

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

Para 4.7 Officewise Statement

MEETING NUMBER : 16/82-ALC4/2007 **MEETING DATE** : 21.08.2007

1	Case No.:1/12/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/82/050/01673/AM05/	RLA File :09/24/040/00314/AM05/	Lic.No/Date:0910021404 06.01.2005	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Azoline under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 21.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: Azoline-----1Kg. Import items: 1. Cis-2-(2,4 difluorophenyl)-2-(1H-1,2,4-triazole-1-ylmethyl)-1,3-dioxalane-4-methanol CDM3-----3.05kg/kg 2. Dichloromethane-----1.53kg/kg 3. CAL-B enzyme-----0.30kg/kg 4. Hexane-----11.43kg/kg 5. Isopropyl alcohol-----1.53kg/kg 6. 1-(4-(4-(4-methoxyphenyl)-1-Piperazinyl)phenyl)-3-(1-methethyl)-2-imidazolidinone HBr Salt-----1.65kg/kg 7. Hydrobromic acid 48%-----7.93Ltrs/kg 8. DMSO-----3.51kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

2	Case No.:5/37/82-ALC1/2005	Party Name:FDC LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/00946/AM06/	RLA File :03/94/040/00798/AM06/	Lic.No/Date:0310356218 22.11.2005	Defer Date:18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Econazole Nitrate BP/JP/USP			

under para 4.7 of HBP.

The Committee noted that the firm has been requested to furnish technical details vide letter dated 16.08.2007. The Committee, therefore, decided to await reply of the firm. Accordingly the case was deferred for four weeks.

3	Case No.:10/47/83-ALC1/2005	Party Name:UNIMARK REMEDIES LIMITED.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/83/050/00648/AM06/	RLA File :03/95/040/01126/AM06/	Lic.No/Date:0310365523 02.02.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Cefadroxil under para 4.7 of HBP. The Committee in light of Report forwarded by PI Division vide their U.O.35011/165/2006/PI-III dated 30.07.2007 decided to ratify the norms as per details below or as applied for by the firm whichever is lower. Export Product: Cefadroxil Monohydrate from Pen G Route-----1Kg. Import items: 1. Penicillin G Potassium 1st Crystal-----2.34BOU/Kg 2. Pyridine Hydrobromide-----0.320kg/kg OR - Hydrobromic acid 48%-----0.375kg/kg 3. Hydrogen Peroxide 60%-----0.363kg/kg 4. Acetic Acid-----0.933kg/kg 5. Trimethyl chloro silane-----2.7027kg/kg OR 5(a). Bis trimethyl silyl urea-----1.543kg/kg 5(b). Hexamethyl disilazane-----0.3284kg/kg 6. Trimethyl chloro silane-----0.2180kg/kg 7. D(-)para hydroxy Phenyl glycine-----0.959kg/kg Methyl/ethyl potassium dane salt OR 7(a). D(-) para hydroxy Phenyl glycine base----0.5402kg/kg 7(b). Methyl Aceto acetate-----0.4113kg/kg			

- 7©. Methanol-----0.3370kg/kg
8. Dimethyl formamide-----2.051kg/kg
9. Toluene-----0.583kg/kg
10. Acetone-----1.1498kg/kg
11. Methylene chloride-----0.407kg/kg
12. Potassium carbonate-----0.2418kg/kg
13. Activated Carbon-----0.0839kg/kg
14. Ethyl Chloro formate-----0.357kg/kg

RLA concerned may take further necessary action as per the above decision of Norms Committee.

It was also decided to publish the Norms for the Export Product "Cefadroxil Monohydrate form Pen G Route.

4	Case No.:4/14/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Withdrawn
	HQ File :01/82/050/00215/AM07/	RLA File :09/24/040/00511/AM06/	Lic.No/Date:0910026249 11.05.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product (4R-Cis)-1, 1-Dimethylethyl-6-(2-amino ethyl)-2,2-dimethyl-1,3-dioxane-4-acetate under para 4.7 of HBP. The Committee decided to withdraw the case as the same has already been approved by NC in its 15/08 meeting held on 14.08.2007.			

5	Case No.:13/16/83-ALC1/2006	Party Name:UNIMARK REMEDIES LIMITED.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/83/050/00352/AM07/	RLA File :03/95/040/00304/AM07/	Lic.No/Date:0310384752 15.06.2006	
	Decision : 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. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 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 whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg 4. Acetone-----0.1254kg			

5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg

OR

5.a) O-chloro Benzaldehyde-----0.5034kg

b) Hydroxy Amine Sulphate-----0.3192kg

c) Methyl Acetoacetate-----0.410kg

d) Chloroform-----0.270kg

e) Methylene chloride-----0.0542kg

6. Methylene Chloride/Ethyl Acetate-----0.620kg

7. 2-Ethyl Hexanoic acid-----0.150kg

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

6	Case No.:11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/87/050/00566/AM07/	RLA File :02/24/040/00189/AM07/	Lic.No/Date:0210094006 25.09.2006	Defer Date:18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Senega Soft Extract under para 4.7 of HBP.			
	The Committee observed that Department of Ayush has been requested demi officially to furnish their comments. The Committee, therefore, decided to await comments of Department of Ayush. Accordingly, the case was deferred for four weeks.			

7	Case No.:8/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/82/050/00998/AM07/	RLA File :09/24/040/00214/AM07/	Lic.No/Date:0910027658 25.09.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Moxifloxacin Hcl under para 4.7 of HBP.			
	The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2007-PI-III dated 17.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Moxifloxacin Hcl-----1Kg. Import items: 1. Pyridine-2,3-dicarboxylic acid-----4.86kg/kg 2. Acetic anhydride-----4.86kg/kg			

3. Toluene-----3.22kg/kg
4. Ethyl acetate-----5.04kg/kg
5. Benzyl amine-----3.00kg/kg
6. Thionyl chloride-----4.28kg/kg
7. 5% Palladium carbon-----0.100kg/kg
8. D(-) Tartaric acid-----1.53kg/kg
9. Sodium hydroxide-----1.99kg/kg
10. Vitride-----4.99kg/kg
11. Acetonitrile-----0.76kg/kg
12. Triethylamine-----0.75kg/kg
13. Methylene chloride-----1.22kg/kg
14. 1-cyclopropyl-6,7-Difluoro-8-Methoxy-4-Oxo-1,4-
dihydro-3-quinoline carboxylic acid (Gatiacid)-----1.31kg/kg
15. Methanol-----2.86kg/kg

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

8	Case No.:9/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/82/050/00999/AM07/	RLA File :09/24/040/00177/AM07/	Lic.No/Date:0910027659 25.09.2006	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Moxifloxacin Hcl under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2007-PI-III dated 17.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Moxifloxacin Hcl-----1Kg. Import items: 1. Pyridine-2,3-dicarboxylic acid-----4.86kg/kg 2. Acetic anhydride-----4.86kg/kg 3. Toluene-----3.22kg/kg 4. Ethyl acetate-----5.04kg/kg 5. Benzyl amine-----3.00kg/kg 6. Thionyl chloride-----4.28kg/kg 7. 5% Palladium carbon-----0.100kg/kg 8. D(-) Tartaric acid-----1.53kg/kg 9. Sodium hydroxide-----1.99kg/kg				

10. Vitride-----4.99kg/kg
 11. Acetonitrile-----0.76kg/kg
 12. Triethylamine-----0.75kg/kg
 13. Methylene chloride-----1.22kg/kg
 14. 1-cyclopropyl-6,7-Difluoro-8-Methoxy-4-Oxo-1,4-
 dihydro-3-quinoline carboxylic acid (Gatiacid)-----1.31kg/kg
 15. Methanol-----2.86kg/kg

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

9	Case No.:33/34/87-ALC1/2006	Party Name:ANJAN DRUGS PRIVATE LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/87/050/00648/AM07/	RLA File :04/24/040/00276/AM07/	Lic.No/Date:0410085063 20.10.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Valproic Acid under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 04.04.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Valproic Acid-----1Kg. Import items: 1. Sodium Metal-----0.52kg/kg 2. N-Propyl Bromide-----2.71kg/kg 3. T-Butanol-----0.45kg/kg 4. Di-ethyl malonate-----1.44kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

10	Case No.:14/36/87-ALC1/2006	Party Name:ALEMBIC LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/87/050/00696/AM07/	RLA File :34/24/040/00183/AM07/	Lic.No/Date:3410017311 06.11.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product AZA Erythromycin under para 4.7 of HBP.			

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/23/2007-PI-III dated 20.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.

Export Product:

AZA Erythromycin-----1Kg.

Import items:

1. Erythromycin base-----1.86kg/kg
2. Hydroxylamine hcl-----0.94kg/kg
3. Methane sulfonyl chloride-----0.69kg/kg
4. Methanol-----1.09kg/kg
5. Acetone-----1.27kg/kg
6. Ethyl alcohol-----3.00Ltrs/kg
7. Platinum metal-----0.298gm/kg

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

11	Case No.:2/43/83-ALC1/2006	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/83/050/00875/AM07/	RLA File :09/24/040/00206/AM07/	Lic.No/Date:0910028138 07.11.2006	

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

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/93/2004-PI-III dated 09.08.2004 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:

Mebeverine Hcl-----1Kg.

Import items:

1. 2-Chloromethyl Propionate-----0.66kg/kg
2. Vanillin-----0.92kg/kg
3. 1,4-Dichloro butane-----0.84kg/kg
4. MIBK-----0.51kg/kg
5. Chloroform-----0.98kg/kg
6. Pot. Permanganate-----3.07kg/kg

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

The Committee has observed that the application of some other product has been forwarded by the RLA inadvertently. They may be asked to forward a complete set of application of the firm for the export product "Mebeverine Hcl" for record.

12	Case No.: 8/38/83-ALC1/2006	Party Name:SKM PHARMA(P)LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status: Case Approved
	HQ File :01/83/050/00964/AM07/	RLA File :07/24/040/00534/AM07/	Lic.No/Date:0710048801 01.12.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Fortified Procaine Pencillin 4 Mega Injection 20ml under para 4.7 of HBP. The Committee noted that the firm initially applied for lower quantity of inputs than the quantity allowed under DML and subsequently they have sought higher quantity vide their letter dated 24.07.2007. The Committee in line with the explanation given by the firm vide their letter dated 24.7.2007 decided to ratify the norms as applied by the firm vide their initial application as per details below; Export product: Fortified Procaine Penicillin 4 Mega Injection 20ml-----1No. Procaine penicillin and benzyl penicillin sodium 3:1) Import item: Fortified Procaine Penicillin (Procaine Penicillin /Benzyl Penicillin Sodium-3:1)-----0.00346 BOU with 4% wastage RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

13	Case No.: 11/44/82-ALC1/2006	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status: Case Deferred
	HQ File :01/82/050/01409/AM07/	RLA File :09/24/040/00374/AM07/	Lic.No/Date:0910028536 07.12.2006	Defer Date: 18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Lisinopril 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.			

14	Case No.: 3/47/87-ALC1/2006	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status: Case Deferred
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HQ File :01/87/050/00826/AM07/	RLA File :09/24/040/00323/AM07/	Lic.No/Date:0910028660 18.12.2006	Defer Date:18.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Ritonavir under para 4.7 of HBP. The Committee observed that the firm was requested to furnish details vide letter dated 14.08.2007, but the same has not been received. The Committee, therefore, decided to await the reply of the firm and to defer the case for four weeks.			

15	Case No.:8/8/83-ALC1/2007	Party Name:LEE PHARMA LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/83/050/00322/AM08/	RLA File :09/24/040/00453/AM07/	Lic.No/Date:0910029315 13.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product (5-Difluoro Methoxy)-2-[3,4-Dimethoxy-2-Pyridinyl)Methyl} Thio]-1H-Benzimidazole (Pentaprazole Sulphide) under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 17.05.2007 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: (5- Difluoro Methoxy)-2-[3,4-Dimethoxy-2-Pyridinyl) Methyl} Thio]-1H-Benzimidazole (Pentaprazole Sulphide)-----1Kg. Import items: 1. 2-chloromethyl-3,4-dimethoxy-pyridine Hcl-----0.75kg/kg 2. 2,5-difluoromethoxy-2-mercapto-1H-benzimidazole-----0.75kg/kg 3. Methanol-----2.95kg/kg 4. Isopropyl ether-----2.10kg/kg 5. Methylene chloride-----3.37kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

16	Case No.:1/16/82-ALC4/2007	Party Name:KE-TECHNICAL TEXTILES PVT.LTD.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Transferred
	HQ File :01/82/050/01697/AM07/	RLA File :02/24/040/00336/AM07/	Lic.No/Date:0210098474 23.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Polyester Yarn under para 4.7 of HBP. The Committee decided to transfer the case to DES-V as the export product pertains to Textile Sector.			

17	Case No.:2/16/82-ALC4/2007	Party Name:KE-TECHNICAL TEXTILES PVT.LTD.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Transferred
	HQ File :01/82/050/01698/AM07/	RLA File :02/24/040/00337/AM07/	Lic.No/Date:0210098475 23.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Tabular Bags under para 4.7 of HBP. The Committee decided to transfer the case to DES-V as the export product pertains to Textile Sector.			

18	Case No.:3/9/83-ALC1/2007	Party Name:VITAL HEALTHCARE PVT.LTD.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/83/050/01284/AM07/	RLA File :03/95/040/01405/AM07/	Lic.No/Date:0310421071 27.02.2007	Defer Date: 04.10.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Dihydroartemisinin under para 4.7 of HBP. The Committee decided to forward copy of application to PI Division for their comments. Accordingly, the case was deferred for six weeks.			

19	Case No.:3/12/83-ALC1/2007	Party Name:VITAL HEALTHCARE PVT.LTD.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/83/050/01304/AM07/	RLA File :03/95/040/01439/AM07/	Lic.No/Date:0310421462 28.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Artemether under para 4.7 of HBP. The Committee in the light of written comments forwarded by PI Division vide their U.O. No.35011/227/2005-PI-III dated 21.08.2007 decided to ratify the norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Artemether-----1Kg. Import item: Artemisinin-----1.50Kg./Kg. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

20	Case No.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/01804/AM07/	RLA File :03/94/040/01443/AM07/	Lic.No/Date:0310422972 13.03.2007	Defer Date:04.10.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Triomune 30 and 40 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.				

21	Case No.:4/10/82-ALC4/2007	Party Name:MSN PHARMACHEM PRIVATE LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/82/050/01807/AM07/	RLA File :09/24/040/00422/AM07/	Lic.No/Date:0910029669 14.03.2007	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Moxifloxacin Hcl under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2007-PI-III dated 17.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Moxifloxacin Hcl-----1Kg. Import items: 1. Pyridine-2,3-dicarboxylic acid-----4.86kg/kg 2. Acetic anhydride-----4.86kg/kg 3. Toluene-----3.22kg/kg 4. Ethyl acetate-----5.04kg/kg 5. Benzyl amine-----3.00kg/kg 6. Thionyl chloride-----4.28kg/kg 7. 5% Palladium carbon-----0.100kg/kg 8. D(-) Tartaric acid-----1.53kg/kg 9. Sodium hydroxide-----1.99kg/kg 10. Vitride-----4.99kg/kg 11. Acetonitrile-----0.76kg/kg 12. Triethylamine-----0.75kg/kg 13. Methylene chloride-----1.22kg/kg 14. 1-cyclopropyl-6,7-Difluoro-8-Methoxy-4-Oxo-1,4-dihydro-3-quinoline carboxylic acid (Gati acid)-----1.31kg/kg 15. Methanol-----2.86kg/kg				

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

22	Case No.: 4/12/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/01861/AM07/	RLA File :09/24/040/00500/AM07/	Lic.No/Date:0910029749 23.03.2007	Defer Date:04.10.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Fluoro Lactone 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.			

23	Case No.: 2/8/83-ALC1/2007	Party Name:AARTI INDUSTRIES LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/83/050/00110/AM08/	RLA File :03/94/040/01210/AM07/	Lic.No/Date:0310426693 13.04.2007	Defer Date: 18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Budesonide under para 4.7 of HBP. The Committee observed that the application of the firm was forwarded to Chemical Division of Min. of C&PC inadvertantly. The Committee decided to forward copy of application to PI Division for their comments. Accordingly, the case was deferred for four weeks.			

24	Case No.: 17/7/83-ALC1/2007	Party Name:R L FINE CHEM	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/83/050/00149/AM08/	RLA File :07/24/040/00017/AM08/	Lic.No/Date:0710051334 19.04.2007	Defer Date:18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Clomipramine 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.			

25	Case No.: 6/12/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
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HQ File :01/83/050/00170/AM08/	RLA File :03/94/040/00041/AM08/	Lic.No/Date:0310427432 20.04.2007	Defer Date 18.09.2007:
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Matformin 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 their Department and he sough deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.			

26	Case No.: 8/12/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status: Case Deferred
	HQ File :01/83/050/00205/AM08/	RLA File :22/24/040/00005/AM08/	Lic.No/Date:2210006683 26.04.2007	Defer Date: 04.10.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Clopidogrel Hydrogen Sulphate 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 their Department and he sough deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.			

27	Case No.: 9/12/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status: Case Approved
	HQ File :01/83/050/00206/AM08/	RLA File :22/24/040/00006/AM08/	Lic.No/Date:2210006684 26.04.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Clarithromycin Granules 27.5% (Suspension Grade) under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/159/2005-PI-III dated 18.10.2005 decided to ratify the norms on repeat basis as per details below or as applied by the firm whichever is lower. Export Product: Clarithromycin 27.5% (Suspension Grade)-----1Kg. Import items: 1. Clarithromycin-----0.2777kg/kg Or its raw material as per SION A-2263 on pro-rata basis. 2. Carbopol-----0.20kg/kg 3. HPMC Phthalate-----0.54kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

28	Case No.:16/12/83-ALC1/2007	Party Name:HONEST BIO-VET PVT. LTD	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/83/050/00272/AM08/	RLA File :08/24/040/00032/AM08/	Lic.No/Date:0810064691 07.05.2007	Defer Date: 18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Menadione Dimethyl Pyrimidinol Bisulphite (MPB 50%) under para 4.7 of HBP. The Committee decided to forward copy of application to PI Division for their comments. Accordingly, the case was deferred for four weeks.			

29	Case No.:6/4/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/00031/AM08/	RLA File :03/95/040/00095/AM08/	Lic.No/Date:0310428999 10.05.2007	Defer Date: 18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Diprosone Lotion 30ml 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.			

30	Case No.:3/16/82-ALC4/2007	Party Name:NIRAYU PRIVATE LIMITED,	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/00050/AM08/	RLA File :34/24/040/00034/AM08/	Lic.No/Date:3410018853 28.05.2007	Defer Date: 04.10.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Azithromycin Dihydrate (Micronised) under para 4.7 of HBP. The Committee decided to call for complete specification of import and exports item and manufacturing activity involved from the firm. Accordingly, the case was deferred for six weeks.			

31	Case No.:12/12/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Deferred
	HQ File :01/82/050/00069/AM08/	RLA File :34/24/040/00047/AM08/	Lic.No/Date:3410018988 15.06.2007	Defer Date: 04.10.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Azithromycin Dihydrate (Micronised) under para 4.7 of HBP.			

The Committee decided to call for complete specification of import and export item and manufacturing activity involved from the firm. Accordingly, the case was deferred for six weeks.

32	Case No.:4/16/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:16/82-ALC4/2007 21.08.2007	Status:Case Approved
	HQ File :01/82/050/00118/AM08/	RLA File :09/24/040/00144/AM08/	Lic.No/Date:0910030947 19.07.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 2-(6-Methoxy-2-Naphthyl)Propionic acid (DL-Acid) under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 21.08.2007 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: 2-(6-Methoxy-2-Naphthyl)Propionic acid (DL-Acid)---1Kg. Import items: 1. 2-Acetyl-6-Methoxy Naphthalene-----1.231kg/kg 2. Hydroxylamine Sulphate-----0.513kg/kg 3. Toluene-----0.68kg/kg 4. Carbon-----0.100kg/kg 5. Secondary Butanol-----1.02kg/kg 6. Mono chloro acetic acid-----0.492kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

Date:21.08.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

CASE NO. A- 501	M/S MISSION PHARMACEUTICAL LTD
M. No. 16/08	F.NO. 01/82/50/1614/AM07
DATED 21.8.2007	RLA NO.03/95/40/1249/AM07
	ADV. LIC.NO. 0310415874 DT. 15.1.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product erythromycin Ethyl Succinate Caps. under para 4.7 of HBP. Shri S.N. Shukla, General Manager of the company appeared before the Committee and explained his case. He stated that by mistake, they could not include the word 'equivalent' in the specification of the export product while in the DML, the word 'equivalent' has been included. The Committee after deliberations 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: Erythromycin Ethyl Succinate Capsules 250mg Each Capsule contains- Erythromycin Ethyl Succinate BP equivalent to Erythromycin 250mg. Import item: Erythromycin Ethyl Succinate BP/USP-----298.35 mg/capsule RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. A-502	M/S MANGALAM DRUGS & ORGANICES LTD
M. No. 16/08	F.NO. 01/83/50/826/AM08
DATED 21.8.2007	RLA NO.03/95/40/355/AM08
	ADV. LIC.NO. 0310437196 DT.
The Committee considered this case as per agenda for ratification of	

Norms for the Export Product ARTESUNATE under para 4.7 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/39/2007-PI-III dated 08.05.2007 in the case of M/S Calyx Chemicals & Pharmaceuticals Pvt. 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:

Artesunate-----1Kg.

Import items:

1. Artemisinin-----0.9259kg/kg
2. Sodium borohydride-----0.150kg/kg

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

CASE NO. A- 503	M/S MANGALAM DRUGS & ORGANICS LTD
M. No. 16/08	F.NO. 01/83/50/825/AM08
DATED 21.8.2007	RLA NO.03/95/40/362/AM07
	ADV. LIC.NO. 0310437194 DT. 23.07.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product AMODIAQUINE BASE under para 4.7 of HBP.	
The Committee decided to defer the case for four weeks.	

CASE NO. A- 504	M/S CADILA HEALTHCARE LTD
M. No. 16/08	F.NO. 01/82/50/132/AM08
DATED 21.8.2007	RLA NO.08/24/40/90/AM08
	ADV. LIC.NO. 0810065759 DT. 4.7.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product "ATENOLOL 25 MG TB" 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 their Department and he sought	

deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.

CASE NO. A- 505	M/S CADILA HEALTHCARE
M. No. 16/08	F.NO. 01/82/50/133/AM08
DATED 21.8.2007	RLA NO.08/24/40/91/AM08
	ADV. LIC.NO. 0810065758 DT.4.7.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product "CARVEDILOL 3.125 MG" 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

CASE NO. A- 506	M/S CIPLA LTD
M. No. 16/08	F.NO. 01/82/50/136/AM08
DATED 21.8.2007	RLA NO.03/94/40/383/AM08
	ADV. LIC.NO. 0310436156 DT. 13.07.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product "STAVIR 15 MG CAPSULES/STAVUDINE 15 MG" 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

CASE NO. A- 507	M/S CIPLA LTD
M. No. 16/08	F.NO. 01/82/50/134/AM08
DATED 21.8.2007	RLA NO.03/94/40/422/AM08
	ADV. LIC.NO. 0310437449 DT.26.07.2007
The Committee considered this case as per agenda for ratification of	

Norms for the Export Product "TENOFVIR DISPROXIL FUMARATE TABLETS 300 MG/TENVIR TABLETS" 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.

CASE NO. A- 508	M/S CIPLA LTD
M. No. 16/08	F.NO. 01/82/50/135/AM08
DATED 21.8.2007	RLA NO.03/94/40/391/AM08
	ADV. LIC.NO. 0310436717 DT. 19.07.2007

The Committee considered this case as per agenda for ratification of Norms for the Export Product "GCS DOG (POWDER) PER PACK 150 GRAMS" under para 4.7 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2005-PI-III dated 21.08.2007 decided to ratify norms on repeat basis as per details below or as applied by the firm whichever is lower.

Export product:

GCS Max Powder (pack size 500gms)

Import items:

1. Glucosamine hcl-----0.275kg/pack of 500gm.
2. Sodium chondroitin sulphate---0.09kg/pack of 500gm.
3. Manganese-----0.00122kg/pack of 500gm.
4. Ascorbic acid-----0.0159kg/pack of 500gm.

Export product:

GCS Dog Powder (pack 150gm)

Import items:

1. Glucosamine hcl-----0.0825kg/pack of 150gm.
2. Sodium chondroitin sulphate---0.027kg/pack of 150gm.
3. Manganese-----0.000366kg/pack of 150gm.
4. Ascorbic acid-----0.00477kg/pack of 150gm.

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

CASE NO. A- 509	M/S GLENMARK PHARMACEUTICAL LTD
M. No. 16/08	F.NO. 01/82/50/137/AM08
DATED 21.8.2007	RLA NO.03/94/40/412/AM08
	ADV. LIC.NO. 0310437384 DT. 25.07.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product "ETHOXY CARBONYLALANINE 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

CASE NO. A- 510	M/S ALKALI METALS LTD
M. No. 16/08	F.NO. 01/83/50/211/AM08
DATED 21.8.2007	RLA NO.09/24/40/375/AM07
	ADV. LIC.NO. 0910030113 DT. 27.04.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product 2,6-DIAMINO PYRIDINE under para 4.7 of HBP. The Committee decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.	

CASE NO. A- 511	M/S AARTI DRUGS LTD
M. No. 16/08	F.NO. 01/83/50/745/AM08
DATED 21.8.2007	RLA NO.03/94/40/292/AM08
	ADV. LIC.NO. 0310433522 DT. 22.06.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product CIPROFLOXACIN HYDROCHLORIDE under para 4.7 of HBP.	

The Committee in light of earlier decision taken in its 11/08 meeting held on 17.07.2007 vide Case No.20/46/87-ALC1/2006 decided to ratify the norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.

Export product

Ciprofloxacin Hcl-----1 Kg.

Import items

1. 2-(2,4-dichloro-5-fluoro-benzoyl)-3-cyclopropylamino-Acylic-Ethylester -----0.906kg/kg
2. Dimethyl carbonate-----Not required in the process
3. Sodium Hydride-----Not required in the process
4. Toluene-----0.77kg/kg
5. Dimethyl formamide-----Not required in the process
6. Acetic Acid-----Not required in the process
7. Cycloropropyl amine-----Not required in the process
8. Caustic Soda flake-----0.515kg/kg
9. Piperazine-----0.407kg/kg
10. Butanol-----0.275kg/kg
11. Liq. Ammonia-----Not required in the process
12. Methanol-----1.05kg/kg.

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

CASE NO. A- 512	M/S GLENMARK PHARMACEUTICAL LTD
M. No. 16/08	F.NO. 01/82/50/772/AM08
DATED 21.8.2007	RLA NO.03/94/40/345/AM08
	ADV. LIC.NO. 0310436567 DT. 18.07.2007

The Committee considered this case as per agenda for ratification of Norms for the Export Product ETHOXY CARBONYLALANINE (PERINDOPRIL ERBUMINE STAGE D) 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 their Department and he sought

deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.

CASE NO. A- 513	M/S ANJAN DRUGS PVT LTD
M. No. 16/08	F.NO. 01/83/50/701/AM08
DATED 21.8.2007	RLA NO.04/24/40/109/AM08
	ADV. LIC.NO. 0410090236 DT. 12.07.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product MAGNESIUM VALPROATE(OR) VALPROATE MAGNESIUM under para 4.7 of HBP. The Committee decided to forward the application to PI Division for their comments. Accordingly, the case was deferred for six weeks.	

CASE NO. A- 514	M/S AMOLI ORGANICES PVT LTD
M. No. 16/08	F.NO. 01/83/50/158/AM08
DATED 21.8.2007	RLA NO.03/94/40/04/AM08
	ADV. LIC.NO. 0310427363 DT.20.04.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product PYRODIXINE ACETONIDE HCL under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/124/2006-PI-III dated 14.08.2006 decided to ratify norms on repeat basis as per details below or as applied by the firm whichever is lower. Export product: Pyridoxine Acetonide Hcl-----1Kg. Import items: 1. Pyridoxine Hcl-----0.99kg/kg 2. Diglyme-----0.41kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. A- 515	M/S AUROBINDO PHARMA LTD
M. No. 16/08	F.NO. 01/87/50/985/AM07
DATED 21.8.2007	RLA NO.09/24/40/261/AM07
	ADV. LIC.NO. 0910029298 DT. 12.02.2007
The Committee considered this case as per agenda for ratification of Norms for the 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

CASE NO. A- 516	M/S GLENMARK PHARMACEUTICAL LTD
M. No. 16/08	F.NO. 01/82/50/108/AM08
DATED 21.8.2007	RLA NO.03/94/40/16/AM08
	ADV. LIC.NO. 0310426673 DT. 13.04.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product NATEGLINIDE under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/24/2006-PI-III dated 21.03.2006 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: Nateglinide-----1Kg. Import items: 1. Trans-4-Isopropylcyclohexyl Carboxylic Acid-----0.69kg/kg 2. D-Phenylalanine-----0.70kg/kg 3. Methylene chloride/Methylene Dichloride/MDC—2.17kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. A- 517	M/S SUN PHARMA INDUSTRIES
M. No. 16/08	F.NO. 01/82/61/05/AM08
DATED 21.8.2007	RLA NO.03/24/40/43/AM01
The Committee considered this case as per agenda for ratification of Norms for the Export Product CLOMIPRAMINE HCL under para 4.4.2 of HBP. The Committee observed that the firm had submitted the application under para 4.4.2 of HBP during 2000-01, but fixation of norms are pending. The Committee, therefore, decided to call for a detailed report in the matter from the office of Jt. DGFT, Mumbai alongwith the correspondence, if any, exchanged between Hqrs. and RLA. The case was accordingly deferred for six weeks.	

CASE NO. A- 518	M/S SUN PHARMA INDUSTRIES
M. No. 16/08	F.NO. 01/82/61/04/AM08
DATED 21.8.2007	RLA NO.03/24/40/187/AM01
The Committee considered this case as per agenda for ratification of Norms for the Export Product CLOMIPRAMINE HCL under para 4.4.2 of HBP. The Committee observed that the firm had submitted the application under para 4.4.2 of HBP during 2000-01, but fixation of norms are pending. The Committee, therefore, decided to call for a detailed report in the matter from the office of Jt. DGFT, Mumbai alongwith the correspondence, if any, exchanged between Hqrs. and RLA. The case was accordingly deferred for six weeks.	

CASE NO. A- 519	M/S RA CHEM PHARMA LTD
M. No. 16/08	F.NO. 01/82/50/1149/AM07
DATED 21.8.2007	RLA NO.09/24/40/432/AM07
	ADV. LIC.NO. 0910029095 DT. 19.01.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product MEBEVERINE HCL under para 4.7 of HBP.	

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/93/2004-PI-III dated 09.08.2004 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:

Mebeverine Hcl-----1Kg.

Import items:

1. 2-Chloromethyl Propionate-----0.66kg/kg
2. Vanillin-----0.92kg/kg
3. 1,4-Dichloro butane-----0.84kg/kg
4. MIBK-----0.51kg/kg
5. Chloroform-----0.98kg/kg
6. Pot. Permanganate-----3.07kg/kg

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

CASE NO. A- 520	M/S IPCA LABS LTD
M. No. 16/08	F.NO. 01/82/61/03/AM08
DATED 21.8.2007	RLA NO.03/95/40/1395/AM07

The Committee considered this case as per agenda for ratification of Norms for the Export Product MOMETASONE FUROATE under para 4.4.2 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/179/2006-PI-III dated 21.08.2007 in the case of M/S Avik Pharmaceutical 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:

Mometasone Furoate-----1Kg.

Import items:

1. 17 Alpha, 21 Dihydroxy 9 beta, 11 beta oxido-16

Alpha Methyl Pregna-1,4-Diene,3,20-Dione(Epoxyde)----1.04kg/kg

2. 4 Dimethyl Amino Pyridine----No justification for utilization of the item in process details. Hence not allowed.

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

CASE NO. A- 521	M/S NICHOLAS PIRAMAL INDIA LTD
M. No. 16/08	F.NO. 01/82/50/138/AM08
DATED 21.8.2007	RLA NO.03/95/40/389/AM08
	ADV. LIC.NO. 0310437508 DT. 26.07.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product "HYDROCARE TABLETS (CONTACT LENS CLEANING TABLETS)" under para 4.7 of HBP. The Committee observed that at the time of making application for issue of Advance Authorization, it is not clear whether the item of import/export is biotechnology item and on the basis of declaration given by the firm in terms of para 4.7 of HBP (Vol.I), R.As issue authorizations. In this case, the firm has given a declaration that the item of import/export are not biotechnology items. With a view to ascertain the same, the Committee decided to refer a copy of application to Department of Biotechnology for their comments and deferred the case for four weeks.	

CASE NO. A- 522	M/S MEDRIECH LTD
M. No. 16/08	F.NO. 01/82/50/1790/AM07
DATED 21.8.2007	RLA NO.07/24/40/718/AM07
	ADV. LIC.NO. 0710049763 DT. 24.01.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product PARACETAMOL 450 MG 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.

CASE NO. A- 523	M/S METROCHEM API (P) LTD
M. No. 16/08	F.NO. 01/83/50/145/AM08
DATED 21.8.2007	RLA NO.09/24/40/436/AM07
	ADV. LIC.NO. 0910029425 DT. 22.09.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product LANSOPRAZOLE PELLETS 11.2% under para 4.7 of HBP. The Committee was informed that the norms for this export product with 8.5% strength are available at S.No.A-1926 and the firm has requested for Lansoprazole Pellets of 11.2% strength. The Committee in consultation with the representative of technical authority present in the meeting decided to ratify norms under para 4.7 of HBP as per SION A-1926 on pro-rata basis or as applied by the firm which ever is lower. RLA concerned may calculate the quantities of inputs on pro-rata basis and may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. A- 524	M/S JUBILANT ORGANOSYS LTD
M. No. 16/08	F.NO. 01/83/50/127/AM08
DATED 21.8.2007	RLA NO.05/24/40/41/AM08
	ADV. LIC.NO. 0510202622 DT. 17.04.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product 3,4 DIHYDRO-4-OXO-6-ACETYLOXY-7-METHOXYQUINAZOLINE under para 4.7 of HBP.	

The Committee observed that the firm themselves have stated that the Export Product is a new fine chemical and not Bulk Drugs. It was, therefore, decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.

CASE NO. A- 525	M/S NGL FINE CHEM LTD
M. No. 16/08	F.NO. 01/83/162/449/AM07
DATED 21.8.2007	RLA NO.03/95/40/573/AM07
The Committee considered this case as per agenda for ratification of Norms for the Export Product "ISOMETAMIDIUM CHLORIDE HYDROCHLORIDE under para 4.7 of HBP. The Committee observed that the firm was requested to furnish consumption data certified by Central Excise Authority called for vide letter dated 02.08.2007, but the same has not been received. The Committee, therefore, decided to defer the case for two weeks.	

CASE NO. A- 526	M/S LEE PHARMA LTD
M. No. 16/08	F.NO. 01/83/50/233/AM08
DATED 21.8.2007	RLA NO.09/24/40/05/AM08
	ADV. LIC.NO. 0910030159 DT. 3.5.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product 5-(DIFLUORO METHOXY)-2-{{3,4-DIMETHOXY-2-PYRIDINYL} METHYL} THIO}- -1H BENZIMIDAZOLE (PENTAPRAZOLE SULPHIDE) under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 17.05.2007 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: (5- DIFLUORO Methoxy)-2-[3,4-Dimethoxy-2-Pyridinyl) Methyl}Thio]-1H-Benzimidazole (Pentaprazole Sulphide)-----1Kg.	

Import items:

1. 2-chloromethyl-3,4-dimethoxy-pyridine Hcl-----0.75kg/kg
2. 2,5-difluoromethoxy-2-mercapto-1H-benzimidazole-----0.75kg/kg
3. Methanol-----
-2.95kg/kg
4. Isopropyl ether-----
-2.10kg/kg
5. Methylene chloride-----3.37kg/kg

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

CASE NO. B- 222	M/S MISSION PHARMA LTD
M. No. 16/08	F.NO. 01/82/50/1585/AM06
DATED 21.8.2007	ADV. LIC.NO. 0310368720 DT. 24.2.2006

The Committee considered this case as per agenda for ratification of Norms for the Export Product ERYTHROMYCIN ETHYL SUCCINATE CAPSULES 250MG(METCINATEES 250) under para 4.7 of HBP.

Shri S.N. Shukla, General Manager of the company appeared before the Committee and explained his case. He stated that by mistake, they could not include the word 'equivalent' in the specification of the export product while in the DML, the word 'equivalent' has been included.

The Committee after patient hearing 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:

Erythromycin Ethyl Succinate Capsules 250mg
Each Capsule contains-
Erythromycin Ethyl Succinate BP equivalent to
Erythromycin 250mg.

Import item:

Erythromycin Ethyl Succinate BP/USP-----298.35 mg/capsule

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

CASE NO. B-223	M/S MISSION PHARMA LTD
M. No. 16/08	F.NO. 01/82/50/595/AM06
DATED 21.8.2007	ADV. LIC.NO. 0310345871 DT. 2.9.2005

The Committee considered this case as per agenda for ratification of Norms for the Export Product under para 4.7 of HBP.

Shri S.N. Shukla, General Manager of the company appeared before the Committee and explained his case. He stated that by mistake, they could not include the word 'equivalent' in the specification of the export product while in the DML, the word 'equivalent' has been included.

The committee after patient hearing 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:

Erythromycin Ethyl Succinate Oral Suspension BP 125mg/5ml, 100ml Bottle
Each 5ml after reconstitutions contains-
Erythromycin Ethyl Succinate BP equivalent to
Erythromycin 125mg.

Import item:

Erythromycin Ethyl Succinate -----3.07125gm/100ml Bottle

Export product:

Erythromycin Ethyl Succinate Capsules 250mg
Each Capsule contains-
Erythromycin Ethyl Succinate BP equivalent to
Erythromycin 250mg.

Import item:

Erythromycin Ethyl Succinate BP/USP-----298.35 mg/capsule

Export product:

Erythromycin Stearate Oral Suspension 250mg/5ml, 100ml Bottle
Each 5ml after reconstitutions contains-
Erythromycin Stearate BP equivalent to
Erythromycin 250mg.

Import item:

Erythromycin Stearate BP-----7.2975gm/100ml Bottle

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

CASE NO. B- 224	M/S IPCA LABORATORIES LTD
M. No. 16/08	F.NO. 01/82/50/661/AM07
DATE 21.08.2007	

The Committee considered this case as per agenda for ratification of Norms for the Export Product under para 4.7 of HBP.

The Committee considered this case as per agenda for correction of the description of import and export items.

The Committee decided to allow correction in the description of import and export items after due verification as per details below;

Sl.No.	Advance licence No. 7 date	Description of item as per earlier decision of NC	Correction allowed in the description
1.	0310392753 dated 2.8.06	Import item: Allpha Naphthol	Import item: Alpha Naphthol
		Import item: Epichlorohydrine	Import item: Epichlorohydrin
2.	0310370771 dated 9.3.06	Import item: Di-p-tolyl tartaric acid (DPTTA)	Import item: Di{P-Toluoyl-L-Tartaric acid} (DPTTA)
		Import item: Methylene chloride	Import item: Methylene Di Chloride
3.	0310240505	Import item:	Import item:

	dated 8.12.03	6-Methoxy-2Naphthaldehyde (6MNA)	6-Methoxy-2-Naphthaldehyde (6MNA)
RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

CASE NO. B-225	M/S LIFE LINE DRUGS AND INTERMEDIATES
M. No. 16/08	F.NO. 01/82/50/1087/AM05
DATED 21.8.2007	RLA NO.03/24/40/1305/AM05
	ADV. LIC.NO. 0310289915 DT.6.9.2004
The Committee considered this case as per agenda for ratification of norms for the export product 9-Fluoro-11 Beta-17-Dihydroxy-16 Beta-Methyl-3,20 Dioxopregna-1,4-Diene-21,-YL-Actate under para 4.7 of HBP. The Committee observed that the Advance licence was issued on 06.09.2004 and the Committee had rejected the case vide letter dated 02.03.2005 for non-submission of information/documents by the firm which had been called for from the firm vide letter dated 29.11.2004. The Committee observed that the firm has represented on 11.06.2007 against the rejection made on 02.03.2005 i.e. nearly after 2 years & 3 months. The Committee, therefore, decided to maintain status quo. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. B-226	M/S MEGA FINE LTD
M. No. 16/08	F.NO. 01/82/50/557/AM04
DATED 21.8.2007	ADV. LIC.NO. 0310224423 DT. 12.9.2003
The Committee considered this case as per agenda for correction in the description of import/export items. The Committee decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.	

CASE NO. B-227	M/S NICHOLAS PIRAMAL INDIA LTD
M. No. 16/08	F.NO. 01/83/50/15/AM08
DATED 21.8.2007	RLA NO.04/53/40/10/AM01
	ADV. LIC.NO. 0410006197 DT.24.05.2000
The Committee considered this case as per agenda for ratification of Norms for the Export Product under para 4.7 of HBP. The Committee observed that the issue regarding realization of less amount than the GR value pertains to Policy Division. The Committee, therefore, decided to refer the case to Policy Division. As regards modification of norms ratified by NC under para 7.5 of HBP, the committee decided to maintain status quo as the licence is quite old i.e. issued on 24.05.2000. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

CASE NO. B- 228	M/S BAKUL PHARMA PVT. LTD
M. No. 16/08	F.NO. 01/82/50/1193/AM06
DATED 21.8.2007	
Adv.lic.No. 0310353064 dt.21.10.05 0310365661 dt.2.2.06 0310358545 dt.6.12.05	
The Committee considered this case as per agenda for ratification of Norms for the Export Product Theophylline micronized (>75 microns) under para 4.7 of HBP. The Committee in light of earlier decision taken in its13/08 meeting held on 31.07.2007 vide case No.A-359 in the case of M/S Wockhardt Ltd. decided to ratify norms as per details below or as applied by the firm whichever is lower.	

Export product:
Theophylline micronized (>75 microns)-----1Kg.

Import item:
Theophylline (200+/- 10% microns)-----1.01kg/kg

RLA concerned may take further necessary action as per above decision of Norms committee.

CASE NO. B-229	M/S AUROBINDO PHARMA LTD
M. No. 16/08	F.NO. 01/87/50/917/AM06
DATED 21.8.2007	RLA NO.09/24/40/286/AM06
	ADV. LIC.NO. 0910024429 DT.26.10.2005
The Committee considered this case as per agenda for ratification of Norms for the Export Product "7-AMINO-3-VINYL CEPHALOSPORANIC ACID "[7-AVNA]" under para 4.7 of HBP. The Committee decided to forward copy of application to PI Division for their comments. Accordingly, the case was deferred for four weeks.	

CASE NO. B-230	M/S ALKEM LABORATORIES LTD
M. No. 16/08	F.NO. 01/82/50/471/AM04
DATED 21.8.2007	RLA NO.03/24/40/683/AM04
	ADV. LIC.NO. 0310219090 DT. 16.08.2003
The Committee considered this case as per agenda for ratification of Norms for the Export Product CEFTAZIDIME FOR INJECTION USP I GM USP under para 4.7 of HBP. The Committee in light of earlier decision taken in its 2/08 meeting held on 16.05.2007 vide case No.A042 (Minutes enclosed with the agenda) decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product Ceftazidime for injection -----1gm vial.	

Import item

Ceftazidime Pentahydrate-----1.32gm per vial

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

CASE NO. B- 231	M/S MAKSON INDS.PVT. LTD
M. No. 16/08	F.NO. 01/82/50/744/AM06
DATED 21.8.2007	RLA NO.03/95/40/812/AM06
	ADV. LIC.NO. 0310350412 DT. 5.10.2005
The Committee considered this case as per agenda for ratification of Norms for the Export Product "VICKS VAPORUB IN PACKS" under para 4.7 of HBP. The Committee decided to defer the case for four weeks for want of comments of DC(SSI).	

CASE NO. B- 232	M/S MSN PHARMA PVT. LTD
M. No. 16/08	F.NO. 01/82/50/1233/AM07
DATED 21.8.2007	RLA NO.09/24/40/215/AM07
	ADV. LIC.NO. 0910028088 DT. 3.11.2006
The Committee considered this case as per agenda for ratification of Norms for the Export Product MOXIFLOXACIN HYDROCHLORIDE API under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2007-PI-III dated 17.08.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export Product: Moxifloxacin Hcl-----1Kg.	

Import items:

1. Pyridine-2,3-dicarboxylic acid-----	4.86kg/kg
2. Acetic anhydride-----	4.86kg/kg
3. Toluene-----	3.22kg/kg
4. Ethyl acetate-----	5.04kg/kg
5. Benzyl amine-----	3.00kg/kg
6. Thionyl chloride-----	4.28kg/kg
7. 5% Palladium carbon-----	0.100kg/kg
8. D(-) Tartaric acid-----	1.53kg/kg
9. Sodium hydroxide-----	1.99kg/kg
10. Vitride-----	4.99kg/kg
11. Acetonitrile-----	0.76kg/kg
12. Triethylamine-----	0.75kg/kg
13. Methylene chloride-----	1.22kg/kg
14. 1-cyclopropyl-6,7-Difluoro-8-Methoxy-4-Oxo-1,4-dihydro-3-quinoline carboxylic acid (Gati acid)-----	1.31kg/kg
15. Methanol-----	2.86kg/kg

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

CASE NO. B-233	M/S INTAS PHARMA LTD
M. No. 16/08	F.NO. 01/82/50/1239/AM07
DATED 21.8.2007	RLA NO.08/24/40/162/AM07
	ADV. LIC.NO. 0810059348 DT. 7.09.2006
The Committee considered this case as per agenda for ratification of Norms for the Export Product Azithromycin Tablets 250mg and 500mg under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 14.08.2007 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: Azithromycin tablets 250mg.	

Import items:

Azithromycin monohydrate (average
water content NLT 5%)-----268.42mg/tablet

Export product:

Azithromycin tablets 500mg.

Import items:

Azithromycin monohydrate (average
water content NLT 5%)-----536.84mg/tablet

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

CASE NO. B- 234	M/S SUN PHARMACEUTICAL INDUSTRIES	
M. No. 16/08	F.NO. 01/87/50/804/AM06	
DATED 21.8.2007	RLA NO.03/95/40/788/AM06	
	ADV. LIC.NO. 0310350153 DT. 3.10.2005	
The Committee considered this case as per agenda for ratification of Norms for the Export Product PENTOXIFYLINE PURE under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/267/2004-PI-III dated 28.04.2007 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: Pentoxifylline BP/PH.EUR (Assay by HPLC 98% to102% on anhydrous basis)-----1Kg. Import items:		
Sl.No.	Description of import item	Quantity allowed
1.	3,7,dimethyl-1(5-oxohexyl)-3,7 hydro-1-H-Purine-2,6-dione(crude),assay not	1.02kg/kg.

	more than 97.5% by potentiometer on anhydrous basis	
2.	Methylene chloride	1.00kg/kg

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

CASE NO. B- 235	M/S SUN PHARMACEUTICAL INDUSTRIES
M. No. 16/08	F.NO. 01/87/50/660/AM06
DATED 21.8.2007	RLA NO.03/95/40/656/AM06
	ADV. LIC.NO. 0310346213 DT. 5.09.2005

The Committee considered this case as per agenda for ratification of Norms for the Export Product METOPROLOL TARTRATE under para 4.7 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/267/2004-PI-III dated 21.08.2007 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:
Metoprolol Tartarate EP/BP-----1Kg.

Import item:

Sl.No.	Description of import item	Quantity allowed
1.	BIS[(2-RS)-1-4-(2 Methoxy ethyl) Phenoxy]-3-[(1-methyl) amino] propan-2-ol-2,3-dihydroxy butanedioate crude (Assay not more than 97.5% by potentiometer)on anhydrous basis	1.02kg/kg

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

CASE NO. C- 09	M/S S.M.HERBALS PVT. LTD
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M. No.	16/08	F.NO.	01/82/162/443/AM08
DATED	21.8.2007		
The Committee considered this case as per agenda for fixation of SION for the Export Product CAMPTOTHECIN. The Committee decided to forward copy of application to Deptt. of Ayush for their comments. Accordingly, the case was deferred for six weeks.			

CASE NO.	C-10	M/S	IPCA LABS LTD
M. No.	16/08	F.NO.	01/82/50/1004/AM07
DATED	21.8.2007		
The Committee considered this case as per agenda for amendment in the description of Export Product PROPRANOLOL HYDROCHLORIDE under para 4.7 of HBP. The Committee decided to allow amendment in the description of export product from Propranolol Hydrochloride to Propranolol Hydrochloride. The other decision taken by NC will remain the same.			

Clarification sought by CBI, Gandhi Nagar regarding SION at Sl.No.A-1945	
The case was considered by the Committee as per agenda. The representative of PI Division present in the meeting informed the Committee that the issue will take time for finalization. The Committee, therefore, decided to defer the case for two weeks.	