

**Directorate General of Foreign Trade
Ministry of Commerce & Industry, Maulana Azad Road, Udyog
Bhawan New Delhi -110011**

Para 4.7 Decision

MEETING NUMBER : 25/82-ALC4/2007 MEETING DATE : 23.10.2007

	Case No.:31/30/87-ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00870/AM06/	RLA File : 02/24/040/00154/AM06/	Lic.No/Date:02100827 77 17.10.2005	Defer Date: 20.11.2007
1	Decision :Committee considered case as per agenda for ratification of norms for export product Cascara Dry Extract under para 4.7 of HBP. Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms. Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.			
2	Case No.:1/10/83-ALC1/2006	Party Name:SPC LIFE SCIENCES PVT. LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Transferred
	HQ File : 01/83/050/00091/AM07/	RLA File : 34/24/040/00020/AM07/	Lic.No/Date:34100159 35 25.04.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-N-Butyk Bebzifyrab Clear Liquid under para 4.7			

of HBP.

Committee decided to transfer case to DES-IV as export product pertains to Chemical Sector.

3	Case No.:39/9/82-ALC1/2006	Party Name:KDL BIOTECH LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00209/AM07/	RLA File : 03/94/040/00021/AM07/	Lic.No/Date:03103798 82 10.05.2006	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Flu-Cloxacillin Sodium BP/USP/EP under para 4.7 of HBP. Committee observed that SION for export product had been deleted and firm as well as Pharmexcil have been requested to furnish Data for export product, but same has not been received. Committee, therefore, decided to remind firm/Pharmexcil to furnish data. Accordingly, case was deferred for four weeks.			

4	Case No.:9/49/82-ALC1/2006	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Transferred
	HQ File : 01/82/050/01311/AM07/	RLA File : 05/24/040/00690/AM07/	Lic.No/Date:05101947 16 20.11.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 7-Methoxy Tryptamine under para 4.7 of HBP. Committee observed that export product falls under Chapter 28 of ITC(HS). It was, therefore, decided to transfer case to DES-IV.			

5	Case No.:685/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
	HQ File : 01/82/050/01326/AM07/	RLA File : 03/94/040/00931/AM07/	Lic.No/Date:03104090 06 21.11.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide			

their U.O. No.35011/83/2007-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Carvedilol-----1kg.

Import item:

Guaiacol-----0.96kg/kg

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

Case No.:707/21/82-ALC4/2007	Party Name:LUPIN LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
HQ File : 01/82/050/01379/AM07/	RLA File : 03/95/040/01077/AM07/	Lic.No/Date:0310410456 01.12.2006	

Decision : Committee considered case as per agenda for ratification of norms for export product Ethambutol Hcl under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/107/2006-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Ethambutol Hcl-----1kg.

Import item:

1. DL-2 Aminobutanol-----1.6014kg/kg
2. Tartaric Acid-----0.1977kg/kg
3. Methanol-----0.5620kg/kg
4. Iso Propyl Alcohol-----0.3436kg/kg
5. Ethylene dichloride-----0.490kg/kg
6. Caustic Soda Flakes-----0.4264kg/kg
7. Cyclohexane-----0.0056kg/kg
8. Calcium Hydroxide-----2.4525kg/kg

Committee also decided to call for All Industry Data from Pharmexcil for revision of norms for above export product.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

7	Case No.:1/48/83-ALC1/2006	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01068/AM07/	RLA File : 09/24/040/00376/AM07/	Lic.No/Date:0910028791 28.12.2006	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 5-O Trityl-2,3 Anhydro Thymidine under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

8	Case No.:2/50/83-ALC1/2006	Party Name:SODIUM METAL (P) LTD	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
	HQ File : 01/83/050/01086/AM07/	RLA File : 34/24/040/00209/AM07/	Lic.No/Date:3410017775 03.01.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 1,1Cyclohexane Diacetic Acid Monoamide under para 4.7 of HBP. Committee observed that application has been transferred from DES-IV Section only on 12.10.07 and in light of its earlier decision taken in its meeting held on 20.08.2006 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: 1,1Cyclohexane Diacetic Acid Monoamide-----1kg. Import item: 1,1Cyclohexane Diacetic Acid-----1.12kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

9	Case No.:16/49/82-ALC1/2006	Party Name:LUPIN LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01721/AM07/	RLA File : 03/95/040/01297/AM07/	Lic.No/Date:0310416716 22.01.2007	Defer Date: 20.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium-Non Infringing under para 4.7 of HBP.

Committee decided to remind firm to furnish production and consumption data duly certified by Central Excise Authority. After receipt of data, case may be examined on file. Accordingly, case was deferred for four weeks.

10	Case No.:5/9/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01646/AM07/	RLA File : 05/24/040/00937/AM07/	Lic.No/Date:05101992 68 09.02.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 3,4 Dihydroxy-4-Oxo-6Acetoxy-7Methoxyquinazole under para 4.7 of HBP. Committee decided to call for technical details as per Appendix 33 from firm. Accordingly, case was deferred for four weeks.			

11	Case No.:4/9/82-ALC4/2007	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01644/AM07/	RLA File : 03/94/040/01206/AM07/	Lic.No/Date:03104195 86 14.02.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium USP under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

12	Case No.:839/21/82-ALC4/2007	Party Name:LUPIN LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
	HQ File : 01/82/050/01656/AM07/	RLA File : 03/95/040/01390/AM07/	Lic.No/Date:03104201 10 20.02.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Ethambutol Hcl under para 4.7 of HBP.			

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/107/2006-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Ethambutol Hcl-----1kg.

Import item:

1. DL-2 Aminobutanol-----1.6014kg/kg
2. Tartaric Acid-----0.1977kg/kg
3. Methanol-----0.5620kg/kg
4. Iso Propyl Alcohol-----0.3436kg/kg
5. Ethylene dichloride-----0.490kg/kg
6. Caustic Soda Flakes-----0.4264kg/kg
7. Cyclohexane-----0.0056kg/kg
8. Calcium Hydroxide-----2.4525kg/kg

Committee also decided to call for All Industry Data from Pharmexcil for revision of norms for above export product.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

13	Case No.:3/19/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01663/AM07/	RLA File : 05/24/040/00951/AM07/	Lic.No/Date:05101998 28 21.02.2007	Defer Date: 20.11.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Nalidixic Acid under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.				

14	Case No.:840/21/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:09100293	Defer

01/82/050/01658/AM07/	09/24/040/00472/AM07/	72 21.02.2007	Date: 20.11.2007
Decision : Committee considered case as per agenda for ratification of norms for export product 7-Amino 3-Vinyl Cepholosparanic Acid (7 AVNA) under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

Case No.:850/21/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
HQ File : 01/82/050/01677/AM07/	RLA File : 09/24/040/00069/AM07/	Lic.No/Date:09100294 23 22.02.2007	Defer Date: 20.11.2007
15	Decision : Committee considered case as per agenda for ratification of norms for export product 7-Amino 3-Vinyl Cepholosparanic Acid (7 AVNA) under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.		

Case No.:860/21/82-ALC4/2007	Party Name:G AMPHRAY LABORATORIES,	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
HQ File : 01/82/050/01691/AM07/	RLA File : 03/94/040/01193/AM07/	Lic.No/Date:03104204 96 22.02.2007	Defer Date: 20.11.2007
16	Decision : Committee considered case as per agenda for ratification of norms for export product Piperazine Adipate BP/USP under para 4.7 of HBP. Committee decided to call for complete set of application from RLA/firm. Accordingly, case was deferred for four weeks.		

Case No.:874/21/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
HQ File : 01/82/050/01710/AM07/	RLA File : 05/24/040/00972/AM07/	Lic.No/Date:05102001 16 27.02.2007	Defer Date: 20.11.2007
17			

Decision : Committee considered case as per agenda for ratification of norms for export product Azacyclonol under para 4.7 of HBP.

Committee decided to call for complete set of application from RLA/firm. Accordingly, case was deferred for four weeks.

Case No.:879/21/82-ALC4/2007

Party Name:LAKE
CHEMICALS PRIVATE
LIMITED

Meet No/Date:25/82-
ALC4/2007
23.10.2007

**Status:Ca
se
Deferred**

HQ File :
01/82/050/01714/AM07/

RLA File :
07/24/040/00780/AM07/

Lic.No/Date:07100503
14
27.02.2007

Defer
Date:
20.11.2007

18 **Decision :** Committee considered case as per agenda for ratification of norms for export product Dorzolamide Hcl under para 4.7 of HBP.

Committee observed that file has been transferred from DES-IV only on 5.10.2007 and decided to forward a copy of application to PI Division for comments. Accordingly, case was deferred for four weeks.

Case No.:6/9/82-ALC4/2007

Party Name:COVALENT
LABORATORIES PRIVATE
LIMITED

Meet No/Date:25/82-
ALC4/2007
23.10.2007

**Status:Ca
se
Deferred**

HQ File :
01/82/050/01728/AM07/

RLA File :
09/24/040/00488/AM07/

Lic.No/Date:09100295
04
01.03.2007

Defer
Date:
20.11.2007

19 **Decision :** Committee considered case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP.

Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

20 **Case No.:891/21/82-ALC4/2007**

Party Name:DIVIS
PHARMACEUTICALS
PRIVATE LIMITED

Meet No/Date:25/82-
ALC4/2007
23.10.2007

**Status:Ca
se
Approved**

HQ File :
01/82/050/01727/AM07/

RLA File :
09/24/040/00484/AM07/

Lic.No/Date:09100294
99
01.03.2007

Decision : Committee considered case as per agenda for ratification of norms for export product 2,3 Dibromo-5-Benzoyl Pyrrole under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 3/82 meeting held on 23.05.2007 decided to ratify norms under para 4.7 of HBP as per details

blow or as applied by firm whichever is lower.

Export product:

2,3 Dibromo-5-benzoyl pyrrole-----1kg.

Import items:

1. Pyrrole-----0.43kg/kg
2. Dichloro Methane-----5.25kg/kg
3. Morpholine-----1.29kg/kg

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

Case No.:919/21/82-ALC4/2007

Party Name:HARMAN FINOCHEM LTD.

Meet No/Date:25/82-ALC4/2007
23.10.2007

Status:Case Approved

HQ File :
01/82/050/01768/AM07/

RLA File :
03/94/040/01242/AM07/

Lic.No/Date:03104223
94
08.03.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Phenobarbital (Phenobrbitone) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/99/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details blow or as applied by firm whichever is lower.

Export product:

Phenobarbitone-----1kg.

Import items:

1. Benzyl cyanide-----0.662kg/kg
2. Dimethyl carbonate-----0.59kg/kg
3. Sodium Metal-----0.31kg/kg
4. Methanol-----1.09kg/kg

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

22

Case No.:940/21/82-ALC4/2007

Party Name:GRANULES INDIA LIMITED

Meet No/Date:25/82-ALC4/2007
23.10.2007

Status:Case Approved

HQ File :
01/82/050/01801/AM07/

RLA File :
09/24/040/00458/AM07/

Lic.No/Date:09100296
52

		13.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Paracetamol Granules DC Grade 96% under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/34/2005-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details blow or as applied by firm whichever is lower. Export product: Paracetamol Granules DC Grade 96%-----1kg. Import items: 1. Paracetamol -----0.96kg/kg Or Its raw materials as per SION at A-3488 2. Povidone (K-30)-----0.04kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.			

23	Case No.:1/17/82-ALC4/2007	Party Name:BIOLOGICAL E LTD	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01860/AM07/	RLA File : 09/24/040/00481/AM07/	Lic.No/Date:0910029748 23.03.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Noscapine Hcl under para 4.7 of HBP. Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for four weeks.			

24	Case No.:25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00016/AM08/	RLA File : 04/24/040/00501/AM07/	Lic.No/Date:0410088727 02.04.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Allylestrenol under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

25	Case No.:26/9/82-ALC4/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00010/AM08/	RLA File : 09/24/040/00555/AM07/	Lic.No/Date:09100299 33 10.04.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-Chloro methyl-3-methyl-4-(2,2,2-trifluoroethoxy)pyridine Hcl (Lansoprazole-Chloro intermediate) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/97/2007-PI-III dated 23.10.2007 decided to call for following information from firm. 1. Complete and balanced chemical reactions for each step of manufacturing process alongwith molecular weight and % yield of molar basis. 2. Material balance for the entire process. 3. Requirement and recovery of solvents at each step of manufacturing process. 4. Copy of technical literature in support of the yields envisaged in each step. Accordingly, case was deferred for four weeks.			

26	Case No.:566/24/83-ALC1/2007	Party Name:MOREPEN LABORATORIES LTD.,	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00239/AM08/	RLA File : 05/24/040/00080/AM08/	Lic.No/Date:05102032 07 03.05.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium Min Assay 97% under para 4.7 of HBP. Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for four weeks.			

27	Case No.:577/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
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HQ File : 01/83/050/00273/AM08/	RLA File : 09/24/040/00444/AM07/	Lic.No/Date:09100302 07 08.05.2007	Defer Date: 20.11.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carbosalate under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

Case No.:8/13/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
HQ File : 01/82/050/00038/AM08/	RLA File : 34/24/040/00028/AM08/	Lic.No/Date:34100187 60 17.05.2007	Defer Date: 20.11.2007
28	Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.		

29	Case No.:31/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
	HQ File : 01/82/050/00042/AM08/	RLA File : 34/24/040/00031/AM08/	Lic.No/Date:34100188 11 21.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefepime (For Injection USP) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/182/2005-PI-III dated 23.10.2007 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Cefepime for Injection USP (Cefepime + Arginine Sterile)-----1Kg. Import items:			

1. 7 Amino Cephalosporonic Acid-----1.20kg/kg
2. Trimethylsilyl iodide-----1.59kg/kg
3. Hexamethyl Disilazane-----0.88kg/kg
4. N-Methyl Pyrrolidine-----0.588kg/kg
5. Methylene Chloride-----6.63kg/kg
6. Cyclohexane-----4.77kg/kg
7. Acetone-----13.88kg/kg
8. Isopropyl Alcohol-----11.08kg/kg
9. 2-Mercapto Benzothiazolyl (Z)-2-(2-Amino
Thiazoyl-4-YL)-2-Methoxy Imino acetate-----0.77kg/kg
10. Triethyl amine-----
0.147kg/kg
11. Dimethyl Formamide-----
1.27kg/kg
12. Activated Carbon-----
0.100kg/kg
13. Methanol-----
1.00kg/kg
14. L-Arginine-----
0.30kg/kg

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

30	Case No.:614/24/83- ALC1/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:25/82- ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00369/AM08/	RLA File : 03/95/040/01471/AM07/	Lic.No/Date:03104300 58 21.05.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ultrazyme Tablets (7458X) [Contact Lens Cleaning Tablets) under para 4.7 of HBP. Committee decided to ask Department of Bio-technology whether 'NOC' is required for export of Ultrazyme Tablets (7458X) [Contact Lens Cleaning Tablets) under last sub-para of para 4.7 of HBP. Accordingly, case was deferred for four weeks.			

31	Case No.:38/9/82- ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:25/82- ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00061/AM08/	RLA File : 34/24/040/00039/AM08/	Lic.No/Date:34100188 74 01.06.2007	Defer Date: 20.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin USP under para 4.7 of HBP.

Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.:3/15/82-ALC4/2007	Party Name:HARMAN FINOCHEM LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
HQ File : 01/82/050/00103/AM08/	RLA File : 03/94/040/00179/AM08/	Lic.No/Date:03104319 49 07.06.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Phenobarbital (Phenobarbitone) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/99/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details blow or as applied by firm whichever is lower.

Export product:
Phenobarbitone-----1kg.

Import items:
 1. Benzyl cyanide-----0.662kg/kg
 2. Dimethyl carbonate-----0.59kg/kg
 3. Sodium Metal-----0.31kg/kg
 4. Methanol-----1.09kg/kg

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

Case No.:712/24/83-ALC1/2007	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
HQ File : 01/83/050/00584/AM08/	RLA File : 03/94/040/00192/AM08/	Lic.No/Date:03104329 14 18.06.2007	Defer Date: 20.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Testosterone under para 4.7 of HBP.

Representative of PI Division present in meeting informed committee

that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.:3/17/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
HQ File : 01/82/050/00073/AM08/	RLA File : 09/24/040/00093/AM08/	Lic.No/Date:09100306 26 21.06.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Finasteride under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.			
34 Export product: Finasteride-----1kg.			
Import items: 1. 3-oxo-4-Aza-5-alpha-androstane-17-b-carboxylic acid----- 2.38kg/kg 2. Benzene Selenic Anhydride----- 3.80kg/kg 3. Methylene chloride-----7.50kg/kg 4. Cyclohexane----- 12.50kg/kg			
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.			

35 Case No.:93/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
HQ File : 01/82/050/00143/AM08/	RLA File : 03/94/040/00422/AM08/	Lic.No/Date:03104374 49 26.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate Tablets 300mg/Tenvir Tablets under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 23.10.2007 decided to ratify			

norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Tenofovir Disoproxil Fumerate Tablets 300mg/Tenvir Tablets-----33,51,485 Nos.

Total weight of Tenofovir Disoproxil Fumerate—306 X 3351485 = 1025.5544kgs.

Import items:

1. 9-[2-(Phosphonyl Methoxy)Propyl] Adenine---0.8026kg/kg of export product
2. Chloromethyl Isopropyl carbonate-----2.08670kg/kg of export product

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.

36	Case No.:95/21/82-ALC4/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00144/AM08/	RLA File : 03/95/040/00389/AM08/	Lic.No/Date:0310437508 26.07.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocare Tablets (Contact Lens Cleaning Tablets) under para 4.7 of HBP. Committee decided to ask Department of Bio-technology whether 'NOC' is required for export of Ultrazyme Tablets (7458X) [Contact Lens Cleaning Tablets) under sub-para of para 4.7 of HBP. Accordingly, case was deferred for four weeks.			

37	Case No.:9/27/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01083/AM08/	RLA File : 03/95/040/00534/AM08/	Lic.No/Date:0310441537 31.08.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of			

norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.

Committee decided to call for following information from firm and to defer the case for four weeks.

1. Percentage yield on molar basis for each step of manufacturing process.
2. Technical literature in support of the yields envisaged in the application.
3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%.
4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement.
5. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated.
6. In the process flow chart export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended.
7. Copy of valid DML for above export product.

38	Case No.:72/27/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01146/AM08/	RLA File : 03/95/040/00570/AM08/	Lic.No/Date:03104424 36 11.09.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium Non infringing under para 4.7 of HBP. Committee decided to call for Production and Consumption Data certified by Central Excise Authority from firm. Accordingly, case was deferred for four weeks.			

39	Case No.:1/25/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00195/AM08/	RLA File : 13/24/040/00019/AM08/	Lic.No/Date:13100250 71 01.10.2007	Defer Date 20.11.2007 ;
	Decision : Committee considered case as per agenda for ratification of norms for export product Alpha Lipoic Acid Granules 95% under para 4.7 of			

HBP.

Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.

Case No.:2/25/82-ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:25/82-ALC4/2007
23.10.2007

Status:Case Deferred

HQ File :
01/82/050/00196/AM08/

RLA File :
03/94/040/00664/AM08/

Lic.No/Date:03104450
42
03.10.2007

Defer
Date:
20.11.2007

40 **Decision :** Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP.

Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.

Case No.:3/25/82-ALC4/2007

Party Name:SANJAY SALES CORPORATION

Meet No/Date:25/82-ALC4/2007
23.10.2007

Status:Case Deferred

HQ File :
01/82/050/00197/AM08/

RLA File :
03/95/040/00590/AM08/

Lic.No/Date:03104450
94
04.10.2007

Defer
Date:
20.11.2007

41 **Decision :** Committee considered case as per agenda for ratification of norms for export product Acetyl Salicylic Acid (Aspirin) under para 4.7 of HBP.

Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.

Case No.:4/25/82-ALC4/2007

Party Name:SANJAY SALES CORPORATION

Meet No/Date:25/82-ALC4/2007
23.10.2007

Status:Case Deferred

HQ File :
01/82/050/00198/AM08/

RLA File :
03/95/040/00591/AM08/

Lic.No/Date:03104450
97
04.10.2007

Defer
Date:
20.11.2007

42 **Decision :** Committee considered case as per agenda for ratification of norms for export product Acetyl Salicylic Acid (Aspirin) under para 4.7 of HBP.

Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.

43	Case No.:5/25/82-ALC4/2007	Party Name:TTK LIG LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Transferred
	HQ File : 01/82/050/00199/AM08/	RLA File : 04/24/040/00250/AM08/	Lic.No/Date:0410091387 05.10.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Durex Play Longer-1.0 oz (28.4g) Active ingredient: Benzocaine 7.5% under para 4.7 of HBP. Committee decided to transfer case to DES-VII as export product pertains to Plastic Sector.			

44	Case No.:6/25/82-ALC4/2007	Party Name:NICHIPLAST INDIA PVT LTD.	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Transferred
	HQ File : 01/82/050/00200/AM08/	RLA File : 05/24/040/00499/AM08/	Lic.No/Date:0510210118 05.10.2007	:
	Decision : Committee considered case as per agenda for ratification of norms for export product Dettol Medicated Fabric Plaster under para 4.7 of HBP. Committee decided to transfer case to DES-VII as export product pertains to Plastic Sector.			

45	Case No.:7/25/82-ALC4/2007	Party Name:MADAUS PHARMACEUTICALS PRIVATE LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00201/AM08/	RLA File : 17/24/040/00068/AM08/	Lic.No/Date:1710001775 09.10.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Agiolax under para 4.7 of HBP. Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.			

46	Case No.:10/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00204/AM08/	RLA File : 04/24/040/00255/AM08/	Lic.No/Date:0410091462	Defer Date:

		10.10.2007	20.11.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (100mg) under para 4.7 of HBP. Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.			

47	Case No.:8/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:25/82- ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00202/AM08/	RLA File : 04/24/040/00253/AM08/	Lic.No/Date:04100914 59 10.10.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets 25mg under para 4.7 of HBP. Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.			

48	Case No.:9/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:25/82- ALC4/2007 23.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00203/AM08/	RLA File : 04/24/040/00254/AM08/	Lic.No/Date:04100914 60 10.10.2007	Defer Date: 20.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (50mg) under para 4.7 of HBP. Committee decided to call for copy of application alongwith copy of Advance licence from RA. Accordingly, case was deferred for four weeks.			

Date:22.10.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Case No.A-783	M/S Ranbaxy Laboratoreis Ltd.
NC Meeting No.25/08	F.No.01/82/50/205/AM'08
Meeting Date: 23.10.2007	RLA F.No.05/24/40/305/AM08
Adv.Lic.No.0510207201 dated 06.08.2007	
Committee considered case as per agenda for ratification of norms for export product Simvastatin Tablets 10mg, 20mg and 40mg under para 4.7 of HBP. The Committee in light of the written comments of the Deptt. of C&PC forwarded vide their U.O.No.35011/224/2006-PI-III dated 30.5.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower. Export product Simvastatin tablets 10/20/40 Mg. Import items For export of Simvastatin 10mg tablets - Simvastatin - 10.20mg/tablet For export of Simvastatin 20mg tablets - Simvastatin - 20.40mg/tablet For export of Simvastatin 40mg tablets - Simvastatin - 40.80mg/tablet Lovastatin-----1.648 Kg./kg of Simvastatin Acetone-----1.042 Kg./kg of Simvastatin Activated Carbon-----0.035 Kg./kg of Simvastatin Cyclohexane-----1.33 Kg./kg of Simvastatin Cycloproxylamine-----1.23 Kg./kg of Simvastatin Methanol-----19.82 Kg./kg of Simvastatin N Butyl Lithium-----2.382 Kg./kg of Simvastatin Pyrrolidine-----1.53 Kg./kg of Simvastatin Tetrahydrofuran-----6.58 Kg./kg of Simvastatin Caustic flakes-----1.484 Kg./kg of Simvastatin Iodine-----0.63 Kg./kg of Simvastatin Ethyl acetate-----4.49 Kg./kg of Simvastatin RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-784	M/S Ranbaxy Laboratoreis Ltd.
NC Meeting No.25/08	F.No.01/82/50/206/AM'08
Meeting Date: 23.10.2007	RLA F.No.05/24/40/401/AM08

Adv.Lic.No.0510207640 dated 17.08.2007	
Committee considered case as per agenda for ratification of norms for export product Citalopram Hydrobromide Tablets 10mg, 20mg and 40mg under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-785	M/S Symbiotec Pharmalab Ltd.
NC Meeting No.25/08	F.No.01/82/50/207/AM'08
Meeting Date: 23.10.2007	RLA F.No.11/24/40/28/AM08
Adv.Lic.No.1110016033 dated 25.09.2007	
Committee considered case as per agenda for ratification of norms for export product Hydrocortisone Sodium Succinate USP (Sterile) under para 4.7 of HBP. The Committee in light of its earlier decision taken in its 10/08 meeting held on 10.07.2007 vide Case No.A-222 decided to ratify the norms of the export product under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: HYDROCORTISONE SODIUM SUCCINATE (BP/USP) -----1Kg. Import items: Hydrocortisone-----1.10kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-786	M/S Symbiotec Pharmalab Ltd.
NC Meeting No.25/08	F.No.01/82/50/208/AM'08
Meeting Date: 23.10.2007	RLA F.No.11/24/40/30/AM08
Adv.Lic.No.1110016034 dated 25.09.2007	
Committee considered case as per agenda for ratification of norms for export	

product Hydrocortisone Sodium Succinate Buffered 5% Sterile under para 4.7 of HBP.

The Committee in light of its earlier decision taken in its 10/08 meeting held on 10.07.2007 vide Case No.A-222 decided to ratify the norms of the export product under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.

Export product:

HYDROCORTISONE SODIUM SUCCINATE (BP/USP) -----1Kg.

Import items:

Hydrocortisone-----1.10kg/kg

RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

Case No.A-787	M/S Sandoz Pvt. Ltd.
NC Meeting No.25/08	F.No.01/82/50/209/AM'08
Meeting Date: 23.10.2007	RLA F.No.03/95/40/488/AM08
Adv.Lic.No.0310441155 dated 29.08.2007	
Committee considered case as per agenda for ratification of norms for export product Blistersheet (Pauci-Bacillary) Child, MB-Blistersheet (Multi-Bacillary) Child and MB-Blistersheet (Multi-Bacillary Adult under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.	

Case No.A-788	M/S Cadila Healthcare Ltd.
NC Meeting No.25/08	F.No.01/82/50/191/AM'08
Meeting Date: 23.10.2007	RLA F.No.08/24/40/150/AM08
Adv.Lic.No.0810067103 dated 11.09.2007	
Committee considered case as per agenda for ratification of norms for export product Hydroxy Chloroquine Sulfate 200mg Tab. under para 4.7 of HBP. Representative of PI Division present in meeting informed committee	

that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.A-789	M/S Cadila Healthcare Ltd.
NC Meeting No.25/08	F.No.01/82/50/192/AM'08
Meeting Date: 23.10.2007	RLA F.No.08/24/40/158/AM08
Adv.Lic.No.0810067315 dated 24.09.2007	
Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate Pharma Grade under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-790	M/S Cipla Ltd.
NC Meeting No.25/08	F.No.01/82/50/193/AM'08
Meeting Date: 23.10.2007	RLA F.No.03/94/40/540/AM08
Adv.Lic.No.0310440643 dated 23.08.2007	
Committee considered case as per agenda for ratification of norms for export product Cyproterone Acetate Tablets 10mg and 50mg under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-791	M/S Cipla Ltd.
NC Meeting No.25/08	F.No.01/82/50/194/AM'08
Meeting Date: 23.10.2007	RLA F.No.03/94/40/582/AM08
Adv.Lic.No.0310441827 dated 05.09.2007	

Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets and Nevirapine oral Suspension 50mg/5ml under para 4.7 of HBP.

Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.A-792	M/S Granules India Ltd.
NC Meeting No.25/08	F.No.01/83/50/393/AM'08
Meeting Date: 23.10.2007	RLA F.No.09/24/40/46/AM08
Adv.Lic.No.0910030337 dated 24.05.2007	
Committee considered case as per agenda for ratification of norms for export product Compresso ANG90 (Metamizole Sodium Granules DC Grade 90%) under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-793	M/S Cadila Healthcare Ltd.
NC Meeting No.25/08	F.No.01/82/50/133/AM'08
Meeting Date: 23.10.2007	RLA F.No.08/24/40/91/AM08
Adv.Lic.No.0810065758 dated 04.07.2007	
Committee considered case as per agenda for ratification of norms for export product Carvedilol 3.125mg, 6.25mg, 12.5mg25mg tablets under para 4.7 of HBP. Committee in the light of written comments forwarded by PI Division vide their U.O.No.35011/73/2007-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: 1. Carvedilol tablets 3.125mg-----2,71,17,200 Nos. 2. Carvedilol tablets 6.25mg-----4,47,70,400 Nos. 3. Carvedilol tablets 12.5mg-----4,05,58,100 Nos. 4. Carvedilol tablets 25mg-----5,34,54,400 Nos.	

Import items:	Total requirement in Kgs.
1. Carvedilol-----	2252.05kgs.
2. Cross Povidone-----	1942.95kgs.
3. Povidone K30-----	706.53kg
4. Magnesium Stearate-----	317.94kg.
5. Bottles and caps (import item a to j)-----	As per packing policy
RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-794	M/S Cadila Healthcare Ltd.
NC Meeting No.25/08	F.No.01/82/50/132/AM'08
Meeting Date: 23.10.2007	RLA F.No.08/24/40/90/AM08
Adv.Lic.No.0810065759 dated 04.07.2007	
Committee considered case as per agenda for ratification of norms for export product Atenolol 25mg, 50mg and 100mg tablets under para 4.7 of HBP. Committee in the light of written comments forwarded by PI Division vide their U.O.No.35011/73/2007-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: - Atenolol 25mg tablets-----29,29,06,000 Nos. - Atenolol 50mg tablets-----26,60,30,000 Nos. - Atenolol 100mg tablets-----8,84,64,000 Nos. Import items: - Atenolol-----30059.90kg - HD Silicified Microcrystalline Celklulose (Prosol V HD90)-----80985.071kg - Povidone K30-----677.823kg - Citric Acid Anhydrous-----294.706kg - Croscarmellose Sodium NF-----4273.23kg - Magnesium Stearate-----854.646kg - Bottles & caps (import item No. a to j)-----As per packing policy RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-795	M/S Aurobindo Pharma Ltd.
NC Meeting No.25/08	F.No.01/82/50/127/AM'08
Meeting Date: 23.10.2007	RLA F.No.09/24/40/469/AM08
Adv.Lic.No.0910030086 dated 24.04.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Sulbactam Sodium (2:1) under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-796	M/S Lupin Ltd.
NC Meeting No.25/08	F.No.01/82/50/119/AM'08
Meeting Date: 23.10.2007	RLA F.No.03/95/40/293/AM08
Adv.Lic.No.0310433980 dated 26.06.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriazone Sodium 1gm, 2gm and 250mg Injection under para 4.7 of HBP. Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-797	M/S Lyka BDR Intl. Ltd.
NC Meeting No.25/08	F.No.01/82/50/89/AM'08
Meeting Date: 23.10.2007	RLA F.No.03/95/40/1309/AM07
Adv.Lic.No.0310419266 dated 12.02.2007	
Committee considered case as per agenda for ratification of norms for export product Clobetasole Propionate Cream 10gm, 15gm, 30gm and Clobetasol Propionate Topical Solution 0.05% W/V under para 4.7 of HBP.	

Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.A-798	M/S Medreich Ltd.
NC Meeting No.25/08	F.No.01/82/50/1790/AM07
Meeting Date: 23.10.2007	RLA F.No.07/24/40/718/AM07
Adv.Lic.No.0710049763 dated 24.01.2007	
Committee considered case as per agenda for ratification of norms for export product Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 45mg + Codeine Phosphate 10mg Tablets, Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 50mg + Codeine Phosphate 10mg Tablets and Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 30mg + Codeine Phosphate 10mg tablets under para 4.7 of HBP. Committee decided to forward a copy of application alongwith a copy of reply received from firm to PI Division for their comments. Accordingly, case was deferred for four weeks.	

Case No.A-799	M/S Medreich Ltd.
NC Meeting No.25/08	F.No.01/82/50/48/AM'08
Meeting Date: 23.10.2007	RLA F.No.07/24/40/810/AM07
Adv.Lic.No.0710050467 dated 06.03.2007	
Committee considered case as per agenda for ratification of norms for export product Paracetamol Codeine Phosphate, Caffeine and Doxylamine Succinate Tablets, Paracetamol, Codeine Phosphate, Caffeine and Diphenhydramine Hydrochloride Tablets and Paracetamol, Codeine Phosphate, Daffeine and Doxylamine Succinate Tablets under para 4.7 of HBP. Committee decided to forward a copy of application alongwith a copy of reply received from firm to PI Division for their comments. Accordingly, case was deferred for four weeks.	

Case No.A-800	M/S Nexuz Pharma Ltd.
NC Meeting No.25/08	F.No.01/82/50/76/AM'08
Meeting Date: 23.10.2007	RLA F.No.08/24/40/317/AM07
Adv.Lic.No.0810062842 dated 09.02.2007	
Committee considered case as per agenda for ratification of norms for export product Dexamethasone IP/BP 2005/USP 28 under para 4.7 of HBP. Committee observed that item of import and export are chemically same. Committee, therefore, in consultation with representative of technical authorities present in meeting decided to ratify norms under para 4.7 of HBP on net to net basis. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-348	M/s Divis Laboratories Ltd
M.No.25/08	F.No.01/82/50/56/AM 07
Meeting Date 23.10.2007	RLA F.No.09/24/40/182/AM2001
Adv.Lic No.0910019924 dated 30.08.2004	
The Committee considered the case as per agenda for ratification of norms for the export product Capecitabine under para 4.7 of HBP. Committee decided to call for a copy of application from firm. Accordingly, case was deferred for six weeks.	

Case No.B-349	M/s Divis Laboratories Ltd
M.No.25/08	F.No.01/82/50/1315/AM 04
Meeting Date 23.10.2007	RLA F.No.09/24/40/354/AM04
Adv. Lic. No.0910017100 dated 13.01.2004	

The Committee considered the case as per agenda for ratification of norms for the export product Cyclocytidine under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/183/2004-PI-III dated 23.20.2007 decided to ratify norms under para 4.7 of HBP as per details given below or as applied by firm whichever is lower.

Export product:

Cyclocytidine Hcl (O,2-cyclocytidine Hcl)-----1kg

Import items:

1. Cytidine-----2.93kg/kg
2. N-Heptane/Heptane-----3.70kg/kg
3. Acetonitrile-----6.01kg/kg
4. Iso Propyl Alcohol-----2.86kg/kg
5. Methanol-----4.36kg/kg

RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

Case No.B-350	M/s Zandu Chemicals Ltd
M.No.25/08	F.No.01/83/50/242/AM 07
Meeting Date 23.10.2007	RLA F. No.03/95/40/127/am07
Adv. Lic. No. 0310382709 dt. 1.6.2006	

The Committee considered the case as per agenda for ratification of norms for the export product under para 4.7 of HBP.

Committee in consultation with representative of PI Division present in meeting decided to call for following information/documents from firm/RLA.

1. Complete set of application.
2. Details of chemistry and yield as given by foreign buyer.
3. Any other published technical literature on export product process and yield.

Accordingly, case was deferred for four weeks.

Case No.B-351	M/s Alkem Laboratories Ltd
M.No.25/08	F.No.01/83/50/409/AM 08
Meeting Date 23.10.2007	RLA F. No. 03/94/40/187/AM08
Adv. Lic. No. 0310430680 dt. 25.5.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Sucralose USP under para 4.7 of HBP.

Representative of PI Division present in meeting informed committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.B-352	M/s Gulf Oil Corporation Ltd
M.No.25/08	F.No.01/82/50/1215/AM 07
Meeting Date 23.10.2007	RLA F. No. 09/24/40/194/AM07
Adv.Lic.No.0910028005 dt. 31.10.2006	

The Committee considered the case as per agenda for ratification of norms for the export product Sodium Cromo Glycate under para 4.7 of HBP.

Committee decided to forward a copy of application alongwith a copy of representation received from firm to PI Division for their comments. Accordingly, case was deferred for four weeks.

Case No.B-353	M/s Alchem International Ltd.
M.No.25/08	F.No.01/87/50/1374/AM 05
Meeting Date 23.10.2007	RLA F. No. 05/24/40/542/AM05
Adv. Lic. No. 0510148830 dt. 17.01.2005	

The Committee considered the case as per agenda for ratification of norms for the export product Hyocine -n-Butyl Bromide under para 4.7 of HBP.

Committee decided to call for Production and Consumption Data certified by Central Excise Authority from firm. Accordingly, case was deferred for four weeks.

Case No.B-354	M/s Nestor Pharmaceutical Ltd
M.No.25/08	F.No.01/83/50/1080/AM 07
Meeting Date 23.10.2007	RLA F. No. 05/24/40/760/AM07
Adv. Lic. No. 0510197129 dt. 2.1.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Ampicillin Anhydrous from Pen-G Route)under para 4.7 of HBP.

Committee observed that revised SION for Ampicillin Anhydrous were published on the basis of All Industry Data. Committee, therefore, decided to maintain status quo.

Case No.B-355	M/s Nestor Pharmaceutical Ltd
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M.No.25/08	F.No.01/83/50/268/AM 07
Meeting Date 23.10.2007	RLA F. No. 05/24/40/21/AM07
Adv. Lic. No. 051018618 dt. 29.5.2006	
The Committee considered the case as per agenda for ratification of norms for the export product (Cloxacillin Sodium from Pen-G Routet) under para 4.7 of HBP. Committee observed that revised SION for Cloxacillin Sodium were published on the basis of All Industry Data. Committee, therefore, decided to maintain status quo.	

Case No.B-356	M/s Nestor Pharmaceutical Ltd
M.No.25/08	F.No.01/83/50/1081/AM 07
Meeting Date 23.10.2007	RLA F. No. 05/24/40/743/AM07
Adv. Lic. No. 0510197130 dt. 2.1.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Cloxacillin Sodium from Pen G route under para 4.7 of HBP. Committee observed that revised SION for Cloxacillin Sodium were published on the basis of All Industry Data. Committee, therefore, decided to maintain status quo.	

Case No.B-357	M/s Nestor Pharmaceutical Ltd
M.No.25/08	F.No.01/83/50/661/AM 07
Meeting Date 23.10.2007	RLA F. No. 05/24/40/875/AM07
0510176456 dt. 5.2.2006	
The Committee considered the case as per agenda for ratification of norms for the export product Ampicillin Anhydrous from Pen G route under para 4.7 of HBP. Committee observed that revised SION for Ampicillin Anhydrous were published on the basis of All Industry Data. Committee, therefore, decided to maintain status quo.	

Case No.B-358	M/s Nestor Pharmaceutical Ltd
M.No.25/08	F.No.01/83/50/925/AM 07
Meeting Date 23.10.2007	RLA F. No. 05/24/40/585/AM07
Adv. Lic. No. 0510194529 dt. 16.11.2006	

The Committee considered the case as per agenda for ratification of norms for the export product Ampicillin Capsules 250mg under para 4.7 of HBP.

Committee observed that revised SION for Ampicillin Trihydrate were published on the basis of All Industry Data. Committee, therefore, decided to maintain status quo.

Case No.B-359	M/s Indo German Alkaloids
M.No.25/08	F.No.01/82/50/299/AM 04
Meeting Date 23.10.2007	RLA F. No.03/24/40/274/AM04
Adv. Lic.No. 0310212182 dt. 7.4.2003	
The Committee considered the case as per agenda for deletion of condition regarding requirement of NOC from NCB for import of Papaverine/Crude Noscapine under para 4.7 of HBP. Committee observed that Department of Revenue vide their letter No.1/34/2007-NC.II dated 04.10.2007 has confirmed that Noscapine and Papaverine are not covered under Narcotics Drugs and Psychotropic substances Act, 1985 and NDPS Rules, 1985 and hence NOC Import Certificate is not required for their import/export under NDPS Act, 1985. Committee, therefore, decided to delete condition regarding obtaining NOC from NCB for import of Papavarine/Noscapine Crude. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-360	M/s Mecleods Ltd.
M.No.25/08	F.No.01/82/50/1580/AM 06
Meeting Date 23.10.2007	RLA F. No. 03/95/40/1320/AM06
Adv. Lic. No. 0310366830 dt. 14.2.2006	
The Committee considered the case as per agenda for ratification of norms for the export product Ciprofloxacin Tablets 500mg under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below. Export product: Ciprofloxacin Tablets BP 500mg (Proxacin 500) Import item: Ciprofloxacin hcl-----591/60mg/tablet as applied RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-361	M/s Alkaloids Corporation
M.No.25/08 Meeting Date 23.10.2007	F.No.01/87/50/772/AM 07 F.No.01/87/50/1488/AM 06 F.No.01/87/50/505/AM 06 F.No.01/87/50/639/AM 07 F.No.01/87/50/292/AM 06 F.No.01/87/50/376/AM 07 F.No.01/87/50/653/AM 07 F.No.01/87/50/99/AM 07 F.No.01/87/50/169/AM 06
	RLA F. No. 02/24/40/284/AM06 RLA F. No. 02/24/40/91/AM06 RLA F. No. 02/24/40/198/AM07 RLA F. No. 02/24/40/50/AM06 RLA F. No. 02/24/40/106/AM07 RLA F. No. 02/24/40/202/AM07 RLA F. No. 02/24/40/23/AM07 RLA F. No. 02/24/40/31/AM06
The Committee considered the case as per agenda for deletion of condition regarding requirement of NOC from NCB for import of Papaverine/Crude Noscapine under para 4.7 of HBP. Committee observed that Department of Revenue vide their letter No.1/34/2007-NC.II dated 04.10.2007 has confirmed that Noscapine and Papaverine are not covered under Narcotics Drugs and Psychotropic substances Act, 1985 and NDPS Rules, 1985 and hence NOC Import Certificate is not required for their import/export under NDPS Act, 1985. Committee, therefore, decided to delete condition regarding obtaining NOC from NCB for import of Papavarine/Noscapine Crude. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-362	M/s Wockhardt Ltd.
M.No.25/08	F.No.01/82/162/548/AM 07
Meeting Date 23.10.2007	
The Committee considered the case as per agenda for fixation of Value Addition for DEPB rate in respect of export product D-Oxyphene Base(Powder) and decided to call for the data of Import and Export through Pharmexcil.	

Case No.B-363	M/s Lupin Ltd.
M.No.25/08	F.No.01/82/162/285/AM 06
Meeting Date 23.10.2007	

The Committee considered the case as per agenda for fixation of Value Addition for DEPB rate in respect of export product "3C7ACCA" under Sion A-2119.

Committee observed that firm have given import data from April, 2006 onwards while export data has been given from December, 2006 onwards. Committee, therefore, decided to call for export data for the relevant period through Pharmexcil. Accordingly, case was deferred for four weeks.