

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

Para 4.7 Decision

MEETING NUMBER : 23/82-ALC4/2007 MEETING DATE : 09.10.2007

1	Case No.:10/20/87-ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00429/AM06/	RLA File : 02/24/040/00081/AM06/	Lic.No/Date:02100800 76 15.07.2005	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.			

2	Case No.:8/10/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00096/AM07/	RLA File : 02/24/040/00020/AM07/	Lic.No/Date:02100887 34 28.04.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.			

3	Case No.:1/23/87-ALC1/2006	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00336/AM07/	RLA File : 05/24/040/00255/AM07/	Lic.No/Date:05101852 76 21.06.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of			

norms for export product Silymarin Extract under para 4.7 of HBP.

Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.

Case No.:363/21/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/82/050/00581/AM07/	RLA File : 09/24/040/00148/AM07/	Lic.No/Date:0910026938 21.07.2006	Defer Date: 06.11.2007

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 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:
Lisinopril-----1kg.

Import items:

1. N 2-[(1-S)-Ethoxy Carbonyl-3-Phenyl Propyl]
-N 6-trifluoro acetyl-L-lysine benzyl ester-----2.58kg/kg
2. Palladium on carbon 5%-----0.011kg/kg
3. L-Proline-----0.927kg/kg
4. Methanol-----5.45kg/kg
5. Methylene chloride-----10.77kg/kg

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

5	Case No.:2/34/82-ALC1/2006	Party Name:DISHMAN PHARMACEUTICALS & CHEMICALS LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00593/AM07/	RLA File : 08/24/040/00247/AM06/	Lic.No/Date:0810058323 24.07.2006	Defer Date: 06.11.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product 1-Carbethoxy Ethylidene Triphenyl Phosphorane under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the reply received from the firm is under examination in his Department and he sought deferment of four weeks. The Committee accordingly decided to defer the case for four weeks.

6	Case No.:16/27/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00419/AM07/	RLA File : 02/24/040/00123/AM07/	Lic.No/Date:02100921 25 02.08.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Kola Extract under para 4.7 of HBP. Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.			

7	Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00911/AM07/	RLA File : 03/94/040/00615/AM07/	Lic.No/Date:03103990 69 12.09.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Terbinafine Hydrochloride Tablets 250mg (Terbinafine Hcl equi. Qty. 1873kg-30s Packs) under para 4.7 of HBP. The Committee observed that the firm was requested to furnish certain technical information vide letter dated 28.09.2007, but the same has not been received. The Committee, therefore, decided to await reply of the firm. Accordingly, case was deferred for four weeks.			

8	Case No.:2/31/83-ALC1/2006	Party Name:PRADEEP SHETYE PVT. LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00707/AM07/	RLA File : 03/95/040/00433/AM07/	Lic.No/Date:03104006 43 22.09.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Micronized Rafoxanide under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he			

sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

9	Case No.:2/46/87-ALC1/2006	Party Name:AVON ORGANICS LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00663/AM07/	RLA File : 09/24/040/00271/AM07/	Lic.No/Date:09100279 81 30.10.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidazolone (AABZ) or 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

10	Case No.:3/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01214/AM07/	RLA File : 09/24/040/00174/AM07/	Lic.No/Date:09100280 04 31.10.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Fexofenadine Hcl under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

11	Case No.:4/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Withdrawn
	HQ File : 01/82/050/01215/AM07/	RLA File : 09/24/040/00194/AM07/	Lic.No/Date:09100280 05 31.10.2006	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Sodium Cromo Glycate under para 4.7 of HBP. Committee decided to withdraw this case as the same has already been rejected in its 17/08 meeting held on 30.08.2007.			

Case No.:608/21/82-ALC4/2007	Party Name:HETERO LABS LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
HQ File : 01/82/050/01217/AM07/	RLA File : 09/24/040/00286/AM07/	Lic.No/Date:0910028008 31.10.2006	
Decision : Committee considered the case as per agenda for ratification of norms for export product Stavudine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. 12 Export product: Stavudine-----1kg. Import items: 1. 5-Methyl Uridin-----3.29kg/kg 2. Acetonitrile-----3.72kg/kg 3. Methanol-----3.43kg/kg 4. Dimethyl Amino Pyridine-----0.230kg/kg 5. Trimethyl Ortho Acetate-----2.00kg/kg 6. Methylene Chloride-----5.59kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

Case No.:37/36/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
HQ File : 01/83/050/00874/AM07/	RLA File : 09/24/040/00307/AM07/	Lic.No/Date:0910028137 07.11.2006	
Decision : Committee considered the case as per agenda for ratification of norms for export product Lamotrigine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/101/2004-PI-III dated 09.10.2007 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: Lamotrigine-----1kg.			

Import items:

1. Amino Guanidine Hcl-----1.23kg/kg
2. 1-Methyl-2-Pyrrolidinone-----3.30kg/kg

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

14	Case No.:12/45/87-ALC1/2006	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/87/050/00747/AM07/	RLA File : 09/24/040/00128/AM07/	Lic.No/Date:0910028249 17.11.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Salbactam Sodium (2:1) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

15	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01441/AM07/	RLA File : 09/24/040/00390/AM07/	Lic.No/Date:0910028634 13.12.2006	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-Lysine-Praline (Lyspro Isolated) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

16	Case No.:800/21/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/82/050/01541/AM07/	RLA File : 09/24/040/00396/AM07/	Lic.No/Date:0910028952 10.01.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP.			

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 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:
Sertaline Hcl-----1Kg.

Import items:
1. Alpha Naphthol-----3.10kg/kg
2. Sodium Borohydride-----0.331kg/kg
3. D(-) Mandelic Acid-----0.392kg/kg

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

Case No.:804/21/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
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HQ File : 01/82/050/01552/AM07/	RLA File : 09/24/040/00415/AM07/	Lic.No/Date:09100290 06 12.01.2007	
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Decision : Committee considered the case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 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:
Sertaline Hcl-----1Kg.

Import items:
1. Alpha Naphthol-----3.10kg/kg
2. Sodium Borohydride-----0.331kg/kg
3. D(-) Mandelic Acid-----0.392kg/kg

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

Case No.:805/21/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
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HQ File : 01/82/050/01553/AM07/	RLA File : 09/24/040/00418/AM07/	Lic.No/Date:09100290 07 12.01.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 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: Lamivudine-----1Kg. Import items: 1. Glyoxylic acid 50%-----1.80kg/kg 2. 1,4-dithiane-2,5-dihydroxy-----0.739kg/kg 3. Cytosine-----0.955kg/kg 4. Hexamethyl disilazane-----1.89kg/kg 5. Salicylic acid-----0.79kg/kg 6. Sodium borohydride-----0.48kg/kg 7. Dimethyl formamide-----0.83kg/kg 8. N-Hexane-----3.75kg/kg 9. Methylene dichloride-----5.75kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

19	Case No.:806/21/82-ALC4/2007	Party Name:HETERO LABS LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/82/050/01554/AM07/	RLA File : 09/24/040/00417/AM07/	Lic.No/Date:09100290 08 12.01.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Stavudine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 09.10.2007 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: Stavudine-----1kg.				

Import items:

1. 5-Methyl Uridin-----3.29kg/kg
2. Acetonitrile-----3.72kg/kg
3. Methanol-----3.43kg/kg
4. Dimethyl Amino Pyridine-----0.230kg/kg
5. Trimethyl Ortho Acetate-----2.00kg/kg
6. Methylene Chloride-----5.59kg/kg

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

Case No.:807/21/82-ALC4/2007

Party Name:HETERO LABS LTD.

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status: Case Approved

HQ File :
01/82/050/01555/AM07/

RLA File :
09/24/040/00419/AM07/

Lic.No/Date:09100290
09
12.01.2007

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/237/2006-PI-III dated 09.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.

20

Export product:

Nevirapine-----1kg.

Import items:

1. Malononitrile-----1.088kg/kg
2. Methylene chloride-----6.71kg/kg
3. 2-chloro Nicotininic acid-----1.13kg/kg
4. Pyridine-----0.566kg/kg
5. Methyl Tert. Butyl ether-----3.01kg/kg
6. Cyclopropylamine-----1.20kg/kg

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

21

Case No.:2/48/83-ALC1/2006

Party Name:SURYA PHARMACEUTICAL LTD

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status: Case Deferred

HQ File :
01/83/050/01135/AM07/

RLA File :
22/24/040/00291/AM07/

Lic.No/Date:22100064
00
17.01.2007

Defer Date:
06.11.2007

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

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:411/24/83-ALC1/2007

Party Name:NEULAND LABORATORIES LTD

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status: Case Approved

HQ File :
01/83/050/01139/AM07/

RLA File :
09/24/040/00378/AM07/

Lic.No/Date:0910029084
18.01.2007

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/86/2007-PI-III dated 25.09.2007 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:

22 Ipratropium Bromide-----1Kg.

Import items:

1. 2,5 Dimethoxy Tetrahydrofuran-----2.42kg/kg
2. Isopropylamine-----1.36kg/kg
3. Methanol-----7.22kg/kg
4. Methyl Phenyl Acetate-----2.78kg/kg
5. Ethyl formate-----3.64kg/kg
6. Sodium Hydride-----1.16kg/kg
7. Methylene chloride-----7.33kg/kg
8. Sodium Borohydride-----0.27kg/kg
9. Isopropyl alcohol-----2.38kg/kg

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

Case No.:425/24/83-ALC1/2007

Party Name:SMILAX LABORATORIES LIMITED

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Deferred

HQ File :
01/83/050/01203/AM07/

RLA File :
09/24/040/00466/AM07/

Lic.No/Date:0910029229
07.02.2007

Defer Date:
06.11.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product 5-Methoxy-2-((4-Methoxy-3,5-Dimethyl-2-Pyridinyl) Methyl) Thio-1H-Benzimidazole under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:500/24/83-ALC1/2007

Party Name:IND-SWIFT LABORATORIES LTD.,

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Deferred

HQ File :
01/83/050/00062/AM08/

RLA File :
22/24/040/00297/AM07/

Lic.No/Date:22100064
82
13.02.2007

Defer
Date:
06.11.2007

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

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

25 **Case No.:3/4/82-ALC1/2007**

Party Name:HETERO LABS LTD.

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Approved

HQ File :
01/82/050/01648/AM07/

RLA File :
09/24/040/00482/AM07/

Lic.No/Date:09100293
48
15.02.2007

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/87/2007-PI-III dated 03.10.2007 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:
Oseltamivir Phosphate-----1kg.

Import items:
1. Shikimic Acid-----4.025kg/kg
2. 2,2 Dimethoxy Propane-----0.043kg/kg
3. 3-Pentanone-----14.239kg/kg
4. Trifluoromethane Sulfonic acid-----0.204kg/kg

5. Triethylsilane-----3.00kg/kg
6. Methanol-----2.41kg/kg
7. Methylene Dichloride-----13.52kg/kg
8. Tetrahydrofuran-----2.77kg/kg
9. Dimethyl Formamide-----1.57kg/kg

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

26	Case No.:4/3/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01267/AM07/	RLA File : 03/95/040/01424/AM07/	Lic.No/Date:03104204 07 21.02.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. The Committee observed that the information received from the firm is incomplete. The firm has not furnished copy of complete DML. The Committee, therefore, decided to call for complete set of DML. Accordingly, case was deferred for four weeks.			

27	Case No.:1/11/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01270/AM07/	RLA File : 03/95/040/01095/AM07/	Lic.No/Date:03104205 22 22.02.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

28	Case No.:449/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/01279/AM07/	RLA File : 05/24/040/00975/AM07/	Lic.No/Date:05102001 10 27.02.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Ramipril under para 4.7 of HBP.			

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 19.09.2007 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:

Ramipril-----1kg.

Import items:

1. (+/-)(2A,3AB,AB)Octahydro Cyclopenta (B) Pyrole-2 Carboxylic Acid Phenyl Methyl Ester Hcl 99%-----2.70kg/kg
2. Acetone-----1.50kg/kg
3. Methylene chloride-----2.00kg/kg
4. Diisopropyl ether-----3.15kg/kg
5. Triethylamine-----1.38kg/kg
6. Toluene-----2.50kg/kg
7. Dibenzoyl-L-Tartaric Acid Monohydrate---1.699kg/kg
8. ECPP-Alanine-----1.23kg/kg
9. Methanol-----0.85kg/kg

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

29	Case No.:450/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
	HQ File : 01/83/050/01280/AM07/	RLA File : 05/24/040/00964/AM07/	Lic.No/Date:05102001 11 27.02.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Lisinopril tablets 5mg, 10mg, 20mg, 2.5mg under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 19.09.2007 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: Lisinopril tablets 5mg-----78,44,00,000Nos. (OR) Lisinopril tablets 10mg-----39,22,00,000Nos. (OR) Lisinopril Tablets 20mg-----19,61,00,000Nos. (OR) Lisinopril Tablets 2.5mg-----1,56,88,00,000Nos.				

Import items:

1. N TFA L-Proline-----5560kg.
2. Ethyl-2-oxo-4-Phenyl Butanoate---3400kg.
3. Molecular sieves-----1500kg.
4. Methylene chloride-----22360kg
5. Toluene-----12800kg.
6. Activated carbon-----400kg.
7. Isopropyl Alcohol-----8840kg.
8. Methanol-----11600kg.

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

Case No.:455/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
HQ File : 01/83/050/01297/AM07/	RLA File : 09/24/040/00477/AM07/	Lic.No/Date:09100294 96 01.03.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/254/2006-PI-III dated 09.10.2007 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:

Doxofylline-----1kg.

Import items:

1. Theophylline-----1.17kg/kg
2. Chloro acetaldehyde dimethyl acetal-----0.81kg/kg
3. Potassium carbonate-----0.89kg/kg
4. Methanol-----0.63kg/kg
5. Dimethyl formamide-----0.56kg/kg

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

31	Case No.:6/9/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:09100295	Defer

01/82/050/01728/AM07/	09/24/040/00488/AM07/	04 01.03.2007	Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

Case No.:3/1/87-ALC1/2007	Party Name:AVON ORGANICS LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/87/050/01107/AM07/	RLA File : 09/24/040/00487/AM07/	Lic.No/Date:0910029668 14.03.2007	Defer Date: 06.11.2007
32	Decision : Committee considered the case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidazolone (AABZ (OR) 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.		

33	Case No.:469/24/83-ALC1/2007	Party Name:NEULAND LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/01337/AM07/	RLA File : 09/24/040/00513/AM07/	Lic.No/Date:0910029660 14.03.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Moxifloxacin Hcl under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/86/2007-PI-III dated 25.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Moxifloxacin-----1kg Import items: 1-Cyclopropyl-6,7-difluoro-8-methoxy-4-oxo 1,4-dihydro quinoline-3-carboxylic acid-----1.31kg/kg			

2. (S,S)-2,8-diazabicyclo (4,3,0) nonane-----0.55kg/kg
3. Acetonitrile-----3.80kg/kg
4. Dimethyl formamide-----1.90kg/kg
5. 1,4-dizabieyclo(2,2,2)octane-----0.100kg/kg

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

34	Case No.:7/7/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01378/AM07/	RLA File : 03/95/040/01605/AM07/	Lic.No/Date:03104246 23 27.03.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. The Committee observed that the information received from the firm is incomplete. The firm has not furnished copy of complete DML. The Committee, therefore, decided to call for complete set of DML. Accordingly, case was deferred for four weeks.			

35	Case No.:23/9/82-ALC4/2007	Party Name:LUPIN LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/01901/AM07/	RLA File : 03/95/040/01622/AM07/	Lic.No/Date:03104249 15 29.03.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

36	Case No.:6/11/82-ALC4/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/82/050/01897/AM07/	RLA File : 09/24/040/00529/AM07/	Lic.No/Date:09100298 39 29.03.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Cyclopentadecanolide (Recrystallised) under para 4.7 of HBP.			

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/218/2006-PI-III dated 09.10.2007 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:

Cyclopentadecanolide (Recrystallised) (Purity not less than 99.5%)-----1kg.

Import items:

1. Cyclopentadecanolide (Tech. Grade) (Purity NMT 90.5%)-----1.20kg/kg
2. Methanol-----3.95kg/kg

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

37	Case No.:2/3/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00005/AM08/	RLA File : 34/24/040/00301/AM07/	Lic.No/Date:34100184 54 30.03.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Azithromycin Crude under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

38	Case No.:519/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00107/AM08/	RLA File : 05/24/040/00017/AM08/	Lic.No/Date:05102025 04 13.04.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Isotretinoin under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

39	Case No.:17/7/83-ALC1/2007	Party Name:R L FINE CHEM	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00149/AM08/	RLA File : 07/24/040/00017/AM08/	Lic.No/Date:07100513 34 19.04.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Clomipramine Hcl under para 4.7 of HBP. Committee in light of its earlier decision taken in its 22/82 meeting held on 04.10.2007 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: Clomipramine Hcl-----1kg Import item: 1. 1 Bromo 3 Chloro Propane-----0.85kg/kg 2. 3 Chloro iminodibenzyl-----0.91kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

40	Case No.:575/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00265/AM08/	RLA File : 09/24/040/00445/AM07/	Lic.No/Date:09100301 95 07.05.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Nelfinavir Mesylate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

41	Case No.:577/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00273/AM08/	RLA File : 09/24/040/00444/AM07/	Lic.No/Date:09100302 07 08.05.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R			

Carboxalate (Lamuvudine Intermediate-Stage-III) under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:578/24/83-ALC1/2007

Party Name:VIVIN
LABORATORIES PRIVATE
LIMITED

Meet No/Date:23/82-
ALC4/2007
09.10.2007

**Status:Ca
se
Deferred**

HQ File :
01/83/050/00274/AM08/

RLA File :
09/24/040/00043/AM08/

Lic.No/Date:09100302
08
08.05.2007

Defer
Date:
06.11.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamuvudine Intermediate-Stage-III) under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:579/24/83-ALC1/2007

Party Name:VIVIN
LABORATORIES PRIVATE
LIMITED

Meet No/Date:23/82-
ALC4/2007
09.10.2007

**Status:Ca
se
Deferred**

HQ File :
01/83/050/00275/AM08/

RLA File :
09/24/040/00039/AM08/

Lic.No/Date:09100302
09
08.05.2007

Defer
Date:
06.11.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product 5-O-Benzoyl-3-Mesyl-2,2 Anhydro-5-Methyl Uridine under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:589/24/83-ALC1/2007

Party Name:SUVEN LIFE
SCIENCES LIMITED

Meet No/Date:23/82-
ALC4/2007
09.10.2007

**Status:Ca
se
Deferred**

HQ File :
01/83/050/00308/AM08/

RLA File :
09/24/040/00013/AM08/

Lic.No/Date:09100302
50
14.05.2007

Defer
Date:
06.11.2007

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

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

45	Case No.:29/9/82-ALC4/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00039/AM08/	RLA File : 05/24/040/01075/AM07/	Lic.No/Date:05102037 51 16.05.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP. Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.				

46	Case No.:615/24/83-ALC1/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00370/AM08/	RLA File : 03/95/040/01389/AM07/	Lic.No/Date:03104300 66 21.05.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Concept Quick Unit Dose Solution (9247X) under para 4.7 of HBP. The Committee observed that RA has been requested to clarify as to why Advance Authorisation has been issued to the firm without submission of NOC from DBT when the export product is DBT item. Committee also observed that the firm has been requested to furnish NOC obtained from DBT. Both the information have not been received. Committee, therefore, decided to await reply of RA/firm. Accordingly, case was deferred for four weeks.				

47	Case No.:622/24/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00388/AM08/	RLA File : 09/24/040/00048/AM08/	Lic.No/Date:09100303 34 24.05.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of				

norms for export product 2-(2-Methoxy Phenoxy) Ethylamine under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:623/24/83-ALC1/2007

Party Name:SHODHANA LABORATORIES LTD.

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Deferred

HQ File :
01/83/050/00389/AM08/

RLA File :
09/24/040/00049/AM08/

Lic.No/Date:09100303
35
24.05.2007

Defer
Date:
06.11.2007

48

Decision : Committee considered the case as per agenda for ratification of norms for export product 4-(2,3-Epoxy Propoxy) carbaxole under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:624/24/83-ALC1/2007

Party Name:SHODHANA LABORATORIES LTD.

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Deferred

HQ File :
01/83/050/00390/AM08/

RLA File :
09/24/040/00040/AM08/

Lic.No/Date:09100303
36
24.05.2007

Defer
Date:
06.11.2007

49

Decision : Committee considered the case as per agenda for ratification of norms for export product 3-Oxo-4-Aza-5a-Androstane-17b-Carboxylic Acid under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:628/24/83-ALC1/2007

Party Name:INVENTIS DRUG DELIVERY SYSTEMS PVT LTD.

Meet No/Date:23/82-ALC4/2007
09.10.2007

Status:Case Deferred

HQ File :
01/83/050/00397/AM08/

RLA File :
09/24/040/00047/AM08/

Lic.No/Date:09100303
44
25.05.2007

Defer
Date:
06.11.2007

50

Decision : Committee considered the case as per agenda for ratification of

norms for export product Fenofibrate Pellets under para 4.7 of HBP.

Committee observed that the firm has been requested to furnish copy of relevant DML alongwith content of Active gradient, but the same has not been received. Committee, therefore, decided to await reply of the firm. Accordingly, case was deferred for four weeks.

Case No.:35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/82/050/00051/AM08/	RLA File : 34/24/040/00035/AM08/	Lic.No/Date:34100188 54 28.05.2007	Defer Date: 06.11.2007

51 **Decision :** Committee considered the case as per agenda for ratification of norms for export product Azithromycin Step-3 under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:642/24/83-ALC1/2007	Party Name:DEVATS (INDIA) PVT.LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00422/AM08/	RLA File : 05/24/040/00921/AM07/	Lic.No/Date:05102041 73 29.05.2007	Defer Date: 06.11.2007

52 **Decision :** Committee considered the case as per agenda for ratification of norms for export product Nystatin Oral Suspension (USP) under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:653/24/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00456/AM08/	RLA File : 03/95/040/00187/AM08/	Lic.No/Date:03104310 79 30.05.2007	Defer Date: 06.11.2007

53 **Decision :** Committee considered the case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:40/9/82-ALC4/2007	Party Name:WOCKHARDT LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
HQ File : 01/82/050/00066/AM08/	RLA File : 03/95/040/00161/AM08/	Lic.No/Date:03104314 94 04.06.2007	

Decision : Committee considered the case as per agenda for ratification of norms for export product Hot Lemon Cold Relief Powders 5gm Sachet under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/84/2007-PI-III dated 09.10.2007 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:
Hot Lemon Cold Relief Powder 5gm. Sachet
(each 5mg Sachet contains 650mg. Paracetamol Ph. Eur.)

Import items:
Paracetamol Ph. EUR-----656.5mg/Sachet of 5gm.

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

Case No.:657/24/83-ALC1/2007	Party Name:LEPRO HERBALS PVT. LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00469/AM08/	RLA File : 05/24/040/00155/AM08/	Lic.No/Date:05102045 04 05.06.2007	Defer Date: 06.11.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product Griffonia Dry Extract under para 4.7 of HBP.

Committee observed that technical comments were called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for comments. Accordingly, case was deferred for four weeks.

56	Case No.:661/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00490/AM08/	RLA File : 09/24/040/00094/AM08/	Lic.No/Date:0910030486 08.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

57	Case No.:778/24/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00725/AM08/	RLA File : 03/95/040/00230/AM08/	Lic.No/Date:0310432141 08.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Iso Sorbide 5-Mononitrate under para 4.7 of HBP. The Committee observed that the information received from the firm is incomplete. The firm has not furnished copy of complete DML. The Committee, therefore, decided to call for complete set of DML. Accordingly, case was deferred for four weeks.			

58	Case No.:714/24/83-ALC1/2007	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00589/AM08/	RLA File : 03/94/040/00248/AM08/	Lic.No/Date:0310432927 18.06.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Testosterone Propionate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/116/2005-PI-III dated 09.10.2007 in the case of M/S Avik Pharmaceuticals Ltd 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: Testosterone Propionate BPUSP-----1kg.			

Import items:

1. 4-Anrostene 3,17 Dione (Androstenedione)—1.25kg/kg
2. Trimethyl Ortho formate-----0.57kg/kg

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

59	Case No.:715/24/83-ALC1/2007	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:23/82- ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00590/AM08/	RLA File : 03/94/040/00243/AM08/	Lic.No/Date:03104329 29 18.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Norethisterone under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

60	Case No.:706/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82- ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00563/AM08/	RLA File : 09/24/040/00080/AM08/	Lic.No/Date:09100306 41 22.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Efavirenz under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

61	Case No.:789/24/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:23/82- ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00742/AM08/	RLA File : 03/95/040/00276/AM08/	Lic.No/Date:03104335 02 22.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP.			

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

62	Case No.:726/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00613/AM08/	RLA File : 04/24/040/00113/AM08/	Lic.No/Date:04100901 30 28.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 2-Fluoro Adenosin Triacetate (2-Fat) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

63	Case No.:727/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00614/AM08/	RLA File : 04/24/040/00112/AM08/	Lic.No/Date:04100901 31 28.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

64	Case No.:728/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00615/AM08/	RLA File : 04/24/040/00111/AM08/	Lic.No/Date:04100901 32 28.06.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Clopidogrel Bisulphate under para 4.7 of HBP.			

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:739/24/83-ALC1/2007	Party Name:PONALAB	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00640/AM08/	RLA File : 07/24/040/00223/AM08/	Lic.No/Date:07100522 85 03.07.2007	Defer Date: 06.11.2007

65 **Decision :** Committee considered the case as per agenda for ratification of norms for export product 8-Hydroxyquinoline under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:742/24/83-ALC1/2007	Party Name:NEULAND LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
HQ File : 01/83/050/00662/AM08/	RLA File : 09/24/040/00132/AM08/	Lic.No/Date:09100307 43 04.07.2007	

66 **Decision :** Committee considered the case as per agenda for ratification of norms for export product 1-(3-Hydroxymethyl-Pyridine-2-YL)-4-Methyl-2-Phenyl Piperazine (M Alcohol) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/86/2007-PI-III dated 25.09.2007 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-(3-hydroxymethyl-pyridine-2-YL)-4-Methyl-2-Phenyl Piperazine (M Alcohol) (Drug intermediate of Mirtazapine)-----1Kg.

Import items:

- 1-Methyl 3 Phenyl Piperazine-----1.35 Kg/Kg
- 2-chloro Nicotinonitrile-----1.06 Kg/Kg
- Chloroform-----6.37 Kg/Kg
- Dimethyl formamide-----5.38 Kg/Kg
- Sodium Bis(2-methoxyethoxy aluminiumhydride) -----2.44 Kg /Kg

(Vitride)

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

67	Case No.:743/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00665/AM08/	RLA File : 09/24/040/00511/AM07/	Lic.No/Date:0910030757 04.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 5,11-Dihydro(l)-Benzoxepino(3,4-b)-Pyridin-5-One under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

68	Case No.:751/24/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00675/AM08/	RLA File : 22/24/040/00023/AM08/	Lic.No/Date:2210006857 05.07.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Atorvastatin Calcium under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/7/2007-PI-III dated 09.10.2007 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: Atorvastatin Calcium-----1kg. Import items: 1. Methyl Isobutyl Acetate-----1.76 Kg/Kg 2. Betaalanine-----0.100Kg/Kg 3. 3-Ethyl-5-0(2-hydroxyethyl)-4-Methyl Thiozolium-----0.30 Kg/Kg Bromide 4. (4R-cis)-1,1-dimethyl ethyl-6-cyanomethyl-2,-----1.08Kg/Kg 2-dimethyl-1,3-dioxane-4-acetate(ATS-8)			

- | | |
|-------------------------------------|-------------|
| 5. Sodium Metabisulphide----- | 0.037 Kg/Kg |
| 6. Parafluoro benzaldehyde----- | 0.85Kg/Kg |
| 7. IPA----- | 8.375Kg/Kg |
| 8. Tertiary Butyl Methyl Ether----- | 4.37Kg/Kg |

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

69	Case No.:757/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00687/AM08/	RLA File : 09/24/040/00112/AM08/	Lic.No/Date:0910030802 06.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product L-Menthyl Glyoxylate Hydrate (MGH) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

70	Case No.:762/24/83-ALC1/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00695/AM08/	RLA File : 09/24/040/00141/AM08/	Lic.No/Date:0910030846 11.07.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Cyclopentadecanolide (Recrystallised) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/218/2006-PI-III dated 09.10.2007 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: Cyclopentadecanolide (Recrystallised) (Purity not less than 99.5%)-----1kg. Import items: 3. Cyclopentadecanolide (Tech. Grade) (Purity NMT 90.5%)-----			

1.20kg/kg
4. Methanol-----3.95kg/kg
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

Case No.:764/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00698/AM08/	RLA File : 05/24/040/00274/AM08/	Lic.No/Date:05102060 46 11.07.2007	Defer Date: 06.11.2007
71	Decision : Committee considered the case as per agenda for ratification of norms for export product Fisinopril Sodium under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.		

72	Case No.:765/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00699/AM08/	RLA File : 05/24/040/00278/AM08/	Lic.No/Date:05102060 47 11.07.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Lisinopril under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 19.09.2007 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: Lisinopril-----1Kg. Import items: 1. Activated carbon-----0.100Kg/Kg 2. Cyclohexane-----0.837Kg/Kg 3. Ethyl-2-oxo-4-Phenyl Butanoate-----0.85Kg/Kg 4. Isopropyl Alcohol-----2.21Kg/Kg 5. Methylene chloride-----5.59Kg/Kg 6. N TFA L-Lysl-L-Proline-----1.39Kg/Kg 7. Raney Nickel-----0.26Kg/Kg 8. Toluene-----1.823Kg/Kg			

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

	Case No.:766/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
	HQ File : 01/83/050/00700/AM08/	RLA File : 05/24/040/00279/AM08/	Lic.No/Date:0510206048 11.07.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 19.09.2007 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: Cefpodoxime Proxetil-----1Kg. Import items: 73 1. 7 ACA-----1.25Kg/Kg 2. 1-chloroethyl chloro formate-----0.558Kg/Kg 3. 1,8 Diazabicyclo[5,4.0]-undec-7-Ene(DBU)-----0.364Kg/Kg 4. Iodine-----0.47Kg/Kg 5. Sulfolane-----3.70Kg/Kg 6. Trimethylborate-----3.37Kg/Kg 7. Hexamethyl Disilazane-----0.54Kg/Kg 8. Activated carbon-----0.100Kg/Kg 9. Pyridine-----0.412Kg/Kg 10. Acetone-----0.86Kg/Kg 11. Cyclohexane-----0.28Kg/Kg 12. Ethyl Acetate-----1.17Kg/Kg 13. Isopropyl alcohol-----0.335Kg/Kg 14. Methanol-----1.89Kg/Kg 15. Methylene chloride-----2.72Kg/Kg 16. N,Ndimethyl Acetamide-----0.56Kg/Kg 17. Toluene-----0.29Kg/Kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.				

74	Case No.:771/24/83-ALC1/2007	Party Name:PRACHI PHARMACEUTICALS PVT LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
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HQ File : 01/83/050/00709/AM08/	RLA File : 03/95/040/00308/AM08/	Lic.No/Date:03104357 14 11.07.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Thiamine Hydrochloride BP/USP under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

Case No.:768/24/83-ALC1/2007	Party Name:LIQUORS INDIA LTD,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00702/AM08/	RLA File : 09/24/040/00142/AM08/	Lic.No/Date:09100308 64 12.07.2007	Defer Date: 06.11.2007
75	Decision : Committee considered the case as per agenda for ratification of norms for export product Lovastatin under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.		

Case No.:774/24/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00718/AM08/	RLA File : 09/24/040/00118/AM08/	Lic.No/Date:09100308 69 12.07.2007	Defer Date: 06.11.2007
76	Decision : Committee considered the case as per agenda for ratification of norms for export product Lopinavir under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.		

Case No.:797/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File :	RLA File :	Lic.No/Date:05102063	Defer

01/83/050/00755/AM08/	05/24/040/00286/AM08/	21 16.07.2007	Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Citalopram Hydrobromide under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

Case No.:5/17/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
HQ File : 01/82/050/00115/AM08/	RLA File : 09/24/040/00101/AM08/	Lic.No/Date:0910030910 17.07.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Glimepride 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 09.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. 78 Export product: Glimepride-----1Kg. Import items: 1. 3-Ethyl 4-Methyl-3-Pyrroline-2-one-----0.81Kg/Kg 2. Cyclohexane-----0.78Kg/Kg 3. Methanol-----6.75Kg/Kg 4. Trans 4-Methyl Cyclohexyl Isocynate-----0.40Kg/Kg 5. Potassium Carbonate-----1.02Kg/Kg 6. Acetone-----3.51Kg/Kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

79 Case No.:801/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Deferred
HQ File : 01/83/050/00760/AM08/	RLA File : 09/24/040/00115/AM08/	Lic.No/Date:0910030917 18.07.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of			

norms for export product (S)-5-Chloro-a-(Cyclopropylethynyl)-2-(((4-Methoxy Phenyl) methyl) amino)-a-(Trifluoromethyl) Benzene Methanol under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

Case No.:6/17/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
HQ File : 01/82/050/00117/AM08/	RLA File : 09/24/040/00122/AM08/	Lic.No/Date:09100309 46 19.07.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/16/2007-PI-III dated 09.10.2007 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:
Ramipril-----1Kg.

Import items:

1. ECPP-Alanine-----1.23Kg/Kg
2. Methylene chloride-----2.50Kg/Kg
3. (S.S.S.) 2-azabicyclo (3.3.0) octane -3-carboxylic-----1.20Kg/Kg
acid benzylester Hcl.

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

Case No.:905/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
HQ File : 01/83/050/00915/AM08/	RLA File : 03/95/040/01473/AM07/	Lic.No/Date:03104368 39 19.07.2007	Defer Date: 06.11.2007

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

The representative of PI Division present in the meeting informed the

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

82	Case No.:906/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00916/AM08/	RLA File : 03/95/040/01472/AM07/	Lic.No/Date:03104368 43 19.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Setralone (Tetralone)under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

83	Case No.:817/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00803/AM08/	RLA File : 09/24/040/00151/AM08/	Lic.No/Date:09100309 52 20.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product N-Carbethoxy-4-Piperidinol (OR) 4-Hydroxy-N0Carbethoxy Piperidine (OR) N-Carbethoxy-4-Hydroxy Piperidine under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

84	Case No.:908/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00919/AM08/	RLA File : 03/95/040/01517/AM07/	Lic.No/Date:03104369 87 20.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Ibuprofen DC Granules 90% under para 4.7 of HBP. The representative of PI Division present in the meeting informed the			

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

85	Case No.:909/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00920/AM08/	RLA File : 03/95/040/01516/AM07/	Lic.No/Date:03104369 93 20.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Ibuprofen DC Granules 65% under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

86	Case No.:829/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00821/AM08/	RLA File : 09/24/040/00042/AM08/	Lic.No/Date:09100309 72 23.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Cis-4-Amino-3-Methoxy-Piperidine-1-Carboxylic Acid Ethyl Ester Monohydrochloride under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

87	Case No.:830/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00822/AM08/	RLA File : 09/24/040/00068/AM08/	Lic.No/Date:09100309 73 23.07.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 2-Butyl-4-Chloro-5-Formyl Imidazole (OR) 2(n-Butyl)-4-Chloro-5-Formyl Imidazole under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he			

sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.

88	Case No.:832/24/83-ALC1/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00825/AM08/	RLA File : 03/95/040/00362/AM08/	Lic.No/Date:0310437194 23.07.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Amodiazuine Base under para 4.7 of HBP. Committee observed that All Industry Data was called for from Pharmexcil, but the same has not been received. Committee, therefore, decided to await data. Accordingly, case was deferred for four weeks.				

89	Case No.:840/24/83-ALC1/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00837/AM08/	RLA File : 09/24/040/00155/AM08/	Lic.No/Date:0910030999 25.07.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product {3-5[Bromo-1-(fluorophenyl)(1,3-dihydro isobenzofuranyl)]-Propyl]dimehylamine oxalate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.				

90	Case No.:4/19/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/82/050/00145/AM08/	RLA File : 03/95/040/00204/AM08/	Lic.No/Date:0310437530 26.07.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Betasol Lotion 30ml under para 4.7 of HBP. The representative of PI Division present in the meeting handed over U.O. No.35011/86/2006-PI-III dated 20.09.2007 wherein PI Division has mentioned that the firm has applied for import of Betamethasone base whereas DML specifies use of Clobetasol Propionate. The firm has not given any technical justification for import of above item. Committee, therefore,				

decided to seek clarification from the firm. Accordingly, case was deferred for four weeks.

91	Case No.:869/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/00871/AM08/	RLA File : 09/24/040/00138/AM08/	Lic.No/Date:0910031028 01.08.2007	Defer Date: 06.11.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 5-O Benzoyl-2,3-Didehydro-5-Methyl Uridine under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

92	Case No.:878/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Approved
	HQ File : 01/83/050/00882/AM08/	RLA File : 05/24/040/00354/AM08/	Lic.No/Date:0510207161 03.08.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product 1-benzyl-3,4-dimethyl-2-(4-methoxy benzyl)-1,2,5,6-tetrahydropyridine Oxalate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/143/2006-PI-III dated 09.10.2007 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-benzyl-3,4-dimethyl-2-(4-methoxy benzyl)-1,2,5,6, tetrahydropyridine Oxalate (Petazocine intermediate)-----1Kg. Import items: 1. 3,4 Lutidine -----0.55Kg/Kg 2. Sodium boro hydride-----0.153Kg/Kg 3. Acetone-----9.24Kg/Kg 4. Toluene-----2.18Kg/Kg 5. Methanol-----0.71Kg/Kg 6. Iodine-----0.100Kg/Kg 7. Tetrahydrofuran-----0.45Kg/Kg			

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

Case No.:902/24/83-ALC1/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status: Case Approved
HQ File : 01/83/050/00912/AM08/	RLA File : 22/24/040/00027/AM08/	Lic.No/Date:2210006952 07.08.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Amoxycillin Trihydrate enzymatic route under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/165/2006-PI-III dated 09.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.			
93			
Export product: Amoxycillin Trihydrate enzymatic route-----1kg.			
Import items: 1. Penicillin G Pot. 1st crystal-----1.664 BOU/Kg 2. D(-) Para hydroxy phenyl glycine methyl ester-----0.608Kg 3. Oxilasa enzyme-----5.0gm. 4. Penicillin G Amidase enzyme-----0.852gm. 5. Methanol-----0.0215Kg 6. Butyl Acetate-----0.122Kg 7. Boric acid-----0.032Kg			
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

94	Case No.:989/24/83-ALC1/2007	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:23/82-ALC4/2007 09.10.2007	Status:Case Deferred
	HQ File : 01/83/050/01007/AM08/	RLA File : 22/24/040/00034/AM08/	Lic.No/Date:22100069 91 21.08.2007	Defer Date: 06.11.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Cefprozil under para 4.7 of HBP.				
The representative of PI Division present in the meeting informed the Committee that the case is under examination in his Department and he sought deferment for four weeks. Accordingly, the Committee decided to				

defer the case for four weeks.

Case No.B-324	M/S Cadila Pharma Ltd.
NC Meeting No.23/08	F.No.01/82/50/1433/AM05
Meeting date: 09.10.2007	RLA F.No.08/24/40/95/AM05
Adv.Lic. No.0810036678 dated 05.03.2004	
Committee considered the case as per agenda for enhancement in the quantity of input Carbinoxamine under para 4.7 of HBP. Committee decided to call for Production and consumption Data Certified by Central Excise Authority from the firm. It was also decided to call for evidence from the firm that the exports were made through non-infringing process. Accordingly, case was deferred for four weeks.	

Case No.B-325	M/S Cipla Ltd.
NC Meeting No.23/08	F.No.01/82/50/722/AM07
Meeting date: 09.10.2007	RLA F.No.03/94/40/519/AM07
Adv.Lic. No.0310394029 dated 10.08.2006	
Committee considered the case as per agenda for amendment in the description of import items No.2, 3, 4 under para 4.7 of HBP. Committee decided to allow amendment in the description of import item No.1,2, and 3 in the following manner after due verification of the application of the firm. 2.63mcl Aerosol Valves-----As per packing policy 19ml Aluminium Can-----As per packing policy Actuators with Dust Covers/ Caps Fitting to 19ml Aluminium Can----As per packing policy RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-326	M/S Mission Pharma Ltd.
NC Meeting No.23/08	F.No.01/82/50/606/AM07
Meeting date: 09.10.2007	RLA F.No.03/95/40/318/AM04
Adv.Lic. No.0310247155 dated 13.01.2004	
Committee considered the case as per agenda for enhancement in the quantity of inputs under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the item of import is Levamisole BP 98 and not Levamisole Hcl and therefore, the quantity of inputs correctly allowed to them. Committee observed that there is no merit for enhancement in the quantity of inputs and the decision already conveyed to the firm holds good. It was, therefore decided to maintain status quo.	

Case No.B-327	M/S Wockhardt Ltd.
NC Meeting No.23/08	F.No.01/82/162/549/AM07
Meeting date: 09.10.2007	
Committee considered the case as per agenda for fixation of value addition for revision of DEPB rate in respect of export product Dextromethorphan Hydrobromide. Committee observed that the firm has not given data in respect of one input namely Cyclohexanyl Ethyl Amino and after excluding the cif value of this item, the value addition work out to 21.79%. It was also observed that if the cif value of the above input will be included, the value addition will be in minus. Committee, therefore, decided to call for revised data from the firm. Accordingly, the case was deferred for four weeks.	

Case No.B-328	M/S Dhanuka Laboratories Ltd.
NC Meeting No.23/08	F.No.01/82/50/1514/AM07
Meeting date: 09.10.2007	RLA F.No.05/24/40/648/AM07
Adv.Lic. No.0510197222 dated 03.01.2007	
Committee considered the case as per agenda for enhancement in the quantity of inputs under para 4.7 of HBP. The Committee observed that the firm has not given any supporting documents like Production and Consumption Data certified by Central Excise Authority. Committee, therefore, decided to maintain status quo.	

Case No.B-329	M/S Ariane Orgachem Pvt. Ltd. M/S Centaur Chemicals Private Ltd. M/S Surya Pharmaceutical Ltd.
NC Meeting No.23/08	F.No.01/87/50/448/AM07 F.No.01/87/50/662/AM07 F.No.01/87/50/873/AM07 F.No.01/87/50/1025/AM05 F.No.01/82/50/336/AM08 F.No.01/82/50/264/AM06 F.No.01/82/50/875/AM06 F.No.01/82/50/479/AM06 F.No.01/82/50/1169/AM06 F.No.01/82/50/549/AM07 F.No.01/82/50/1657/AM07 F.No.01/87/50/1474/AM05 F.No.01/87/50/1475/AM05
Meeting date: 09.10.2007	

M/S Ariane Orgachem Pvt. Ltd., Mumbai

Committee considered the case as per agenda and heard Shri Rakesh Doshi, representative of the firm who appeared for personal hearing before the Committee. The representative explained that the actual consumption of inputs viz. Lasamide, Furfurylamine and Iso Propyl Alcohol is on a higher side as compared to the quantity allowed by Norms Committee against their six Advance Authorisations mentioned below;

1. 0310394009 dated 10.08.2006
2. 0310429564 dated 16.05.2007
3. 0310405378 dated 24.10.2006
4. 0310414730 dated 05.01.2007
5. 0310300140 dated 02.11.2004
6. 0310278686 dated 02.07.2004

The Committee after detailed deliberations and in consultation with the representative of technical authority present in the meeting decided to allow higher quantities of the above three inputs with reference to the actual consumption certified by the Central Excise Authority.

The Committee after going through the production and consumption data certified by the Central Excise Authority for the period April, 2002 to March, 2007 decided to enhance the quantity of the following inputs (taking into account the minimum quantity) as detailed below against all the six Advance licences mentioned below.

1. Lasamide-----1.24kg/kg
2. Furfurylamine-----1.21kg/kg
3. Iso Propyl Alcohol-----1.79kg/kg

The above decision will be applicable to only six advance licences mentioned above and no repeat licence shall be allowed based on the above decision.

The Committee also decided to fix SION in respect of export product Frusemide BP after calling Production and Consumption Data for the last three years from three major exporters of this export product viz M/S IPCA, M/S Ariane Orgachem and M/S Shree Krishna through Pharmexcil.

M/S Centaur Chemicals Pvt. Ltd., Mumbai

Committee considered the case as per agenda and heard Dr. Girish Kavishwar, Vice President and Dr. Anil Naik, Director of the firm who appeared for personal hearing before the Committee.

The representatives of the firm informed the Committee that their process of production of Clonazepam USP-27 is different from the others and as such the requirement of quantity of input viz. 2-amino-2-chloro-5-nitro Benzophenone is on a higher side than mentioned in the SION at Sl.No.A-3358. He also submitted consumption certificate duly certified by Central Excise Authority to the effect that 2.5kg of 2-amino-2-chloro-5-nitro Benzophenone is required for production of 1Kg of export product. On going through the literature furnished in the meeting, Committee observed that the purity of export product is consistently high with low impurity profile; yield is between 35% to 43% as against 70% yield on the basis of which SION has been fixed and the same is justified by literature explained to the technical authority.

Committee after detailed deliberations and taking into account the fact the SION has been fixed on the basis of certified data of Central Excise and taking into yield of 70%, decided to enhance the quantity of 2-amino-2-chloro-5-nitro Benzophenone to 2.5kg/kg of the export product in respect of the following six Advance Authorisations obtained by the firm.

1. 0310334738 dated 17.06.2005
2. 0310354691 dated 02.11.2005
3. 0310384994 dated 16.06.2006
4. 0310361631 dated 02.01.2006
5. 0310389125 dated 13.07.2006
6. 0310420158 dated 20.02.2007

The Committee also decided to revise SION in respect of export product Clonazepam USP-27 after calling production and consumption data for the last three years from Pharmexcil.

It was also decided to constitute a Committee for plant visit for revision of SION. The member of the Committee and programme of visit may be decided on file.

M/S Surya Pharmaceutical Ltd.

Committee considered the case as per agenda and heard Shri Imran Shaikh, Commercial Adviser of the firm who appeared for personal hearing before the Committee.

The representative of the firm informed the Committee that they have completed export obligation against Advance Authorisation No.2210004190 dated 07.02.2005 and 2210004189 dated 07.02.2005. The quantity of inputs consumed by the firm for production of 7-AVNA and MiCA has been on a higher side as compared to the quantities allowed by the Committee. He stated that they have submitted a copy of Certificate issued by Directorate of Health and Family Welfare, Punjab who has recommended higher input against both the export product.

The Committee after deliberations advised the representative of the firm to furnish Consumption and Production Data duly certified by Central Excise Authority

for the above two licences separately to enable the Committee to take a final view. It was also decided to undertake an exercise for fixation of SION for export product 7-AVNA after calling Production and Consumption Data of major exporters of this export product from Pharmexcil