

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

Para 4.7 Officewise Statement

MEETING NUMBER : 14/82-ALC4/2007 **MEETING DATE** : 07.08.2007

1	Case No.: 1/6/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Deferred
	HQ File :01/82/050/00389/AM04/	RLA File :09/24/040/00068/AM04/	Lic.No/Date:0910015288 05.08.2003	Defer Date:18.09.2007
	Decision :The Committee considered the case as per agenda for ratification of norms of the export product under para 4.7 of HBP. The Committee decided to call for complete set of application alongwith technical details as per annexure, copy of DML and copy of Advance licence from the firm. The Case was accordingly deferred for six weeks.			

2	Case No.: 2/6/82-ALC4/2007	Party Name:HINDUSTAN ANTIBIOTICS LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Deferred
	HQ File :01/82/050/00432/AM04/	RLA File :31/80/040/00163/AM04/	Lic.No/Date:3110012090 08.08.2003	Defer Date:18.09.2007
	Decision :The Committee considered the case as per agenda for ratification of norms of the export product 'Tables I.E. Potassium Phenoxymethyl Pencillin Tablets BP 250mg under para 4.7 of HBP. The Committee to call for complete set of application alongwith technical details as per annexure and copy of DML from the firm. The case was accordingly deferred for six weeks.			

3	Case No.: 2/35/82-ALC1/2004	Party Name:MADHUR PHARMA & RESEARCH LABORATORIES PVT.LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Deferred
	HQ File :01/82/050/01467/AM05/	RLA File :07/24/040/00492/AM05/	Lic.No/Date:0710034246 23.11.2004	Defer Date:18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms of the export product Herpasil Capsules and Stimmune Capsules under para 4.7 of HBP. The Committee decided to remind Department of Ayush demi officially and to call for the complete set of application alongwith technical details as per annexure, copy of DML and copy of advance licence from the firm. The case was accordingly deferred for six weeks.			

4	Case No.:5/37/82-ALC1/2005	Party Name:FDC LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	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 of the export product Econazole Nitrate BP/JP/USP under para 4.7 of HBP.			
	The Committee decided to call for complete set of application alongwith the technical details as per annexure and copy of DML from the firm. After receipt of the documents from the firm, the case may be put up in NC after six weeks.			

5	Case No.:10/47/83-ALC1/2005	Party Name:UNIMARK REMEDIES LIMITED.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	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 of 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/etyl potassium dane salt			

OR

- 7(a). D(-) para hydroxyl 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.

6	Case No.:1/35/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/83/050/00557/AM07/	RLA File :09/24/040/00190/AM07/	Lic.No/Date:0910027254 22.08.2006	Defer Date:18.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms of the export product Cefadroxil under para 4.7 of HBP. The Committee decided to forward the complete set of application to the Technical Authority for their comments. The case was accordingly deferred for six weeks.			

7	Case No.:12/28/87-ALC1/2006	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Approved
	HQ File :01/87/050/00482/AM07/	RLA File :04/24/040/00047/AM07/	Lic.No/Date:0410083795 25.08.2006	Defer Date:
	Decision : The Committee considered the case as per agenda for ratification of norms of the export product 2-Methyl Mercapto Phenothiazine 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 07.08.2007 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: 2-methyl Mercapto Phenothiazene-----1Kg. Import item: 3-methyl Mercapto Aniline-----2.36kg/kg			

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

8	Case No.: 2/33/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Approved
	HQ File :01/83/050/00646/AM07/	RLA File :09/24/040/00220/AM07/	Lic.No/Date:0910027505 11.09.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms of the export product Methyl Alpha-(4,5,6,7-Tetrahydro-5-Thieno) 3,2-C) Pyridyl)(2 Chlorophenyl) Acetate Hcl (CPG-20) under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/125/2006-PI-III dated 15.09.2006 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: Methyl Alpha-(4,5,6,7-Tetrahydro-5-Thieno) 3,2-C) Pyridyl)(2 Chlorophenyl) Acetate Hcl (CPG-20) -----1Kg. Import item: 1. N-bromo succinamide-----0.81kg/kg 2. 4,5,6,7 Tetrahydro theino) 3,2-C Pyridine Hcl-----0.985kg/kg 3. MIBK-----3.75kg/kg 4. IPA-----0.50kg/kg RLA concerned may take further necessary action as per the above decision of Norms Committee.			

9	Case No.: 17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Deferred
	HQ File :01/82/050/00911/AM07/	RLA File :03/94/040/00615/AM07/	Lic.No/Date:0310399069 12.09.2006	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Terbinafine Hydrochloride Tablets 250mg 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.			

10	Case No.:11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:14/82-ALC4/2007 07.08.2007	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 this case as per agenda for fixation of I/O Norms for the Export Product Senega Soft Extract under para 4.7 of HBP. The Committee decided to remind Department of Ayush demi officially for their comments. The case was accordingly deferred for six weeks.			

11	Case No.:8/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/00998/AM07/	RLA File :09/24/040/00214/AM07/	Lic.No/Date:0910027658 25.09.2006	Defer Date:21.08.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Moxifloxacin 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.			

12	Case No.:9/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/00999/AM07/	RLA File :09/24/040/00177/AM07/	Lic.No/Date:0910027659 25.09.2006	Defer Date:21.08.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Moxifloxacin 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.			

13	Case No.:23/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/01100/AM07/	RLA File :03/94/040/00702/AM07/	Lic.No/Date:0310402829 06.10.2006	Defer Date:18.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product 1-Phenyl Proponolamine Hcl (L-Norephedrine Hcl under para 4.7 of HBP. The Committee decided to call for the technical details as per annexure from the firm. The Case was accordingly deferred for six weeks.			

14	Case No.:24/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/01101/AM07/	RLA File :03/94/040/00703/AM07/	Lic.No/Date:0310402830 06.10.2006	Defer Date:18.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product L-Norephedrine Base under para 4.7 of HBP. The Committee decided to call for the technical details as per annexure from the firm. The Case was accordingly deferred for six weeks.			

15	Case No.:27/30/83-ALC1/2006	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Approved
	HQ File :01/83/050/00769/AM07/	RLA File :07/24/040/00428/AM07/	Lic.No/Date:0710047728 06.10.2006	
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Aceclofenac EP under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/264/2006-PI-III dated 18.04.2007 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: Aceclofenac BP-----1Kg. Import items: 1. Diclofenec Sodium-----1.11kg/kg 2. Tertiary Butanol-----0.61kg/kg 3. IPA-----3.77kg/kg RLA concerned may take further necessary action as per the above decision of Norms Committee.			

16	Case No.:29/36/83-ALC1/2006	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/83/050/00841/AM07/	RLA File :03/95/040/00897/AM07/	Lic.No/Date:0310406100 31.10.2006	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Moxifloxacin 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.			

17	Case No.: 31/36/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Approved
	HQ File :01/83/050/00857/AM07/	RLA File :09/24/040/00291/AM07/	Lic.No/Date:0910028095 03.11.2006	Defer Date:
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Clonazepam under para 4.7 of HBP. The Committee decided to ratify the norms under para 4.7 of HBP as per SION at Sl.No.A-3358 or as applied by the firm whichever is lower. RLA concerned may take further necessary action as per the above decision of Norms Committee.			

18	Case No.: 4/43/83-ALC1/2006	Party Name:SREENIVASA PHRAMA PVT LTD.	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Deferred
	HQ File :01/83/050/00942/AM07/	RLA File :09/24/040/00163/AM07/	Lic.No/Date:0910028292 21.11.2006	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Cis-2-Bromo Methyl)-2-(2,4-Dichloro Phenyl)-4-Methane Sulphonyl methyl-1, 3-dioxalane (Cis-Bromo 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.			

19	Case No.: 12/41/80-ALC2/2006	Party Name:BRAWN LABORATORIES LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Withdrawn
	HQ File :01/80/050/01003/AM07/	RLA File :05/24/040/00737/AM07/	Lic.No/Date:0510195559 04.12.2006	
	Decision : Withdrawn as the case has already been approved in the NC Meeting No.12/08 dated 27.07.2007.			

20	Case No.: 11/46/82-ALC1/2006	Party Name:BIOLOGICAL E LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status: Case Approved
	HQ File :01/82/050/01533/AM07/	RLA File :09/24/040/00409/AM07/	Lic.No/Date:0910028883 04.01.2007	Defer Date:
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Noscapine Bulk under para 4.7 of HBP. The Committee perused the details furnished by the firm in their letter dated 6.6.07 and in consultation with the representative of PI present in the meeting 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:
Noscapine Bulk-----1Kg.

Import item:
Noscapine Crude-----1.01kg/kg

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

21	Case No.:7/47/83-ALC1/2006	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Rejected
	HQ File :01/83/050/01170/AM07/	RLA File :05/24/040/00848/AM07/	Lic.No/Date:0510198449 25.01.2007	
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Cefpodoxime Proxetil under para 4.7 of HBP. The Committee noted that the firm has not submitted the technical details alongwith the application and therefore, it is not possible for the Committee to ratify the norms without technical details. The Committee, accordingly, decided to reject the case. RLA concerned may take further necessary action including cancellation of advance licence under para 4.7 of HBP.			

22	Case No.:6/50/87-ALC1/2006	Party Name:ALKEM LABORATORIES LTD.,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/87/050/00967/AM07/	RLA File :03/94/040/01200/AM07/	Lic.No/Date:0310418737 07.02.2007	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Amoxycillin Clavulanate Potassium Tablet 375mg, 625mg and 1000mg 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.			

23	Case No.:4/1/83-ALC1/2007	Party Name:VIJAY PERFUMES PVT.LTD.	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/83/050/01214/AM07/	RLA File :03/95/040/01118/AM07/	Lic.No/Date:0310418795 08.02.2007	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product N-Methyl Benzothiazene Methyl Ester 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.

24	Case No.: 1/10/82-ALC4/2007	Party Name:HAFKINE BIO PHARMACEUTICAL CORPN LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/01645/AM07/	RLA File :03/94/040/01208/AM07/	Lic.No/Date:0310419601 14.02.2007	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Oral Polio Vaccine (OPV) under para 4.7 of HBP. The Committee decided to forward complete set of application to Department of Bio-technology for their comments. Accordingly, the case was deferred for four weeks.			

25	Case No.: 3/2/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/01756/AM07/	RLA File :09/24/040/00382/AM07/	Lic.No/Date:0910029552 06.03.2007	Defer Date:04.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product 2-(6-Methoxy-2-naphthyl)propionic acid (DL-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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.			

26	Case No.: 7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:14/82-ALC4/2007 07.08.2007	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:21.08.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Triomune 30/Lamivudine, Stavudine and Nevirapine 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.			

27	Case No.: 4/10/82-ALC4/2007	Party Name:MSN PHARMACHEM	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case
----	------------------------------------	---------------------------	--	--------------------

	HQ File :01/82/050/01807/AM07/	PRIVATE LIMITED RLA File :09/24/040/00422/AM07/	Lic.No/Date:0910029669 14.03.2007	Deferred Defer Date:21.08.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Moxifloxacin 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.			

28	Case No.:5/10/82-ALC4/2007	Party Name:GLAXOSMITHKLINE PHARMACEUTICALS LIMITED,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/01887/AM07/	RLA File :03/94/040/00324/AM06/	Lic.No/Date:0310424628 27.03.2007	Defer Date:18.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Betamethasone Di-Sodium Phosphate 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.			

29	Case No.:1/14/82-ALC4/2007	Party Name:TTK LIG LIMITED	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Transferred to Different Section
	HQ File :01/82/050/00108/AM08/	RLA File :04/24/040/00107/AM08/	Lic.No/Date:0410090218 09.07.2007	Defer Date:
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Durex Play Longer under para 4.7 of HBP. The Committee decided to transfer the case to DES-VIII as the exports product pertains to Plastic Sector.			

30	Case No.:2/14/82-ALC4/2007	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:14/82-ALC4/2007 07.08.2007	Status:Case Deferred
	HQ File :01/82/050/00116/AM08/	RLA File :22/24/040/00018/AM08/	Lic.No/Date:2210006897 17.07.2007	Defer Date:18.09.2007
	Decision : The Committee considered this case as per agenda for fixation of I/O Norms for the 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.			

Date:08.08.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Minutes of the Norms Committee Meeting No.14/08 held on 07.08.2007 under the Chairmanship of Shri Sanjay Rastogi, Export Commissioner.

The Committee first considered the minutes of the NC Meeting No.13/08 held on 31.07.2007 for confirmation and confirmed and adopted the same.

The Committee considered each case as per agenda.

Case No.A-409	M/S Prachi Pharmaceuticals Pvt. Ltd, Mumbai
N.C. Meeting No.14/08	F.No.01/83/50/709/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/308/AM08
Adv.Lic.No.0310435714 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Thiamine Hcl 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 their Department and he sought deferment for six	

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

Case No.A-410	M/S Merck Ltd
N.C. Meeting No.14/08	F.No.01/82/50/1/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/152/AM08
Adv.Lic.No. Under para 4.4.2 of HBP	
The Committee considered the case as per agenda for fixation of norms for the export product DL-Alpha Tocopheryl Acetate USP (Vitamin E Acetate USP) under para 4.4.2 of HBP. The Committee in light of its earlier decision taken in its 30/82 meeting held on 08.11.2006 vide case no.10/27/82, decided to ratify the norms under para 4.7 of HBP as applied by the firm. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-411	M/S Nicholas Piramal India Ltd
N.C. Meeting No.14/08	F.No.01/83/50/249/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/1474/AM06
Adv.Lic.No.0310382972 dated 02.06.2006	
The Committee considered the case as per agenda for correction in the import item under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/226/2005-PI-III dated 28.02.2007 decided to allow amendment in the import item at Sl.No.3 from Citral to Betaionone under para 4.7 of HBP. All other norms fixed by the Norms Committee shall remain the same. RLA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.A-412	M/S Neuland Laboratories Ltd
N.C. Meeting No.14/08	F.No.01/83/50/1047/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/361/AM07
Adv.Lic.No.0910028737 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-413	M/S Lupin Ltd
N.C. Meeting No.14/08	F.No.01/82/50/119/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/293/AM08
Adv.Lic.No.0310433980 dated 26.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Sterile Ceftriaxone Sodium 1MG/2MG/250MG Injection 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-414	M/S Matrix Ltd
N.C. Meeting No.14/08	F.No.01/82/50/125/AM'08/DES-III

Meeting date: 07.08.2007	RLA F.No.09/24/40/455/AM08
Adv.Lic.No.0910030195 dated 07.05.2007	
The Committee considered the 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 six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-415	M/S Ind-Swift Laboratories Ltd
N.C. Meeting No.14/08	F.No.01/83/50/466/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/11/AM08
Adv.Lic.No.2210006765 dated 05.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Clarithromycin Granules 33% (Suspension Grade) under para 4.7 of HBP. The Committee in light of earlier decision taken by the Norms Committee in its 8/82-ALC1/2006 held on 24.05.2006 vide case No.1/8/82-ALC1/2006, decided to ratify the norms for the export product under para 4.7 of HBP as per details below or as applied by the firm which ever is lower. Export product Clarithromycin Granules 33% (Suspension Grade)-----1kg Import items 1. Clarithromycin-----0.3333kg OR its raw material as per SION A-2263 on prorata basis. 2. Carbopol-----0.25kg 3. HPMC Phthalate-----0.44kg	

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

Case No.A-416	M/S Nicholas Piramal India Ltd
N.C. Meeting No.14/08	F.No.01/82/50/2/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/244/AM08
Adv.Lic.No.Under para 4.4.2 of HBP	
The Committee considered the case as per agenda for fixation of norms for the export product Thiamine Hcl BP/USP under para 4.4.2 of HBP. The Committee decided to forward the complete set of application to Department of Bio-Technology for their comments. Accordingly, the case was deferred for six weeks.	

Case No.A-417	M/S Ranbaxy Lab. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/97/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.05/24/40/36/AM08
Adv.Lic.No.0510202774 dated 20.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ciprofloxacin Tablet 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-418	M/S Shantha Biotech Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/30/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/366/AM07
Adv.Lic.No.0910028896 dated 05.01.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Hepatitis B-Vaccine Human Bodies under para 4.7 of HBP.

The Committee in light of written comments forwarded by Department of Bio-Technology vide their letter No.BT/IL/05/165/2004-PIDdated 11.07.2007 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:

Hepatitis B Vaccine Human Bodies-----1Kg.

Import items:

Consumables-----As per policy

Packing material-----As per packing policy.

Testing Kits-----Net to Net with accountability clause

Balance items-----with 5% wastage

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

Case No.A-419	M/S Sheetal Pharma
N.C. Meeting No.14/08	F.No.01/82/50/2525/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/408/AM07
Adv.Lic.No.0310390246 dated 19.07.2006	

The Committee considered the case as per agenda for ratification of norms for the export product Paracetamol 500mg under para 4.7 of HBP.

The Committee noted that the firm was requested to furnish the copy of DML and Master Batch Formula duly certified by Quality Control Incharge vide letter dated 26.06.2007, but the firm has not responded so far. In view of the decision taken in Senior Officers Meeting held on 31.07.07, it was decided not to reject the case and on the basis of information available, the Committee, therefore, decided to ratify the norms under para 4.7 of HBP allowing only one item as per details below;

Export Product:

Paracetamol Tablet 500 mg-----1No.

Import item:

Paracetamol-----510mg/tablet

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

Case No.A-420	M/S Shiva Pharmachem Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1302AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.34/24/40/257/AM07
Adv.Lic.No.3410018220 dated 01.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product n-Valeryl Chloride 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-421	M/S Wockhardt Ltd
N.C. Meeting No.14/08	F.No.01/82/50/155/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/44/AM08
Adv.Lic.No.0310427335 dated 19.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Hydroxocobalamin Acetate 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 six weeks. The Committee, therefore, decided to defer the case for six weeks.

Case No.A-422	M/S Ranbaxy Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1134/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.05/24/40/819/AM07
Adv.Lic.No.0510197930 dated 16.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ciprofloxacin Tablet USP 250mg, 500mg and 750mg 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-423	M/S Ranbaxy Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/107/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.05/24/40/17/AM08
Adv.Lic.No.0310435714 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.A-424	M/S RA Chem Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1238/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/404/AM07
Adv.Lic.No.0910029307 dated 12.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 2,3-Di Chloro Benzoyl Cyanide under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/66/2007-PI-III dated 07.08.2007 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: 2,3 Dichloro benzoyl cyanide-----1Kg. Import items: 1. 2,3 dichloro benzoyl chloride-----1.50kg/kg 2. Cuprous Cyanide-----0.70kg/kg 3. Hexane-----1.00kg/kg 4. Ortho dichloro benzene-----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-425	M/S Cadila Healthcare Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/123/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.08/24/40/90/AM08
Adv.Lic.No.0810065759 dated 04.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Atenolol 25mg, 50mg and 100mg Tablet 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-426	M/S Cadila Health Care Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/122/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.08/24/40/91/AM08
Adv.Lic.No.0810065758 dated 04.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Carvedilol 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 four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.A-427	M/S Glenmark Pharmaceutical Ltd
N.C. Meeting No.14/08	F.No.01/82/50/120/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/270/AM08
Adv.Lic.No.0310435339 dated 06.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Glimepirid under para 4.7 of HBP. The Committee on the recommendation of the representative of PI Division present in the meeting decided to ratify the Norms under para 4.7 of HBP as per written comments forwarded by PI Division vide their U.O. No.35011/378/2003-PI-III dated 08.12.2003 or as applied for whichever is less.	

Export Product:

Gilimepride-----1Kg.

Import items:

1. 4-(2-3-Ethyl-4-Methyl-2-Oxo-3-Pyrroline-1-Carboxamido Ethyl Phenyl Sulfonamide)-----0.96Kg/Kg.
2. Trans-4-Methyl Cyclohexyl Isocyanate-----0.39Kg/Kg.
3. Acetone-----2.50Kg/Kg.
4. Methanol-----2.50Kg/Kg.
5. Toluene-----Not required in the process(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-428	M/S Cipla Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/121/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/355/AM08
Adv.Lic.No.0310435675 dated 10.07.2007	

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

The Committee decided to call for the copy of DML from the firm and also to forward the copy of application alongwith copy of DML to the technical authority for their comments. Accordingly, the case was deferred for six weeks.

Case No.A-429	M/S Cipla Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/128/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/166/AM08
Adv.Lic.No.0310432617 dated 14.06.2007	

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

The Committee in the light of written comments forwarded by PI Division vide their U.O. No.35011/49/2005-PI-III dated 21.11.2006 decided to ratify the norms under para 4.7 of HBP as per details below or as applied for whichever is lower.

Export Product:

Maxima Powder (Pack size 10Lbs=4.54kgs)

Containing Glucosamine Hydrochloride Net wt. 247.636kgs

Sodium Chondroitin Sulphate Net wt. 82.545kgs

Manganese (as Manganese Sulphate) net wt. 2.201kgs

Ascorbic Acid (as Calcium Ascorbate) Net wt. 14.308kgs.

Import items:

1. Glucosamine hcl-----2.497kg/pack of 4.54kg
2. Sodium chondroitin sulphate-----0.8172kg/pack of 4.54kg
3. Manganese-----0.0110kg/pack of 4.54kg
4. Ascorbic acid-----0.1443kg/pack of 4.54kg

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

Case No.A-430	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/127/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/469/AM08
Adv.Lic.No.0910030086dated 24.04.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Sterile Ampicillin 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.

Case No.A-431	M/S Granules India Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/125/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/456/AM07
Adv.Lic.No.0910029318 dated 13.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Phenazopyridine Hydrochloride Dc Grade 68% (Compresso PPY 68) under para 4.7 of HBP. The Committee in light of the earlier decision taken by the Norms Committee in its 7/82-ALC1/2006 held on 17.05.2006 case No.4/40/82-ALC1/2005 decided to ratify the nors under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: Phenazopyridine Hcl DC Grade 68% (Compresso PPY 68)-----1Kg. Import items: 1. Phenazopyridine Hcl-----0.68kg/kg 2. Starch Pregelatinised-----0.083kg/kg 3. Maize Starch-----0.0428kg/kg 4. Povidone K-30-----0.0098kg/kg 5. Croscarmellose Sodium-----0.0244kg/kg 6. Microcrystalline Cellulose-----0.0977kg/kg 7. Magnesium Stearate-----0.0049kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-432	M/S Cadila Healthcare Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/126/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.08/24/40/87/AM08

Adv.Lic.No.0810065592 dated 26.06.2007

The Committee considered the case as per agenda for ratification of norms for the export product Benzonatate 100 mg Capsules 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.

Case No.A-433	M/S Camphor & Allied Products Ltd.
N.C. Meeting No.14/08	F.No.01/83/50/747/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/274/AM08
Adv.Lic.No.0310433529 dated 22.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Camphor USP 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-434	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/87/50/882/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/412/AM06
Adv.Lic.No.0810065592 dated 26.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Cloxacillin Sodium (From 6-APA 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 which ever is lower.

Export product

Cloxacillin Sodium from 6 APA Stage----1kg

Import items

1. 6-APA-----0.490kg
2. Acetone-----0.0034kg
3. 3-(2-Chlorophenyl)-5-Methyl
Isoxazole Carbonyl Chloride
(CKIC Chloride)-----0.62kg

OR

- 3.a) O-chloro Benzaldehyde-----0.5034kg
- 3.b) Hydroxyl Amine Sulphate-----0.3192kg
- 3.c) Methyl Acetoacetate-----0.410kg
- 3.d) Chloroform-----0.270kg
- 3.e) Methylene chloride-----0.0542kg
4. Methylene chloride/Ethyl Acetate-----0.620kg
5. 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.

Case No.A-435	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1082/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/510/AM07
Adv.Lic.No.0910029551 dated 06.03.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Nevirapine (From DMF Route) 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-436	M/S Alembic Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/48/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.34/24/40/1/AM08
Adv.Lic.No.3410018493 dated 05.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Leflunomide 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-437	M/S Anuh Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1122/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/1299/AM07
Adv.Lic.No.0310423834 dated 21.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Clobetasol Propionate BP under para 4.7 of HBP. The Committee in light of its earlier decision in the meeting No.06/AM07 held on 10.05.2006 vide Case No.A-70 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: Clobetasol Propionate BP-----1Kg. Import item: Betamethasone base BP-----1.19kg/kg	

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

Case No.A-438	M/S Envee Drugs Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/143/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.34/24/40/296/AM07
Adv.Lic.No.3410018601 dated 18.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Betamethasone Valerate 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-439	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/986/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/302/AM07
Adv.Lic.No.0910029299 dated 12.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Stavudine 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-440	M/S Aarti Drugs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/169/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/46/AM08
Adv.Lic.No.0310427426 dated 20.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Diclofenac 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.A-441	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1135/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/522/AM07
Adv.Lic.No.0910029746 dated 23.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Citalopram Hydrobromide (From DMF Route) 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-442	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/141/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/1/AM08
Adv.Lic.No.0910030047 dated 18.04.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Abacavir Sulfate (From DMF Route) 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-443	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/987/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/451/AM07
Adv.Lic.No.0910029300 dated 12.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ampicillin Sodium Sterile 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-444	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1000/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/355/AM07
Adv.Lic.No.0910029746 dated 23.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Quetiapine Fumerate 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-445	M/S Alembic Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/37/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.34/24/40/290/AM07
Adv.Lic.No.3410018404 dated 23.03.2007	
The Committee considered the case as per agenda for ratification of norms for the 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.A-446	M/S Glenmark Pharmaceuticals Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/108/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/16/AM08
Adv.Lic.No.0310426673 dated 13.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Nateglinide 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.	

Case No.A-447	M/S Alembic Ltd.
---------------	------------------

N.C. Meeting No.14/08	F.No.01/82/50/244/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.34/24/40/22/AM08
Adv.Lic.No.3410018712 dated 03.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Venlafaxine 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.	

Case No.A-448	M/S Alliance Laboratories Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/424/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/160/AM08
Adv.Lic.No.0310430399 dated 23.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Iso Sorbide-5-Mononitrate 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-449	M/S Acacia Life Science Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1086/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/492/AM07
Adv.Lic.No.0910029581 dated 08.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product (3Z)-4-(Aminomethyl)-3-Pyrrolidinone-O-Methyloxime	

Hydrochloride 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-450	M/S Astrix Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/792/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/440/AM07
Adv.Lic.No.0910029251 dated 08.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lamivudine (Cyclohexyl Ester Route) 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-451	M/S Vivin Laboratories Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/275/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/39/AM08
Adv.Lic.No.0910029746 dated 23.03.2007	
The Committee considered the case as per agenda for ratification of norms for the 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-452	M/S Vivin Laboratories Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/273/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/444/AM07
Adv.Lic.No.0910030207 dated 08.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamuvudine Intermediate State-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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-453	M/S Vivin Laboratories Pvt. Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/274/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/43/AM08
Adv.Lic.No.0910030208 dated 08.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamuvudine Intermediate State-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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-454	M/S Vivimed Labs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1192/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/449/AM07
Adv.Lic.No.0910030207 dated 08.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Avis (Avo Benzene) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the export product is used in the Cosmetics and therefore it can not be treated as Pharma Product. The Committee, therefore, decided to transfer the case to DES-IV.	

Case No.A-455	M/S Vivimed Labs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/387/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/60/AM08
Adv.Lic.No.0910030333 dated 24.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Avis (Avo Benzene) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the export product is used in the Cosmetics and therefore it can not be treated as Pharma Product. The Committee, therefore, decided to transfer the case to DES-IV.	

Case No.A-456	M/S Smilax Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1268/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/478/AM07
Adv.Lic.No.0910029428 dated 22.02.2007	
The Committee considered the case as per agenda for ratification of norms for the 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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.

Case No.A-457	M/S RA Chem Pharma Ltd
N.C. Meeting No.14/08	F.No.01/82/50/1366/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/521/AM07
Adv.Lic.No.0910029766 dated 23.03.2007	
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.35011/206/2005-PI-III dated 07.08.2007 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: Mebeverine Hcl-----1Kg. Import item: 1. 2-chloromethyl Propionate-----0.66kg/kg 2. Veratric acid-----0.56kg/kg 3. Methyl Isobutyl ketone-----0.51Lts/kg 4. 1,4-dibromo Butane-----0.84kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-458	M/S Smilax Laboratories Ltd.
---------------	------------------------------

N.C. Meeting No.14/08	F.No.01/82/50/1203/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.09/24/40/466/AM07
Adv.Lic.No.0910029229dated 07.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 5-Methoxy-2-((4-Methoxy-3,5-Dimethyl-2Pyridinyl)Methyl]Thio-IH-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 their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-459	M/S Glenmark Pharmaceuticals Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/102/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/12/AM'08
Adv.Lic.No.0310426504 dated 12.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Avis Imiquimod 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 two weeks. The Committee, therefore, decided to defer the case for two weeks.	

Case No.B-199	M/S IPCA Labs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1327/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/924/AM07
Adv.Lic.No.0310409045 dated 22.11.2006	

The Committee considered the case as per agenda for correction in the description of item of import from Seasamol to Sesamol under para 4.7 of HBP.

The Committee decided to allow correction in the description of import item from **Seasamol** to **Sesamol** after due verification. The Committee also decided to reject the request of the firm for enhancement in the quantity of inputs as the norms were ratified on the basis of written comments forwarded by PI Division.

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

Case No.B-200	M/S IPCA Labs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/966/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/662/AM07
Adv.Lic.No.0310400231 dated 20.09.2006	

The Committee considered the case as per agenda for correction in the description of item of import No.1 from Diclosenec Sodium to Diclofenac Sodium and in the description of item of import No.2 from Tertiary butyl chloro acetate to Tertery butyl chloro acetate under para 4.7 of HBP.

The Committee decided to allow correction in the description of import item No.1 from Diclofenec Sodium to Diclofenac Sodium after due verification. The Committee also decided to reject the request for correction in the import item No.2 as the correct chemical name of the item is Tertiary butyl chloro acetate which has been given by the firm in their chemistry.

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

Case No.B-201	M/S IPCA Labs Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1073/AM'07/DES-III

Meeting date: 07.08.2007	RLA F.No.03/94/40/537/AM07
Adv.Lic.No.0310396795 dated 28.08.2006	
The Committee considered the case as per agenda for amendment in the description of export product from Morantel Citrate to Aceclofenac under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/264/2006-PI-III dated 18.04.2007 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: Aceclofenac BP-----1Kg. Import items: 1. Diclofenec Sodium-----1.11kg/kg 2. Tertiary butyl chloro acetate-----0.52kg/kg 3. Dimethyl formamide-----0.60kg/kg 4. Toluene-----3.17kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-202	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1131/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/261/AM07
Adv.Lic.No.2210006123 dated 11.10.2006	
The Committee considered the case as per agenda for allowing input 'L(+)Tartaric 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 their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.B-203	M/S Shilpa Medicare Ltd.
N.C. Meeting No.14/08	F.No.01/83/162/570/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.07/24/40/146/AM03
Adv.Lic.No.0710014440 dated 20.06.2002	
The Committee considered the case as per agenda for enhancement in the quantity of input under para 4.7 of HBP. The Committee noted that the licence is old one issued on 20.06.2002 and therefore it is not possible for the Committee to allow any amendment against such licence. The Committee, therefore, decided to maintain status quo.	

Case No.B-204	M/S Sandoz (P) Ltd
N.C. Meeting No.14/08	F.No.01/83/50/820/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/735/AM07
Adv.Lic.No.0310405563 dated 26.10.2006	
The Committee considered the case as per agenda for enhancement in the quantity of input and allowing the 2nd input under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/238/2006-PI-III dated 08.01.2007 decided to allow import of additional item as per details below; 1-Amino-4-methyl Piperazine-----0.16kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-205	M/S Shalina Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/83/50/1083/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/1164/AM'07
Adv.Lic.No.0310414237 dated 02.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Epiderm 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.	

Case No.B-206	M/S Shalina Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/83/50/1084/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/1163/AM'07
Adv.Lic.No.0310414239 dated 02.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Bitasol 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.	

Case No.B-207	M/S Aarti Drugs Ltd.
N.C. Meeting No.14/08	F.No.01/87/50/767/AM'06/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/414/AM'04
Adv.Lic.No.0310347752 dated 16.09.2005	

The Committee considered the case as per agenda for allowing the input Potassium Hydroxide under para 4.7 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/178/2006-PI-III dated 20.07.2007 decided to allow one additional import item as per details below;

Potassium Hydroxide-----0.400kg/kg

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

Case No.B-208	M/S Glenmark Pharmaceuticals Ltd.
N.C. Meeting No.14/08	F.No.01/83/162/207/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/789/AM'04
Adv.Lic.No.0310217859 dated 11.08.2003	
The Committee considered the case as per agenda for ratification of norms for the export product Cilostazol under para 4.7 of HBP. The Committee decided to call for the copy of application alongwith the decision of NC, if any from RLA. Accordingly, the case was deferred for six weeks.	

Case No.B-209	M/S Glenmark Pharmaceuticals Ltd.
N.C. Meeting No.14/08	F.No.01/82/162/154/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/94/40/1857/AM'04
Adv.Lic.No.0310414237 dated 02.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Amiodrone under para 4.7 of HBP.	

The Committee decided to call for the copy of application alongwith the decision of NC, if any from RLA. Accordingly, the case was deferred for six weeks.

Case No.B-210	M/S Lupin Ltd.
N.C. Meeting No.14/08	F.No.01/83/50/1604/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/1237/AM'07
Adv.Lic.No.0310415404 dated 10.01.2007	
The Committee considered the case as per agenda for correction in the description of import item No.2 and 9 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.B-211	M/S Lupin Ltd.
N.C. Meeting No.14/08	F.No.01/83/50/1458/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/1145/AM'07
Adv.Lic.No.0310414237 dated 02.01.2007	
The Committee considered the case as per agenda for correction in the description of import item No.12 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.B-212	M/S Savers Impex, Thane
N.C. Meeting No.14/08	F.No.01/85/162/102/AM'08/DES-III
Meeting date: 07.08.2007	RLA F.No.03/95/40/41/AM'08
Adv.Lic.No.0310428179 dated 27.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Vitamin Mineral Premix Savit for Flour Fortification under para 4.7 of HBP. The Committee noted that no DML has been issued to the firm and therefore the export product is not a pharmaceutical product. The Committee, therefore, decided to transfer the case to DES-VI.	

Case No.B-213	M/S Ind-Swift Laboratories Ltd
N.C. Meeting No.14/08	F.No.01/82/50/882/AM'06/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/16/AM'06
Adv.Lic.No.2210004954 dated 27.10.2005	
The Committee considered the case as per agenda for correction in the item of import from 2-Acetyloxy Benzoic acid (Asprin) to Acetyloxy Benezoic acid (Asprin). The Committee noted that the norms was fixed in this case as per Chemistry. The Committee, therefore, decided to reject the case.	

Case No.B-214	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/119/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/09/AM07
Adv.Lic.No.2210005475 dated 26.04.2006	
The Committee considered the case as per agenda for correction in the item of import from 2-Acetyloxy Benzoic acid (Asprin) to Acetyloxy Benezoic acid (Asprin).	

The Committee noted that the norms was fixed in this case as per Chemistry. The Committee, therefore, decided to reject the case.

Case No.B-215	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/179/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/18/AM07
Adv.Lic.No.2210005501 dated 04.05.2006	

The Committee considered the case as per agenda for modification of norms for the export product Clopidogrel Hydrogen Sulphate under para 4.7 of HBP.

The Committee decided to forward a copy of application to the technical authority for their comments. The case was accordingly deferred for six weeks.

Case No.B-216	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.14/08	F.No.01/82/50/1130/AM'07/DES-III
Meeting date: 07.08.2007	RLA F.No.22/24/40/262/AM07
Adv.Lic.No.2210006122 dated 11.10.2006	

The Committee considered the case as per agenda for correction in the items of import under para 4.7 of HBP.

The Committee decided to allow corrections in the imports items after due verification as per details below;

Sl.No.	Earlier Description	Amended Description
1.	4-chloro bytyryl	4-Chloro butyryl Chloride
2.	Tonuene	Toluene
3.	Methylene dichloride	Methylene chloride

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

Norms Committee Meeting No.14/08 dated 07.08.2007

Outside Agenda:

The Committee also considered the report forwarded by PI Division vide their U.O. No.35011/274/2006 PI-III dated 20.07.2007 in which PI Division have recommended the following norms in respect of the export product "**Ampicillin Anhydrous from Pen G route.**"

Export Product:

Ampicillin Anhydrous from Pen G Route-----1Kg.

Import items:

1. Penicillin G Potassium 1st Crystal-----2.088BOU/kg
2. Pivaloyl chloride-----0.42kg/kg
3. Triethylamine-----0.0239kg/kg
4. Methylene chloride-----1.50kg/kg
5. D(-)Alpha Phenyl glycine Base-----0.500kg/kg
6. Pen. G Amidase (Enzyme)-----1.078gm/kg
7. Ethyl Aceto acetate-----0.45kg/kg
8. Isopropyl Alcohol-----1.21kg/kg
9. Pot. Carbonate-----0.235kg/kg

The Committee decided to accept the recommendation of PI Division and to fix the SION in respect of the above export product.