry, molecular weight, stoichiometric reaction and % of yield on molar basis at every stage.

In view of above, the Committee decided to issue **Final Reminder** to firm giving 15 days time to furnish its reply, failing which the case will be rejected.

121	**Case No.:1014/15/82-ALC4/2018**	Party Name:TADIMETY AROMATICS PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/02471/AM19/	RLA File :07/24/040/00361/AM18/	Lic.No/Date:0710113089 10.04.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 16.11.2019 has furnished its reply. Deferred for comments of TE.			

122	**Case No.:261/12/82-ALC4/2018**	Party Name:AKTINOS HEALTHCARE PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00888/AM19/	RLA File :09/24/040/00668/AM18/	Lic.No/Date:0910066131 11.04.2018	Defer Date:
	Decision: Deferred for comments of TE.			

123	**Case No.:232/10/82-ALC4/2018**	Party Name:DEEPAK NOVOCHEM TECHNOLOGIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00519/AM19/	RLA File :31/83/040/00171/AM18/	Lic.No/Date:3110067030 12.04.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was recalled that the firm was asked to furnish following information / documents: **(i) Percentage yield on molar basis at every stage.** **(ii) Exact chemical name of the export product** The reply furnished by the firm in respect of similar case was examined by the Committee and it was observed that the firm still has not mentioned the exact chemical name of the export product - DNOVO BP818. In view of above, the Committee decided to **reject** the case. RA concerned may take further necessary action as per above decision of NC.			

124	**Case No.:156/13/82-ALC4/2018**	Party Name:SMS LIFESCIENCES INDIA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01134/AM19/	RLA File :09/24/040/00654/AM18/	Lic.No/Date:0910066137 12.04.2018	Defer Date:
	Decision: Deferred for comments of TE.			

125	**Case No.:26/15/82-ALC4/2018**	Party Name:GLAND CHEMICALS PVT LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01483/AM19/	RLA File :09/24/040/00008/AM19/	Lic.No/Date:0910066148 17.04.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

126	**Case No.:122/13/82-ALC4/2018**	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01100/AM19/	RLA File :09/24/040/00024/AM19/	Lic.No/Date:0910066156 18.04.2018	Defer Date:
	Decision: Deferred for comments of TE.			

127	**Case No.:6/15/82-ALC4/2018**	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01463/AM19/	RLA File :09/24/040/00015/AM19/	Lic.No/Date:0910066157 18.04.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

128	**Case No.:153/12/82-ALC4/2018**	Party Name:ETERNIS FINE CHEMICALS LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00780/AM19/	RLA File :03/94/040/00055/AM19/	Lic.No/Date:0310820647 25.04.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 17.06.2019 has furnished its reply. Deferred for comments of TE.			

129	**Case No.:81/15/82-ALC4/2018**	Party Name:YASH RASAYAN & CHEMICALS	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/01538/AM19/	RLA File :34/24/040/00401/AM18/	Lic.No/Date:3410044109 27.04.2018	
	Decision: The Committee considered the case as per Agenda and it was noted that the firm still has not furnished the information on following deficiencies raised by NC-3 in its Meeting No. 7/**82-ALC4/2019 dated 06.09.2019**, followed by Reminder on **01.07.2019** and Final Reminder on **01.08.2019**: **(i) Complete technical details as per Appendix 4 E alongwith Molecular Weight, percentage of yield and stoichiometric chemical reaction.** Hence, the Committee decided to **reject** the case. RA concerned may take further necessary action as per above decision of NC.			

130	**Case No.:121/13/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01099/AM19/	RLA File :09/24/040/00044/AM19/	Lic.No/Date:0910066198 04.05.2018	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

131	**Case No.:225/10/82-ALC4/2018**	Party Name:DR J PHARMACHEM PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00512/AM19/	RLA File :31/83/040/00014/AM19/	Lic.No/Date:3110067038 07.05.2018	Defer Date:
	Decision: Deferred for comments of TE.			

132	**Case No.:107/13/82-ALC4/2018**	Party Name:OPTRIX LABORATORIES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01085/AM19/	RLA File :09/24/040/00006/AM19/	Lic.No/Date:0910066210 09.05.2018	Defer Date:
	Decision: Deferred for comments of TE.			

133	**Case No.:250/10/82-ALC4/2018**	Party Name:AETHER INDUSTRIES LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00537/AM19/	RLA File :52/24/040/00016/AM19/	Lic.No/Date:5210042638 10.05.2018	Defer Date:
	Decision: Deferred for comments of TE.			

134	**Case No.:196/12/82-ALC4/2018**	Party Name:SHREE BANKEY BEHARI LAL FLAVORS	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00823/AM19/	RLA File :05/24/040/00067/AM19/	Lic.No/Date:0510406412 10.05.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 01.11.2019 has furnished its reply. Deferred for comments of TE.			

135	**Case No.:366/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01823/AM19/	RLA File :07/24/040/00008/AM19/	Lic.No/Date:0710113260 10.05.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

136	**Case No.:93/12/82-ALC4/2018**	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00720/AM19/	RLA File :03/94/040/00104/AM19/	Lic.No/Date:0310820963 14.05.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
FLUCORT N SKIN CREAM (Pack Size 15 gms) (Net Wt.of NEOMYCIN SULPHATE BP is 105.580 Kgs.)	1407736.000 Packs	1	NEOMYCIN SULPHATE BP	301.62 kg
SUPRICORT N CREAM (Pack Size 5 gms) (Net Wt.of NEOMYCIN SULPHATE BP is 120.000 Kgs.)	4800000.000 Packs			
SUPRICORT N CREAM (Pack Size 15 gms) (Net Wt.of NEOMYCIN SULPHATE BP is 70.125 Kgs.)	935000.000 Packs			

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

137	**Case No.:120/13/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01098/AM19/	RLA File :09/24/040/00614/AM18/	Lic.No/Date:0910066236 15.05.2018	Defer Date:

Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.

138	**Case No.:18/13/82-ALC4/2018**	Party Name:SMS LIFESCIENCES INDIA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00996/AM19/	RLA File :09/24/040/00067/AM19/	Lic.No/Date:0910066242 18.05.2018	Defer Date:

Decision: Deferred for comments of TE.

139	**Case No.:168/12/82-ALC4/2018**	Party Name:MANGALAM ORGANICS LIMITED FORMERLY DUJODWALA PRODU	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00795/AM19/	RLA File :03/95/040/01140/AM18/	Lic.No/Date:0310821107 21.05.2018	Defer Date:
	Decision: The Committee considered the case as per online agenda in the presence of technical experts and it was noted that the firm still has not furnished the following information asked for by NC-3 in its Meeting No. 8/**82-ALC4/2019 dated20.09.2019**, followed by Reminder on **31.10.2019**: **(i) Complete 4E with all technical details chemistry, molecular weight, stoichiometric reaction and % of yield at every stage.** In view of above, the Committee decided to issue **Final Reminder** to firm to furnish its reply, failing which the case will be rejected.			

140	**Case No.:216/10/82-ALC4/2018**	Party Name:DEEPAK NOVOCHEM TECHNOLOGIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Rejected**
	HQ File :01/82/050/00503/AM19/	RLA File :31/83/040/00005/AM19/	Lic.No/Date:3110067060 23.05.2018	
	Decision: The Committee considered the case as per agenda and it was recalled that the firm was asked to furnish following information / documents: **(i) Percentage yield on molar basis at every stage.** **(ii) Exact chemical name of the export product.** The reply furnished by the firm was examined by the Committee and it was observed that the firm still has not mentioned the exact chemical name of the export product - DNOVO BP818. In view of above, the Committee decided to **reject** the case. RA concerned may take further necessary action as per above decision of NC.			

141	**Case No.:190/12/82-ALC4/2018**	Party Name:SUN PHARMACEUTICAL INDUSTRIES LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00817/AM19/	RLA File :05/24/040/00098/AM19/	Lic.No/Date:0510406572 23.05.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Azelastine Hydrochloride Nasal Solution (Nasal Spray) 0.1% (137 mcg per spray) 30ML (Each spray contains Azelastine Hydrochloride equivalent to 28.770mg) (Equivalent to 8055.600Grams of bulk drug)	280000.000 Number	1	Azelastine Hydrochloride	7825.44 gram
Azelastine Hydrochloride Ophthalmic Solution 0.05% W/V 6ML) (Each solution contains Azelastine Hydrochloride equivalent to 3.150 mg) (Equivalent to 2000.001 Grams of bulk drug) (Equivalent to total 10055.601Grams of bulk drug)	634921.000 Number	1	Azelastine Hydrochloride	1942.86 gram

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

142	**Case No.:105/13/82-ALC4/2018**	Party Name:NAGARJUNA AGRICHEM LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01083/AM19/	RLA File :09/24/040/00085/AM19/	Lic.No/Date:0910066269 24.05.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
BROMOKETAL LIQUID	1 kg	1	2,4 DICHLORO ACETOPHENONE LIQUID	0.546 kg
		2	n-BUTYLRALDEHYDE LIQUID	0.453 kg
		3	DIMETHYL SULFIDE LIQUID	0.179 kg
		4	95% POTASSIUM HYDROXIDE SOLID	0.415 kg
		5	BROMINE LIQUID	0.475 kg

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

143	**Case No.:373/15/82-ALC4/2018**	Party Name:TADIMETY AROMATICS PVT. LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01830/AM19/	RLA File :07/24/040/00046/AM19/	Lic.No/Date:0710113330 25.05.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 16.11.2019 has furnished its reply. Deferred for comments of TE.			

144	**Case No.:39/13/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01017/AM19/	RLA File :09/24/040/00082/AM19/	Lic.No/Date:0910066291 01.06.2018	Defer Date:
	Decision: Deferred for comments of TE.			

145	**Case No.:376/15/82-ALC4/2018**	Party Name:GRANULES INDIA LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01833/AM19/	RLA File :09/24/040/00099/AM19/	Lic.No/Date:0910066295 04.06.2018	Defer Date:06.09.2019
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

146	**Case No.:378/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01835/AM19/	RLA File :05/23/040/00080/AM19/	Lic.No/Date:0510406733 05.06.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

147	**Case No.:379/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01836/AM19/	RLA File :05/23/040/00070/AM19/	Lic.No/Date:0510406734 05.06.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was observed that the firm was issued Show Cause Notice vide letter dated 10.10.2019.			

148	**Case No.:380/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01837/AM19/	RLA File :05/23/040/00022/AM19/	Lic.No/Date:0510406736 05.06.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

149

Case No.:277/10/82-ALC4/2018	Party Name:CIPLA LIMITED.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
HQ File :01/82/050/00564/AM19/	RLA File :03/94/040/00208/AM19/	Lic.No/Date:0310821558 08.06.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Testosterone Topical Solution Pack Size 110ml, 63 MTD Each Actuation delivers : Testosterone USP -- 30mg Also contains Alcohol USP Approx. 49.55% w/v (QS to 100% w/v)	77200.000 Number	1	Testosterone USP	148.83 kg
		2	Alcohol (Ethanol 95% v/v)	4207.80 kg

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

150	**Case No.:279/10/82-ALC4/2018**	Party Name:J.B. CHEMICALS & PHARMACEUTICALS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00566/AM19/	RLA File :03/94/040/00207/AM19/	Lic.No/Date:0310821556 08.06.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was decided to call for following information from the firm: **(i) DML for each export product showing approved composition.**			

151	**Case No.:81/12/82-ALC4/2018**	Party Name:KOPRAN RESEARCH LABORATORIES LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00708/AM19/	RLA File :03/94/040/00194/AM19/	Lic.No/Date:0310821554 08.06.2018	Defer Date:
	Decision: Deferred for comments of TE.			

152	**Case No.:60/15/82-ALC4/2018**	Party Name:ALPHAMED FORMULATIONS P LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01517/AM19/	RLA File :09/24/040/00075/AM19/	Lic.No/Date:0910066310 08.06.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

153	**Case No.:383/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01840/AM19/	RLA File :05/23/040/00121/AM19/	Lic.No/Date:0510406800 08.06.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was observed that the firm was issued Show Cause Notice vide letter dated 10.10.2019.			

154	**Case No.:385/15/82-ALC4/2018**	Party Name:JODAS EXPOIM PVT.LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01842/AM19/	RLA File :05/23/040/00501/AM18/	Lic.No/Date:0510406802 08.06.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was observed that the firm was issued Show Cause Notice vide letter dated 10.10.2019.			

155	**Case No.:59/13/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01037/AM19/	RLA File :09/24/040/00106/AM19/	Lic.No/Date:0910066318 11.06.2018	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

156	**Case No.:56/12/82-ALC4/2018**	Party Name:SANJIVANI PARANTERAL LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/00683/AM19/	RLA File :03/95/040/00227/AM19/	Lic.No/Date:0310821651 13.06.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
NETLISAN INJECTION 100MG / ml each ML content 100MG, 3 ml per ampoule	66667.000 Number	1	NETILMICIN SULPHATE USP	28.80 kg

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

157	**Case No.:386/15/82-ALC4/2018**	Party Name:VIVIMED LIFE SCIENCES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01843/AM19/	RLA File :09/24/040/00107/AM19/	Lic.No/Date:0910066339 14.06.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Ranitidine Tablets USP 75 Mg (10800000 Numbers)	1 Number Tablet	1	Ranitidine Hydrochloride USP (COMPACTED)	83.707 mg
		2	Microcrystalline Cellulose NF (Avicel PH 112)	62.293 mg
		3	Magnesium stearate (LIGAMED MF-2-V) NF	2.00 mg
		4	Opadry 200 Optimized Performance Coating 203A540005 PINK	5.00 mg
Ranitidine Tablets USP 150 Mg (31200000 Numbers)	1 Number Tablet	1	Ranitidine Hydrochloride USP (COMPACTED)	167.414 mg
		2	Microcrystalline Cellulose NF (Avicel PH 112)	124.586 mg
		3	Magnesium stearate (LIGAMED MF-2-V) NF	4.00 mg
		4	Opadry 200 Optimized Performance Coating 203A540005 PINK	10.00 mg

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

158	**Case No.:35/13/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01013/AM19/	RLA File :09/24/040/00136/AM19/	Lic.No/Date:0910066375 22.06.2018	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

159	**Case No.:71/13/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01049/AM19/	RLA File :09/24/040/00134/AM19/	Lic.No/Date:0910066374 22.06.2018	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

160	**Case No.:76/13/82-ALC4/2018**	Party Name:VIVIMED LABS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01054/AM19/	RLA File :09/24/040/00135/AM19/	Lic.No/Date:0910066376 22.06.2018	Defer Date:
	Decision: The Committee considered the request of firm and it was decided to call for following information from the firm: **(i) Justification for low yield in the process alongwith documentary evidence.** **(ii) Complete set of 4.07 application.**			

161	**Case No.:388/15/82-ALC4/2018**	Party Name:WINTAC LIMITED,	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Approved**
	HQ File :01/82/050/01845/AM19/	RLA File :07/24/040/00063/AM19/	Lic.No/Date:0710113471 22.06.2018	

Decision: The Committee considered case as per agenda in the presence of the technical experts and it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
Tobramycin Ophthalmic Solution USP 0.3% 5mL 450000 vials	450000 vials	1	Tobramycin Ophthalmic USP	6885.00 Gram

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

162	**Case No.:274/10/82-ALC4/2018**	Party Name:MELOG SPECIALITY CHEMICALS PVT. LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00561/AM19/	RLA File :03/95/040/00235/AM19/	Lic.No/Date:0310821895 25.06.2018	Defer Date:
	Decision: The Committee considered the case as per agenda and it was noted that the firm vide its e-mail dated 07.11.2019 has furnished its reply. Deferred for comments of TE.			

163	**Case No.:185/13/82-ALC4/2018**	Party Name:SPC LIFE SCIENCES PVT. LTD.	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01163/AM19/	RLA File :34/24/040/00109/AM19/	Lic.No/Date:3410044282 26.06.2018	Defer Date:
	Decision: Deferred for comments of TE.			

164	**Case No.:117/13/82-ALC4/2018**	Party Name:ORTIN LABORATORIES LTD	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01095/AM19/	RLA File :09/24/040/00150/AM19/	Lic.No/Date:0910066395 27.06.2018	Defer Date:
	Decision: Deferred for comments of TE.			

165	**Case No.:12/15/82-ALC4/2018**	Party Name:AURORE LIFE SCIENCES PRIVATE LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/01469/AM19/	RLA File :09/24/040/00113/AM19/	Lic.No/Date:0910066403 28.06.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

166	**Case No.:221/12/82-ALC4/2018**	Party Name:IOL CHEMICALS AND PHARMACEUTICALS LIMITED	Meet No/Date:12/82-ALC4/2019 17.01.2020	**Status: Deferred**
	HQ File :01/82/050/00848/AM19/	RLA File :30/24/040/00017/AM19/	Lic.No/Date:3010104375 29.06.2018	Defer Date:
	Decision: The Committee noted that the 4.07 application of subject Advance Authorization is not available. Hence, it was decided to call for a copy of 4.07 application of the subject advance authorization directly from the firm as per Policy Circular No. 23/2015-20, dated 15.05.2019.			

MANUAL CASES

Case No.	**B- 01**
Meeting No.	**12/AM20**
Date	**21.01.2020**
Firm's Name	**M/s Almelo Priavate Limited, Hyderabad**
HQ F. No.	01/82/050/00620/AM17/DES-III
RLA F. No.	09/24/040/00056/AM17
Advance Authorization No. and Date	0910063626 dated 17.05.2016
Subject	**Request of M/s ALMELO Pvt. Limited, Hyderabad for fixation of adhoc norms against Advance Authorization No. 0910063626 dated 17.05.2016.**

Decision: The Committee considered the request of firm in the presence of technical experts and it was observed that the export product is an intermediate for a new Drug Discovery molecule – Solithromycin, which is under clinical trial and no comparative data is available at this stage.

2. As per the details given by the firm, it was noticed that the firm has imported only two inputs and rest of the items appear to be procured indigenously. As per the data showing actual import, the Committee decided to fix following adhoc norms:

Export Product	Qty.	Sl. No.	Import items	Qty.
Oxo - Erythronolide A-11,12-Carbamate	1 kg	1.	Erythromycin Thiocyanate	5.00 kg Activity
		2.	1,1-Carbonyldiimidazole	2.052 kg
Note: The above norms are only for regularization and closure purpose. No repeat licence will be issued based on above.				

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

Case No.	**B- 02**
Meeting No.	**12/AM20**
Date	**21.01.2020**
Firm's Name	**M/s Almelo Priavate Limited, Hyderabad**
HQ F. No.	01/82/050/00358/AM15/DES-III 01/82/050/00679/AM15/DES-III
RLA F. No.	09/24/040/00096/AM15 09/24/040/00119/AM15
Advance Authorization No. and Date	0910060207 dated 23.05.2014 0910060403 dated 09.06.2014
Subject	**Request of M/s Almelo Pvt. Ltd., Hyderabad for revision / correction of norms in respect of adhoc norms fixed against Advance Authorization No. 0910060207 dated 23.05.2014 and 0910060403 dated 09.06.2014**

Decision: The Committee considered the request of firm in the presence of technical experts and it was observed that in the past norms were fixed for some other export product. Firm has already completed export and import and now EODC is pending. Firm has given Central Excise Certificate showing export and corresponding consumption of both imported and indigenous items for 166.5 kg export in 2014.

It was also observed that Export product is an intermediate for a new Drug Discovery intermediate for new API – SOLITHROMYCIN under third stage of clinical trial. They exported this item to M/s CEMPRA, USA, who is developing the API – Solithroycin.

2. As per the details given by the firm like chemistry, actual exports and imports made, Central Excise Certificate, the Committee decided to fix following adhoc norms:

For Advance Authorization No. 0910060207 dated 23.05.2014

Export Product	Qty.	Sl. No.	Import items	Qty.
Fluoro Erythronolide A-11,12-Carbamate	1 kg	1.	Clarithromycin	3.835 kg
		2.	1,1-Carbonyldiimidazole	3.322 kg
		3	1,8-Diazabicyclo[5.4.0] undec-7-ene	2.618 kg
		4	Tri Phenyl Phosphine	2.00 kg
		5	4-Dimethyl Amino Pyridine	1.359 kg
Note: The above norms are only for regularization and closure purpose. No repeat licence will be issued based on above.				

3. As the firm has shown only one import item and all other items are procured indigenously. Accordingly, the Committee decided to fix following adhoc norms:

For Advance Authorization No. 0910060403 dated 09.06.2014

Export Product	Qty.	Sl. No.	Import items	Qty.
Fluoro Erythronolide A-11,12-Carbamate (Fluoro Carbamate stage VI, API component	1 kg	1.	Clarithromycin	3.835 kg
Note: The above norms are only for regularization and closure purpose. No repeat licence will be issued based on above.				

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

Case No.	**B- 03**
Meeting No.	**12/AM20**
Date	**21.01.2020**
Firm's Name	**M/s Almelo Priavate Limited, Hyderabad**
HQ F. No.	01/82/050/00063/AM17/DES-III
RLA F. No.	09/24/040/00739/AM16
Advance Authorization No. and Date	0910063533 dated 21.04.2016
Subject	**Request of M/s Almelo Pvt. Ltd., Hyderabad for revision / correction of norms in respect of adhoc norms fixed against Advance Authorization No. 0910063533 dated 21.04.2016**

Decision: The Committee considered the request of firm in the presence of technical experts and it was observed that the export product is a new drug discovery intermediate and hence no comparative data is available at this stage as the API is still in the clinical trial stage and no commercial production has staged so far.

2. RA, Hyderabad in its letter dated 18.11.2019 has also clarified that the export is basically involved in drug development and Research work and have supplied Oxo-Erythronolide A-11, 12 – Carbamate, which is used in the manufacturing of a new drug molecule – Solithromycin, which has not yet been approved for therapeutic use and still at research stage only.

3. As per the details given by the firm, it was noticed that the firm has imported only two inputs and rest of the items appear to be procured indigenously. As per the data showing actual import, the Committee decided to revise the norms as under:

Export Product	Qty.	Sl. No.	Import items	Qty.
Oxo- Erythronolide A-11,12-Carbamate	1 kg	1.	Clarithromycin	3.31 kg
		2.	1,1-Carbonyldiimidazole	2.73 kg
Note: The above norms are only for regularization and closure purpose. No repeat licence will be issued based on above.				

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

Meeting ended with thanks to Chair.

*****