

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

Para 4.7 Officewise Statement

MEETING NUMBER : 18/82-ALC4/2007 **MEETING DATE** : 06.09.2007

1	Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:18/82- ALC4/2007 06.09.2007	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: 18.09.2007
	Decision :The case was considered by Committee as per agenda for ratification of norms for the export product Terbinafine Hcl Tablets 250mg (Terbinafine Hcl equivalent qty. 1873Kgs-30s Packs) and Terbinafine Hcl Tablets 250mg (Terbinafine Hcl equi. Qty. 312Kgs-100s Packs) under para 4.7 of HBP. The representative of PI Division present in the meeting informed Committee that the case is under examination in their Department and he sought deferment for two weeks. The Committee, accordingly, decided to defer the case for two weeks.			
2	Case No.:9/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Withdrawn
	HQ File :01/82/050/00999/AM07/	RLA File : 09/24/040/00177/AM07/	Lic.No/Date:0910027659 25.09.2006	
	Decision :Withdrawn as the case has already been approved in 16/08 meeting held on 21.08.2007.			
3	Case No.:29/36/83-ALC1/2006	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:18/82- ALC4/2007 06.09.2007	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: 04.10.2007
	Decision : Committee considered this case as per agenda for fixation of I/O Norms for the Export Product Epiderm Lotion 30ml under para 4.7 of HBP. Committee decided to forward copy of application together with reply of the firm to PI Division for their comments. Accordingly, the case was deferred for four weeks.			
4	Case No.:8/44/82-ALC1/2006	Party Name:M/S.ENAL DRUGS	Meet No/Date:18/82-	Status:Case

		PVT LTD.,	ALC4/2007 06.09.2007	Approved
	HQ File :01/82/050/01307/AM07/	RLA File : 09/24/040/00237/AM07/	Lic.No/Date:0910028243 17.11.2006	
	Decision : Committee considered the case as per agenda for ratification of norms for the export product 2-Chloro Methyl-3, Methyl-4(2,2,2 Trifluoro Ethoxy) Pyridine Hcl (Lansoprazole Chloro Compound) Powder under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/90/2007-PI-III dated 05.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: 2-Chloro Methyl-3, Methyl-4(222 Trifluoro Ethoxy) Pyridine Hcl-----1Kg. Import items: 1. 2,3 Lutidine-----0.79kg/kg 2. 2,2,2-Trifluoro Ethanol-----0.936kg/kg 3. Methylene chloride-----1.20kg/kg 4. Isopropyl Alcohol-----1.51kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			
	Case No.:4/43/83-ALC1/2006	Party Name:SREENIVASA PHRAMA PVT LTD.	Meet No/Date:18/82-ALC4/2007 06.09.2007	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: 18.09.2007
5	Decision : Committee considered this case as per agenda for fixation of I/O Norms for 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. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. The Committee, accordingly, decided to defer the case for two weeks.			
6	Case No.:3/47/80-ALC2/2006	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:18/82-ALC4/2007 06.09.2007	Status:Case Deferred
	HQ File :01/80/050/01016/AM07/	RLA File : 09/24/040/00324/AM07/	Lic.No/Date:0910028524 06.12.2006	Defer Date: 18.09.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Benzyl(S)-(-)-1,2,3,4-Tetrahydro-3-Isoquinoline Carboxylate-Para-Toluene Sulfonic Acid Salt under para 4.7 of HBP.			

Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. The Committee, accordingly, decided to defer the case for two weeks.

7	Case No.: 6/50/87-ALC1/2006	Party Name:ALKEM LABORATORIES LTD.,	Meet No/Date:18/82-ALC4/2007 06.09.2007	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: 18.09.2007
	Decision : Committee considered this case as per agenda for fixation of I/O Norms for Export Product Amoxycillin Clavulanate Potassium Tablet 375mg, 625mg and 1000mg under para 4.7 of HBP. Committee decided to forward complete set of application to PI Division for their comments. Accordingly, case was deferred for two weeks.			

8	Case No.: 4/1/83-ALC1/2007	Party Name:VIJAY PERFUMES PVT.LTD.	Meet No/Date:18/82-ALC4/2007 06.09.2007	Status: Case Approved
	HQ File :01/83/050/01214/AM07/	RLA File : 03/95/040/01118/AM07/	Lic.No/Date:0310418795 08.02.2007	
	Decision : 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. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/52/2006-PI-III dated 06.09.2007 decided to ratify norms as per details below or as applied by the firm whichever is lower. Export product: N-Methyl Benzothiazene Methyl Ester-----1Kg. Import items: 1. Sodium Saccharine-----1.29kg/kg 2. Dimethyl Formamide-----0.50kg/kg 3. Sodium Metal-----0.337kg/kg 4. Methyl Alcohol-----1.55kg/kg 5. Acetone-----0.645kg/kg 6. Xylene-----0.645kg/kg 7. Methyl Chloro Acetate-----0.98kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

9	Case No.: 1/10/82-ALC4/2007	Party Name:HAFFKINE BIO PHARMACEUTICAL CORPN	Meet No/Date:18/82-ALC4/2007	Status: Case Approved
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	LTD	06.09.2007	
HQ File :01/82/050/01645/AM07/	RLA File : 03/94/040/01208/AM07/	Lic.No/Date:0310419601 14.02.2007	
Decision : Committee considered this case as per agenda for fixation of I/O Norms for Export Product Oral Polio Vaccine (OPV) under para 4.7 of HBP. Committee in light of written comments forwarded by DBT vide their letter No.BT/IL/05/264/2007-PID dated 29.08.2007 decided to ratify norms as per details below or as applied by the firm whichever is lower. Export product: Oral Polio Vaccine (OPV) with VVM-----1550,000 Nos. Import item: Vaccine Vial Monitors (VVM)-----15,81,000 Nos. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

	Case No.:1/18/82-ALC4/2007	Party Name:CENTAUR CHEMICALS PVT. LTD.,	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Approved
	HQ File :01/82/050/01657/AM07/	RLA File : 03/94/040/01263/AM07/	Lic.No/Date:0310420158 20.02.2007	
10	Decision : Committee considered this case as per agenda for fixation of I/O Norms for Export Product Clonazepam under para 4.7 of HBP. Committee in consultation with representative of PI Division present in the meeting decided to ratify 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 under para 4.7 of HBP as per above decision of Norms Committee.			

11	Case No.:3/2/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Approved
	HQ File :01/82/050/01756/AM07/	RLA File : 09/24/040/00382/AM07/	Lic.No/Date:0910029552 06.03.2007	
	Decision : Committee considered this case as per agenda for fixation of I/O Norms for Export Product 2-(6-Methoxy-2-naphthyl)propionic acid (DL-Acid) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 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.

12	Case No.: 6/12/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status: Case Deferred
	HQ File : 01/82/050/01865/AM07/	RLA File : 09/24/040/00496/AM07/	Lic.No/Date:0910029776 26.03.2007	Defer Date:16.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that the case is under examination in their Department and he sought deferment for six weeks. Committee, accordingly, decided to defer the case for six weeks.				

13	Case No.: 10/12/82-ALC4/2007	Party Name:HERMES CHEMICAL COMPANY PVT LTD.	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status: Case Deferred
	HQ File :01/82/050/01900/AM07/	RLA File : 09/24/040/00485/AM07/	Lic.No/Date:0910029843 29.03.2007	Defer Date: 16.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product 1-Thiomethyl 1-Cyclopropane Acetic Acid under para 4.7 of HBP. Representative of PI Division present in the meeting informed the Committee that case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.				

14	Case No.: 8/12/82-ALC4/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status: Case Deferred
	HQ File :01/82/050/01898/AM07/	RLA File : 09/24/040/00524/AM07/	Lic.No/Date:0910029841 29.03.2007	Defer Date: 18.09.2007

	Decision : Committee considered the case as per agenda for ratification of norms for export product Methyl(E)-2-[3(s)-[3-[2-(7-Chloro-2-Quinoliny)] Ethenyl]Phenyl]-3-Hydroxypropyl]Benzoate under para 4.7 of HBP. Representative of PI Division present in meeting informed the Committee that case is under examination in their Department and he sought deferment for two weeks. The Committee, accordingly, decided to defer the case for two weeks.
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15	Case No.:9/12/82-ALC4/2007	Party Name:HERMES CHEMICAL COMPANY PVT LTD.	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Deferred
	HQ File :01/82/050/01899/AM07/	RLA File : 09/24/040/00489/AM07/	Lic.No/Date:0910029842 29.03.2007	Defer Date: 16.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product [S]-1-[[3-(7-Chloro 2-Quinoliny)] Ethenyl] Phenyl}] 3-[2-(1-Hydroxy-1 Methyl Ethyl)-Phenyl} Propan-OL under para 4.7 of HBP.			
Representative of PI Division present in the meeting informed the Committee that case is under examination in their Department and he sought deferment for six weeks. Committee, accordingly, decided to defer the case for six weeks.				

	Case No.: 11/12/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:18/82-ALC4/2007 06.09.2007	Status: Case Deferred
	HQ File :01/82/050/00064/AM08/	RLA File : 34/24/040/00045/AM08/	Lic.No/Date:3410018932 07.06.2007	Defer Date: 04.10.2007
16	Decision : Committee considered the case as per agenda for ratification of norms for export product Azithromycin Step-4 under para 4.7 of HBP. Committee noted that some information has been called for from the firm which has not been received. Committee decided to await reply of the firm and to defer the case for four weeks.			

17	Case No.:13/12/82-ALC4/2007	Party Name:MEDREICH LIMITED	Meet No/Date:18/82-ALC4/2007 06.09.2007	Status:Case Approved
	HQ File :01/82/050/00070/AM08/	RLA File : 07/24/040/00205/AM08/	Lic.No/Date:0710052078 20.06.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Paracetamol 250mg+Ibuprofen 200mg capsules under para 4.7 of HBP.				
Committee in light of its earlier decision taken in its 9/08 meeting held on 03.07.2007 vide case No.28/9/82-ALC4/2007 decided to ratify adhoc norms as per details below or as applied for whichever is less.				

Export product: Paracetamol 250mg + Ibuprofen 200mg Capsules
Import items: 1. Paracetamol Crystals BP/USP/EP -----255mg/capsule 2. Ibuprofen BP/USP/EP-----204mg/capsule 3. Sodium Stearyl Fumarate-----Not shown in DML(Not allowed)
RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of the Norms Committee.

18	Case No.:2/18/82-ALC4/2007	Party Name:HARMAN FINOCHEM LTD.	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Deferred
	HQ File :01/82/050/00114/AM08/	RLA File : 03/94/040/00273/AM08/	Lic.No/Date:0310433397 21.06.2007	Defer Date: 04.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Phenob Arbutal (Phenobarbitone) under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for four weeks. Committee, accordingly, decided to defer the case for four weeks.			

19	Case No.:47/18/83-ALC1/2007	Party Name:PUNJAB CHEMICALS AND CROP PROTECTION LTD.,	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Transferred
	HQ File :01/83/050/00642/AM08/	RLA File : 03/95/040/00223/AM08/	Lic.No/Date:0310433836 25.06.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for the export product 2[(Chloro Methyl) Mercapto] Benzo Thiazole (CMBT) under para 4.7 of HBP. Committee observed that export product is for use in synthesis of Leather Chemicals. Committee, therefore, decided to transfer the case to DES-IV.			

20	Case No.:14/12/82-ALC4/2007	Party Name:WOCKHARDT LIMITED	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Approved
	HQ File :01/82/050/00106/AM08/	RLA File : 03/95/040/00291/AM08/	Lic.No/Date:0310434270 28.06.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Flu Strength Hot Lemon Powders 5gm Sachet under para 4.7 of HBP. Committee in consultation with technical authorities present in the meeting decided to ratify norms under para 4.7 of HBP as applied by the firm with 1% wastage. RLA concerned may take further necessary action under para 4.7 of HBP as per above			

decision of Norms Committee.

21	Case No.:3/18/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:18/82- ALC4/2007 06.09.2007	Status:Case Deferred
	HQ File :01/82/050/00142/AM08/	RLA File : 03/94/040/00455/AM08/	Lic.No/Date:0310438406 06.08.2007	Defer Date: 16.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir/Arved Tablets under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for six weeks. Committee, accordingly, decided to defer the case for six weeks.			

Date:05.09.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Case No.A-586	M/S Astrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/266/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/502/AM07
Adv.Lic.No.0910030196 dated 07.05.2007	
Committee considered the case as per agenda for ratification of norms for export product Stavudine under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that the case is under examination in their Department and he sought deferment for six weeks. Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-587	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/87/50/1136/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/533/AM07
Adv.Lic.No.0910029747 dated 23.03.2007	
Committee considered the case as per agenda for ratification of norms for export product Mica Ester (Mica Thioester) under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. The Committee, accordingly, decided to defer case for two weeks.	

Case No.A-588	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/87/50/889/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/155/AM07
Adv.Lic.No.0910029010 dated 12.01.2007	
Committee considered the case as per agenda for ratification of norms for export product Atorvastatin Diprotected under para 4.7 of HBP. Representative of PI Division present in the meeting informed	

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

Case No.A-589	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/83/50/117/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/535/AM07
Adv.Lic.No.0910030005 dated 17.04.2007	
Committee considered the case as per agenda for ratification of norms for export product Paroxetine Hydrochloride Hemihydrate under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-590	M/S Aurbindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/87/50/986/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/302/AM07
Adv.Lic.No.0910029299 dated 12.02.2007	
Committee considered case as per agenda for ratification of norms for export product Stavudine under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-591	M/S Devats (India) Pvt. Ltd.
NC Meeting No.18/08	F.No.01/82/50/422/AM08
Meeting Date: 05.09.2007	RLA F.No.05/24/40/921/AM07
Adv.Lic.No.0510204173 dated	

29.05.2007	
Committee considered the case as per agenda for ratification of norms for export product Nystatin Oral Suspension (USP) under para 4.7 of HBP. Committee decided to call for copy of DML form the firm. Accordingly, case was deferred for six weeks.	

Case No.A-592	M/S Ranbaxy Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/50/1134/AM07
Meeting Date: 05.09.2007	RLA F.No.05/24/40/819/AM07
Adv.Lic.No.0510197930 dated 16.01.2007	
Committee considered the case as per agenda for ratification of norms for export product Ciprofloxacin Tablets USP 250mg, 500mg and 750mg under para 4.7 of HBP. Representative of PI Division present in the meeting informed the Committee that case is under examination in their Department and he sought deferment for two weeks. Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-593	M/S Ranbaxy Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/50/107/AM08
Meeting Date: 05.09.2007	RLA F.No.-5/24/40/17/AM08
Adv.Lic.No.0510202504 dated 13.04.2007	
Committee considered the case as per agenda for ratification of norms for export product Isotretinoin under para 4.7 of HBP. Committee decided to forward complete set of application to PI Division for their commens. Accordingly, case was deferred for two weeks.	

Case No.A-594	M/S Ranbaxy Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/50/97/AM08
Meeting Date: 05.09.2007	RLA F.No.05/24/40/36/AM08

Adv.Lic.No.0510202774dated 20.04.2007	
Committee considered case as per agenda for ratification of norms for export product Ciprofloxacin Tablet USP 250mg, 500mg and 750mg under para 4.7 of HBP. representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for two weeks. Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-595	M/S Avignon Exim Pvt. Ltd.
NC Meeting No.18/08	F.No.01/87/50/1102/AM07
Meeting Date: 05.09.2007	RLA F.No.03/94/40/1374/AM07
Adv.Lic.No.0310422847 dated 13.03.2007	
Committee considered the case as per agenda for ratification of norms for export product Niacinamide BP/USP under para 4.7 of HBP. Committee decided to forward copy of application to PI Division and DC(SSI) for their comments. Accordingly, case was deferred for four weeks.	

Case No.A-596	M/S Cadila Pharmaceuticals Ltd.
NC Meeting No.18/08	F.No.01/83/50/530/AM08
Meeting Date: 05.09.2007	RLA F.No.08/24/40/66/AM08
Adv.Lic.No.0810065423 dated 15.06.2007	
Committee considered the case as per agenda for ratification of norms for export product Methscopolamine Tannete under para 4.7 of HBP. Representative of PI Division present in the meeting informed Committee that case is under examination in their Department and he sought deferment for four weeks. Committee, accordingly, decided to defer the case for four weeks.	

Case No.A-597	Alembic Ltd.
NC Meeting No.18/08	F.No.01/82/50/244/AM08
Meeting Date: 05.09.2007	RLA F.No.34/24/40/22/AM08
Adv.Lic.No.3410018712 dated 03.05.2007	
Committee considered the case as per agenda for ratification of norms for the export product Venlafaxine Hcl under para 4.7 of HBP. representative of PI Division present in meeting informed Committee that case is under examination in their Department and he sought deferment for four weeks. Committee, accordingly, decided to defer the case for four weeks.	

Case No.A-598	Alembic Ltd.
NC Meeting No.18/08	F.No.01/82/50/37/AM08
Meeting Date: 05.09.2007	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, accordingly, decided to defer the case for four weeks.	

Case No.A-599	M/S Cadila Healthcare Ltd.
NC Meeting No.18/08	F.No.01/82/50/123/AM08
Meeting Date: 05.09.2007	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 Tab. 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, accordingly, decided to defer the case for four weeks.

Case No.A-600	M/S Cadila Healthcare Ltd.
NC Meeting No.18/08	F.No.01/82/50/122/AM08
Meeting Date: 05.09.2007	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 3.15mg tablets, 6.25mg tablets, 12.5mg tablets and 25mg 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, accordingly, decided to defer the case for four weeks.	

Case No.A-601	M/S Cadila Healthcare Ltd.									
NC Meeting No.18/08	F.No.01/82/50/126/AM08									
Meeting Date: 05.09.2007	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 10mg Cap. And 200mg Cap. under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/73//2007-PI-III dated 14.08.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Benzonatate 100mg Capsules-----2,24,27,500 Nos. Benzonatate 200mg Capsules-----1,66,76,500 Nos. Import items; <table><tr><td>Sl.No.</td><td>Description of import items</td><td>Quantity allowed</td></tr><tr><td>1.</td><td>Benzonatate USP</td><td>5689.61kg</td></tr><tr><td>2.</td><td>Gelatin NF</td><td>7620.09kg</td></tr></table>		Sl.No.	Description of import items	Quantity allowed	1.	Benzonatate USP	5689.61kg	2.	Gelatin NF	7620.09kg
Sl.No.	Description of import items	Quantity allowed								
1.	Benzonatate USP	5689.61kg								
2.	Gelatin NF	7620.09kg								

3.	Glycerin USP	1088.584kg
4.	Noncrystallizing sorbitol solution NF	3265.75kg
5.	Triethyl Citrate NF	1674.85kg
6.	Bottles & Caps (packing material in finished form) (import item a to e)	As per packing policy

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

Case No.A-602	M/S Bayer Materialscience Pvt. Ltd.
NC Meeting No.18/08	F.No.01/87/50/267/AM08
Meeting Date: 05.09.2007	RLA F.No.04/24/40/120/AM08
Adv.Lic.No.0410090431 dated 06.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Thermoplastic Polyurethane Desmopan under para 4.7 of HBP. Committee decided to transfer the case to DES-VIII as the case pertains to Plastic Sector.	

Case No.A-603	M/S Cipla Ltd.
NC Meeting No.18/08	F.No.01/82/50/151/AM08
Meeting Date: 05.09.2007	RLA F.No.03/94/40/431/AM08
Adv.Lic.No.0310437633 dated 27.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Telmisartan and Ramipril Tablet 40/2.5mg, 80/2.5mg, 40/10mg, 80/10mg, 40/5mg and 80/5mg 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, accordingly, decided to defer the case for six weeks.	

Case No.A-604	M/S Nicholas Piramal India Ltd.
NC Meeting No.18/08	F.No.01/83/50/370/AM08
Meeting Date: 05.09.2007	RLA F.No.03/95/40/1389/AM07
Adv.Lic.No.0310430066 dated 21.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Concept Quick Unit dose Solution (9247X) (Pack:15ML Vial) under para 4.7 of HBP. Committee observed that para 4.7(v) of Current Hand Book of Procedures provides as under; “Where export and/or import of biotechnology items are involved, Authorization under this paragraph shall be issued by RA only on submission of a ‘No Objection Certificate’ from Department of Biotechnology.” Committee has gone through the application submitted by the firm and found that the firm has not submitted ‘NOC’ from DBT. Committee, therefore, decided to ask firm to produce NOC from Department of Biotechnology. It was also decided to ascertain from DBT whether any NOC has been issued to firm. Accordingly, case was deferred for six weeks.	

Case No.A-605	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/563/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/80/AM08
Adv.Lic.No.0910030641 dated 22.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Efavirenz under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-606	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/490/AM08

Meeting Date: 05.09.2007	RLA F.No.09/24/40/94/AM08
Adv.Lic.No.0910030486 dated 08.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Tenofovir Disoproxil Fumarate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-607	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/760/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/115/AM08
Adv.Lic.No.0910030917 dated 18.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product (S)-5-Chloro-a-(Cyclopropylethynyl)-2-[[[(4-Methoxy phenyl)methyl] amino]-a-(Trifluoromethyl) Benzene Methanol under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-608	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/665/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/511/AM07
Adv.Lic.No.0910030757 dated 04.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 5,11-Dihydro(1)-Benzoxepino(3,4-b)-Pyridin-5-One under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-609	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/687/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/112/AM08
Adv.Lic.No.0910030802 dated 06.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product L-Menthyl Gloxylate Hydrate (MGH) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-610	M/S Matrix Laboratories Ltd.
NC Meeting No.18/08	F.No.01/83/50/562/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/36/AM08
Adv.Lic.No.0910030640 dated 22.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Montelukast Sodium under para 4.7 of HBP. Committee in consultation with technical authorities decided to ratify norms under para 4.7 of HBP as per SION A-3573 or as applied by the firm whichever is lower. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-611	M/S Inventis Drug Delivery Systems Pvt. Ltd.
NC Meeting No.18/08	F.No.01/83/50/397/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/47/AM08
Adv.Lic.No.0910030344 dated 25.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Fenofibrate Pellets under para 4.7 of HBP.	

Committee decided to call for complete description of export product in terms of content of import item in line with the DML and copy of relevant Drug Manufacturing Licence. Accordingly, case was deferred for six weeks.

Case No.A-612	M/S Liquors India Ltd
NC Meeting No.18/08	F.No.01/83/50/702/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/142/AM08
Adv.Lic.No.0910030864 dated 12.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lovastatin under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-613	M/S Malladi Drugs & Pharmaceuticals Ltd
NC Meeting No.18/08	F.No.01/83/50/613/AM08
Meeting Date: 05.09.2007	RLA F.No.04/24/40/113/AM08
Adv.Lic.No.0410090130 dated 28.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 2-Fluoro Adenosin Triacetate (20FAT) 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, accordingly, decided to defer the case for six weeks.	

Case No.A-614	M/S Malladi Drugs & Pharmaceuticals Ltd
NC Meeting No.18/08	F.No.01/83/50/615/AM08
Meeting Date: 05.09.2007	RLA F.No.04/24/40/111/AM08

Adv.Lic.No.0410090132 dated 28.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Clopidogrel Bisulphate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-615	M/S Malladi Drugs & Pharmaceuticals Ltd
NC Meeting No.18/08	F.No.01/83/50/614/AM08
Meeting Date: 05.09.2007	RLA F.No.04/24/40/112/AM08
Adv.Lic.No.0410090131 dated 28.06.2007	
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, accordingly, decided to defer the case for six weeks.	

Case No.A-616	M/S Ayursiddha Inc.
NC Meeting No.18/08	F.No.01/83/50/438/AM08
Meeting Date: 05.09.2007	RLA F.No.05/24/40/105/AM08
Adv.Lic.No.0510204254 dated 30.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Blockbuster All Clear Capsules Made of Citrolive (Olive Leaf Citrus), Sea Prose, Acerola 17.5% Nittokinase, Grape Seed Extract and Polycosanol 98% under para 4.7 of HBP. Committee decided to forward copy of application to Department of Ayush for their comments. Accordingly, case was deferred for six weeks.	

Case No.A-617	M/S Brawn Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/50/154/AM08
Meeting Date: 05.09.2007	RLA F.No.05/24/40/163/AM08
Adv.Lic.No.0510204890 dated 13.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Kanamycin Acid Sulphate Inj. BP 1gm and Lincomycin Capsule 500mg under para 4.7 of HBP. Committee decided to call for copy of valid Drug Manufacturing Licence for the export product alongwith copy of approved items from the firm. Accordingly, case was deferred for six weeks.	

Case No.A-618	M/S Cipla Ltd.
NC Meeting No.18/08	F.No.01/82/50/152/AM08
Meeting Date: 05.09.2007	RLA F.No.03/94/40/437/AM08
Adv.Lic.No.0310437618 dated 27.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Triamune 30/Lamivudine, Stavudine and Nevirapine Tablets, Triomune 40/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 six weeks. The Committee, accordingly, decided to defer the case for six weeks.	

Case No.A-619	M/S Cipla Ltd.
NC Meeting No.18/08	F.No.01/82/50/153/AM08
Meeting Date: 05.09.2007	RLA F.No.03/94/40/485/AM08

Adv.Lic.No.0310439033 dated 09.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Gemcitabine Okasa Pharma (Gemcicross) 1g Injection and Gemcitabine 200mg 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, accordingly, decided to defer the case for six weeks.	

Case No.A-620	M/S Glenmark Pharmaceuticals Ltd.
NC Meeting No.18/08	F.No.01/82/50/102/AM08
Meeting Date: 05.09.2007	RLA F.No.0/94/40/12/AM08
Adv.Lic.No.0310426504 dated 12.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Imiquimod under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/24/2006-PI-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Imiquimod-----1kg. Import items: 1. 4-Hydroxyquinoline-----2.60kg/kg 2. Dimethyl Formamide-----4.375kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.	

Case No.A-621	M/S Alembic Ltd.
NC Meeting No.18/08	F.No.01/82/50/48/AM08
Meeting Date: 05.09.2007	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, accordingly, decided to defer the case for four weeks.

Case No.A-622	Alliance Laboratories Pvt. Ltd.
NC Meeting No.18/08	F.No.01/83/50/424/AM08
Meeting Date: 05.09.2007	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 Committee observed that there are three more cases of M/S Om Shree Pharma for the same export product which are to be considered by the Committee in its 19/08 meeting to be held on 11.09.2007. The Committee, therefore, decided that this case may also be re-listed on 11.09.2007.	

Case No.A-623	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/986/AM07
Meeting Date: 05.09.2007	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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-624	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/141/AM08

Meeting Date: 05.09.2007	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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-625	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/1135/AM07
Meeting Date: 05.09.2007	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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-626	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/1082/AM07
Meeting Date: 05.09.2007	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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-627	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/1000/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/355/AM07
Adv.Lic.No.0910029322 dated 13.02.2007	
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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.	

Case No.A-628	M/S Aarti Drugs Ltd.
NC Meeting No.18/08	F.No.01/82/50/169/AM08
Meeting Date: 05.09.2007	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. Committee decided to call from the firm consumption data duly certified by the Central Excise Authority and also call Excise Data of all manufacturers and exporters of this item from Pharmexcil. Accordingly, case was deferred for six weeks.	

Case No.A-629	M/S Aurobindo Pharma Ltd.
NC Meeting No.18/08	F.No.01/82/50/987/AM07
Meeting Date: 05.09.2007	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, accordingly, decided to defer the case for four weeks.

Case No.A-630	M/S Dr. Reddys Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/162/2222/AM08
Meeting Date: 05.09.2007	RLA F.No.09/24/40/54/AM08
Adv.Lic.No.0910030527 dated 13.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Chlorpromazine Hcl Tablets 25mg, 50mg and 100mg 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, accordingly, decided to defer the case for four weeks.	

Case No.B-252	M/S Shalina Laboratories Pvt. Ltd.
NC Meeting No.18/08	F.No.01/83/50/1083/AM07
Meeting Date: 05.09.2007	RLA F.No.03/94/40/1164/AM07
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 Committee decided to forward copy of application together with copy of reply received from the firm to PI Division for their comments. Accordingly, it was decided to defer the case for two weeks.	

Case No.B-253	M/S Shalina Laboratories Pvt. Ltd.
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NC Meeting No.18/08	F.No.01/83/50/1084/AM07
Meeting Date: 05.09.2007	RLA F.No.03/95/40/1163/AM07
Adv.Lic.No.0310414239 dated 02.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Betasol Lotion 30ml under para 4.7 of HBP. The Committee decided to forward copy of application together with copy of reply received from the firm to PI Division for their comments. Accordingly, it was decided to defer the case for two weeks.	

Case No.B-254	M/S Dr. Reddy's Laboratories Ltd.																																	
NC Meeting No.18/08	F.No.01/82/50/43/AM06																																	
Meeting Date: 05.09.2007	RLA F.No.09/24/40/548/AM06																																	
Adv.Lic.No.0910025936 dated 13.04.2006																																		
The Committee considered the case as per agenda for ratification of norms for the export product Gemcitabine Hcl under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 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: Gemcitabine Hcl-----1Kg. Import items: <table><tr><th>Sl.No.</th><th>Description of import items</th><th>Quantity allowed</th></tr><tr><td>1.</td><td>1,2 Di Methoxy Ethane</td><td>42.01kg/kg</td></tr><tr><td>2.</td><td>2,2 Di Methoxy Propane</td><td>27.12kg/kg</td></tr><tr><td>3.</td><td>Acetonitrile</td><td>17.47kg/kg</td></tr><tr><td>4.</td><td>D-Mannitol</td><td>17.80kg/kg</td></tr><tr><td>5.</td><td>Ethyl Bromo Di Fluro Acetate</td><td>10.15kg/kg</td></tr><tr><td>6.</td><td>Isopropyl alcohol</td><td>17.95kg/kg</td></tr><tr><td>7.</td><td>N-Acetyl Cytocine</td><td>5.19kg/kg</td></tr><tr><td>8.</td><td>Tetrahydrofuran</td><td>23.20kg/kg</td></tr><tr><td>9.</td><td>Trimethsilyl trifluoro methane sulphonate</td><td>7.01kg/kg</td></tr><tr><td>10.</td><td>Vitride</td><td>3.05kg/kg</td></tr></table> RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.		Sl.No.	Description of import items	Quantity allowed	1.	1,2 Di Methoxy Ethane	42.01kg/kg	2.	2,2 Di Methoxy Propane	27.12kg/kg	3.	Acetonitrile	17.47kg/kg	4.	D-Mannitol	17.80kg/kg	5.	Ethyl Bromo Di Fluro Acetate	10.15kg/kg	6.	Isopropyl alcohol	17.95kg/kg	7.	N-Acetyl Cytocine	5.19kg/kg	8.	Tetrahydrofuran	23.20kg/kg	9.	Trimethsilyl trifluoro methane sulphonate	7.01kg/kg	10.	Vitride	3.05kg/kg
Sl.No.	Description of import items	Quantity allowed																																
1.	1,2 Di Methoxy Ethane	42.01kg/kg																																
2.	2,2 Di Methoxy Propane	27.12kg/kg																																
3.	Acetonitrile	17.47kg/kg																																
4.	D-Mannitol	17.80kg/kg																																
5.	Ethyl Bromo Di Fluro Acetate	10.15kg/kg																																
6.	Isopropyl alcohol	17.95kg/kg																																
7.	N-Acetyl Cytocine	5.19kg/kg																																
8.	Tetrahydrofuran	23.20kg/kg																																
9.	Trimethsilyl trifluoro methane sulphonate	7.01kg/kg																																
10.	Vitride	3.05kg/kg																																

Case No.B-255	M/S MSN Pharma Pvt. Ltd.
NC Meeting No.18/08	F.No.01/82/50/611/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/110/AM07
Adv.Lic.No.0910027025 dated 26.07.2006	
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.	

Case No.B-256	M/S Artemis Biotech
NC Meeting No.18/08	F.No.01/87/50/1324/AM05
Meeting Date: 05.09.2007	RLA F.No.03/24/41/175/AM05
Adv.Lic.No.03102310813 dated 05.01.2005	

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

The Committee observed that firm was requested to furnish certain information vide letter dated 07.09.2005. Firm had submitted the same vide their letter dated 04.10.2005 which was received on 05.10.2005. However, the same could not be taken into consideration in the NC meeting held on 07.12.2005. Committee, therefore, decided to forward the reply dated 04.10.2005 received from the firm to PI Division for their comments. The case was accordingly deferred for six weeks.

Case No.B-257	M/S Amoli Organics Pvt. Ltd.
NC Meeting No.18/08	F.No.01/82/50/250/AM04
Meeting Date: 05.09.2007	RLA F.No.03/24/40/378/AM04 03/24/40/1682/AM04 03/24/40/1679/AM04 03/24/40/1933/AM04
Adv.Lic.No.0310210446 dated 26.06.2003 0310240157 dated 05.12.2003 0310240142 dated 05.12.2003 0310244706 dated 31.12.2003	
The Committee considered the case as per agenda for ratification of norms for the export product 1-Phenyloxindole under para 4.7 of HBP. The Committee in consultation with the representative of PI Division present in the meeting decided to ratify norms under para 4.7 of HBP as per SION at Sl.No.A-3428 together with bifurcation of quantity of Solvents i.e. Toluene @2.36kg/kg and IPA @0.75kg/kg. RLA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-258	M/S Alkem Laboratories Ltd.
NC Meeting No.18/08	F.No.01/82/50/1367/AM04
Meeting Date: 05.09.2007	RLA F.No.03/24/40/2213/AM04
Adv.Lic.No.0310249186 dated 22.01.2004	
The Committee considered the case as per agenda for ratification of norms for the export product Ceftazidime for Injection USP 1gm under para 4.7 of HBP. The Committee in light of earlier decision taken in its 16/08 meeting held on 21.08.2007 vide case No.B-230 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-259	M/S Glenmark Pharmaceuticals Ltd.
NC Meeting No.18/08	F.No.01/82/162/138/AM08
Meeting Date: 05.09.2007	RLA F.No.03/94/40/907/AM06
Adv.Lic.No.0310355573 dated 16.11.2005	
The Committee considered the case as per agenda for ratification of norms for the export product Aminodarone Hcl under para 4.7 of HBP. The Committee in the light of its earlier decision in 9/08 meeting held on 03.07.2007 vide case No.10/9/82-ALC4/2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied for whichever is less. Export product: Amiodarone Hcl-----1Kg. Import items: 1. 2-Butyl-3-(3,5-Diiodo-4-Hydroxybenzoyl)---1.04Kg/Kg.	

2. Iso Propyl Alcolol-----0.75Kg/Kg.
3. Toluene-----1.95Kg/Kg.

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

Case No.B-260	M/S Glenmark Pharmaceuticals Ltd.									
NC Meeting No.18/08	F.No.01/82/162/119/AM08									
Meeting Date: 05.09.2007	RLA F.No.03/24/40/1139/AM04									
Adv.Lic.No.0310226463 dated 23.09.2003										
The Committee considered the case as per agenda for ratification of norms for the export product Glimpiride under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/127/2006-PI-III dated 14.08.2006 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: Gilimepride-----1Kg. Import items: <table><tr><th>Sl.No.</th><th>Description of import items</th><th>Quantity allowed</th></tr><tr><td>1.</td><td>4-(2-3-Ethyl-4-Methyl-2-Oxo-3-Pyrroline-1-Carboxamido Ethyl Phenyl Sulfonamide)</td><td>0.96kg/kg</td></tr><tr><td>2.</td><td>Trans-4-Methyl Cyclohexyl Isocyanate</td><td>0.39kg/kg</td></tr></table> RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.		Sl.No.	Description of import items	Quantity allowed	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
Sl.No.	Description of import items	Quantity allowed								
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								

Case No.B-261	M/S Aarti Drugs Ltd.
NC Meeting No.18/08	F.No.01/87/50/465/AM07
Meeting Date: 05.09.2007	RLA F.No.03/94/40/277/AM06 03/94/40/617/AM06 03/94/40/999/AM06
Adv.Lic.No.0130340050 dated 20.07.2005 0310347752 dated16.09.2005	

0310365358 dated 01.02.2006	
The Committee considered the case as per agenda for allowing import of Pottassium Hydroxide under para 4.7 of HBP. Committee decided to allow import of Potassium Hydroxide @0.40kg/kg subject to the condition that firm had included said item in their application for obtaining Advance Authorization. RLA concerned may first check whether the firm had initially applied for import of the above item, if so, they may allow import of Potassium Hydroxide @0.40kg/kg.	

Case No.B-262	M/S SMS Pharmaceutical Ltd
NC Meeting No.18/08	F.No.01/83/162/424/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/02/AM06
Adv.Lic.No.0910023407 dated 05.07.2005	
The Committee considered the case as per agenda for modification of norms for the export product D-erythro, d-threo)-2-Dioxy-2,2-Difluoro Pentafuranos-1-ulose-3,5-Dibenzoate 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, accordingly, decided to defer the case for six weeks.	

Case No.B-263	M/S SMP Pharmaceutical Ltd
NC Meeting No.18/08	F.No.01/83/162/425/AM07
Meeting Date: 05.09.2007	RLA F.No.09/24/40/377/AM06
Adv.Lic.No.0910025027 dated 28.11.2005	
The Committee considered the case as per agenda for ratification of norms for the export product D-erythro, d-threo)-2-Dioxy-2,2-Difluoro Pentafuranos-1-ulose-3,5-Dibenzoate 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, accordingly, decided to	

defer the case for six weeks.

Case No.B-264	M/S Suven Life Science Ltd.	
NC Meeting No.18/08	F.No.01/83/50/916/AM04	
Meeting Date: 05.09.2007	RLA F.No.09/24/40/232/AM04	
Adv.Lic.No.0910016176 dated 16.10.2003		
The Committee considered the case as per agenda for ratification of norms for the export product (2S,5R)-3-(3,5-1Dichlorophenyl)-2-(1,1-Dimethyl Ethyl)-5-Methyl-1-(Trifluoro Acetol)-4-Imedazolidone under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/254/2006-PI-III dated 16.04.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.		
Sl.No.	Description of Export Product	Quantity
1.	(2S,5R)-3-(3,5-Dichlorophenyl)-2-(1,1-Dimethyl Ethyl)-5-Methyl-1-(Trifluoroacetyl)-4-imedazolidone	1Kg.

Import Items:

Sl.No.	Description of import items	Quantity allowed
1.	BOC-D-Alanine	0.93kg/kg
2.	Isobutylchloroformate	0.67kg/kg
3.	3,5-Dichloroaniline	0.80kg/kg
4.	Trimethylacetyldehyde (Pivalaldehyde)	0.29kg/kg
5.	Trifluoroaceticanhydride	0.54kg/kg
6.	Iso-Octane	0.38kg/kg

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

Case No.B-265	M/S Process Chemicals Co.	
NC Meeting No.18/08	F.No.01/83/50/485/AM07	
	F.No.01/83/50/497/AM06	
	F.No.01/83/50/498/AM06	

Meeting Date: 05.09.2007	RLA F.No.02/24/40/116/AM07 02/24/40/189/AM06 02/24/40/190/AM06
Adv.Lic.No.0210092098 dated 01.08.2006 0210083906 dated 01.12.2005 0210083908 dated 01.12.2005	
The Committee considered the case as per agenda for modification of norms for the export product Calcium D-Saccharate USP and Monopotassium Glucarate 99% Purity under para 4.7 of HBP. Committee observed that firm has filed writ petition in the High Court at Kolkata while the case is under active consideration of Norms Committee. Therefore, Writ Petition filed in Calcutta High Court is premature. However, Committee decided to defer the case for four weeks.	

Case No.B-266	Cases approved by NC in its 1/08 to 15/08 meeting for the export product Cloxacillin Sodium from 6-APA Route			
NC Meeting No.18/08				
Meeting Date: 05.09.2007				
Committee observed that during recording of minutes of meeting No.1/08 to 15/08 for ratification of norms for the export product Cloxacillin Sodium from 6APA Route, description of input at Sl.No.3 has been mentioned as ‘3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CKIC Chloride), while as per Report of PI Division, the correct description of input is “3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)”.				
Committee, therefore, decided to allow above correction in the description of the import item as per report of PI Division in respect of following cases;				
Sl.N o.	Name of firm	A/L No. and date	Hqrs. File No.	RLA File No.
1.	DSM Anti-Infectives	2210005059 dt.20.12.05	01/82/50254/AM07	22/21/40/97/AM06
2.	Surya Pharmaceuticals Ltd.	2210005145 dt.9.1.06	01/87/50/1203/AM 06	22/24/40/66/AM06
3.	DSM Anti-Infectives	2210005464 dt.25.4.06	01/82/50/107/AM0 7	22/24/40/5/AM07
4.	Aurobindo Pharma Ltd.	0910026769 dt.6.7.2006	01/87/50/345/AM0 7	09/24/40/42/AM07
5.	DSM Anti-Infectives	2210005749 dt.10.07.2006	01/82/50/527/AM0 7	22/24/40/117/AM07
6.	DSM Anti-Infectives	2210005758 dt.12.7.06	01/82/50/539/AM0 7	22/24/40/118/AM07
7.	DSM Anti-Infectives	2210005855 dt.7.8.06	01/82/50/684/AM0 7	22/24/40/159/AM07
8.	DSM Anti-Infectives	2210005856	01/82/50/685/AM0	22/24/40/160/AM07

		dt.7.8.2006	7	
9.	DSM Anti-Infectives	2210005854 dt.7.8.06	01/82/50/683/AM07	22/24/40/161/AM07
10.	Aurobindo Pharma Ltd.	0910028246 dt.17.11.06	01/87/50/744/AM07	09/24/40/313/AM07
11.	DSM Anti-Infectives	2210006267 dt.7.12.06	01/82/50/1404/AM07	22/21/40/123/AM06
12.	Aurobindo Pharma Ltd	0910024652 dt.23.11.05	01/87/50/995/AM06	09/24/40/299/AM06
13.	-----do-----	0910025312 dt.31.1.06	01/87/50/1315/AM06	09/24/40/413/AM06
14.	DSM Anti-Infectives	2210006408 dt.19.1.07	01/82/50/1589/AM07	22/21/40/73/AM06
15.	DSM Anti-Infectives	2210006409 dt.19.1.07	01/82/50/1590/AM07	22/21/40/105/AM06
16.	DSM Anti-Infectives	2210006461 dt.2.2.07	01/82/50/54/AM08	22/21/42/69/AM05
17.	DSM Anti-Infectives	2210006458 dt.2.2.07	01/82/50/1857/AM07	22/21/42/79/AM05
18.	DSM Anti-Infectives	2210006462 dt.2.2.07	01/82/50/55/AM08	22/21/41/85/AM05
19.	DSM Anti-Infectives	2210006479 dt.8.2.07	01/82/50/60/AM08	22/21/40/61/AM06
20.	Parabolic Drugs Ltd	2210005314 dt.10.3.06	01/83/50/712/AM06	22/24/40/125/AM06
21.	Parabolic Drugs Ltd	2210005500 dt. 4.5.06	01/83/50/122/AM07	22/24/40/12/AM07
22.	Parabolic Drugs Ltd	2210005523 dt.9.5.06	01/83/50/149/AM07	22/24/40/11/AM07
23.	Parabolic Drugs Ltd	2210005662 dt.16.6.06	01/83/50/304/AM07	22/24/40/68/AM07
24.	Penam Lab. Ltd.	0510185515 dt.29.6.06	01/83/50/365/AM07	05/24/40/62/AM07
25.	Parabolic Drugs Ltd.	2210005783 dt.17.7.06	01/83/50/432/AM07	22/24/40/124/AM07
26.	-----do-----	2210005782 dt.17.7.06	01/83/50/431/AM07	22/24/40/113/AM07
27.	-----do-----	2210005805 dt.21.7.06	01/83/50/455/AM07	22/24/40/141/AM07
28.	-----do-----	2210005843 dt.2.8.06	01/83/50/506/AM07	22/24/40/148/AM07
29.	Surya Pharmaceutical Ltd	2210005954 dt.4.9.06	01/83/50/629/AM07	22/21/40/41/AM07
30.	Penam Labs. Ltd.	0510190573 dt.11.9.06	01/83/50/655/AM07	05/24/40/418/AM07
31.	Aurobindo Pharma Ltd.	0910029461 dt.27.2.07	01/82/50/1067/AM07	09/24/40/367/AM07
32.	KDL Biotech Ltd.	0310418079 dt.2.2.07	01/82/50/35/AM08	03/94/40/664/AM07
33.	DSM Anti-Infectives	2210006449 dt.31.1.07	01/82/50/94/AM08	22/21/40/79/AM05
34.	DSM Anti-Infectives	2210006454 dt.31.1.07	01/82/50/96/AM08	22/21/40/04/AM05
35.	DSM Anti-Infectives	2210006431 dt.25.1.07	01/82/50/83/AM08	22/21/40/9/AM07
36.	KDL Biotech Ltd	0310418079 dt.02.02.07	01/82/50/35/AM08	03/94/40/664/AM07
37.	DSM Anti-Infectives	2210006449 dt.31.1.07	01/82/50/94/AM08	22/21/40/79/AM05
38.	Aurobindo Pharma Ltd.	0910030111 dt.27.4.07	01/83/50/209/AM08	09/24/40/558/AM07
39.	-----do----	0910065592 dt.26.06.07	01/87/50/882/AM07	09/24/40/412/AM06

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

Case No.B-267	M/S Sandoz Pvt. Ltd.
NC Meeting No.18/08	F.No.01/82/162/1266/AM01
Meeting Date: 05.09.2007	
Adv.Lic.No.0310002380 dated 27.07.99	
Committee considered the case as per agenda for enhancement in the quantity of inputs under para 4.7 of HBP. Committee observed that no previous record is available and decided to defer the case for four weeks.	