

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

Para 4.7 Officewise Statement

MEETING NUMBER : 15/82-ALC4/2007 **MEETING DATE** : 14.08.2007

1	Case No.: 10/20/87-ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/87/050/00429/AM06/	RLA File :02/24/040/00081/AM06/	Lic.No/Date:0210080076 15.07.2005	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. The Committee decided to defer the case for four weeks for want of comments from the Department of Ayush.			

2	Case No.: 39/38/82-ALC1/2005	Party Name:LUPIN LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Withdrawn
	HQ File :01/82/050/01028/AM06/	RLA File :03/95/040/01052/AM06/	Lic.No/Date:0310358437 06.12.2005	
	Decision : Withdrawn as the case has already been approved by NC in its 13/08 meeting held on 31.07.2007.			

3	Case No.: 8/39/87-ALC1/2005	Party Name:SURYA PHARMACEUTICAL LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Withdrawn
	HQ File :01/87/050/01083/AM06/	RLA File :22/24/040/00045/AM06/	Lic.No/Date:2210005064 12.12.2005	
	Decision : Withdrawn as the case has already been approved by NC in its 13/08 meeting held on 31.07.2007.			

4	Case No.: 7/47/83-ALC1/2005	Party Name:UNIMARK REMEDIES LIMITED.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Withdrawn
	HQ File :01/83/050/00639/AM06/	RLA File :03/95/040/01284/AM06/	Lic.No/Date:0310365479 01.02.2006	
	Decision : Withdrawn as the case has already been approved by NC in its 13/08 meeting held on 31.07.2007.			

5	Case No.: 31/47/82-ALC1/2005	Party Name:CALYX CHEMICALS & PHARMACEUTICALS PVT.LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01335/AM06/	RLA File :03/94/040/01210/AM06/	Lic.No/Date:0310365692 03.02.2006	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Coenzyme Q10 under para 4.7 of HBP. The Committee was informed by Department of Bio-Technology vide their letter No.BT/IL/05/231/06/2006-PID dated 20.07.2007 that the export product is chemical product and not biotech product. The Committee, therefore decided to forward copy of the application alongwith copy of letter received from Department of Biotechnology to PI Division. The Committee also decided to call for production and consumption data certified by the Central Excise Authority from the firm. Accordingly, the case was deferred for six weeks.			

6	Case No.: 8/10/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/87/050/00096/AM07/	RLA File :02/24/040/00020/AM07/	Lic.No/Date:0210088734 28.04.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. The Committee decided to remind Department of Department of Ayush and defer the case for four weeks.			

7	Case No.: 39/9/82-ALC1/2006	Party Name:KDL BIOTECH LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/00209/AM07/	RLA File :03/94/040/00021/AM07/	Lic.No/Date:0310379882 10.05.2006	Defer Date:28.08.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Flu-Cloxacillin Sodium BP/USP/EP 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. The Committee, accordingly decided to defer the case for two weeks.			

8	Case No.: 4/14/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Approved
	HQ File :01/82/050/00215/AM07/	RLA File :09/24/040/00511/AM06/	Lic.No/Date:0910026249 11.05.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product (4R-Cis)-1, 1-Dimethylethyl-6-(2-amino ethyl)-2,2-dimethyl-1,3-dioxane-4-acetate under para 4.7 of HBP.			

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2007-PI-III dated 14.08.2007 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:

(4R-cis)-1,1-dimethyl ethyl-6-(2amino ethyl)-
2,2 dimethyl-1,3 dioxane-4-acetate-----1Kg.

Import items:

1. (4R-cis)-1,1-dimethylethyl-6-cyno
methyl-2,2 dimethyl-1,3 dioxane-4-acetate-----1.05kg/kg
2. Raney nickel-----0.510kg/kg
3. Methanol-----2.99kg/kg

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

9	Case No.:25/14/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/00268/AM07/	RLA File :05/24/040/00021/AM07/	Lic.No/Date:0510183618 29.05.2006	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Cloxacillin Sodium BP (Pen G Route) under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride-----0.407kg 4. Acetone-----0.1254kg 5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg OR 5.a) O-chloro Benzaldehyde-----0.5034kg b) Hydroxy Amine Sulphate-----0.3192kg c) Methyl Acetoacetate-----0.410kg d) Chloroform-----0.270kg e) Methylene chloride-----0.0542kg				

6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

10	Case No.:1/23/87-ALC1/2006	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00336/AM07/	RLA File :05/24/040/00255/AM07/	Lic.No/Date:0510185276 21.06.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Silymarin Extract under para 4.7 of HBP. The Committee decided to defer the case for four weeks for want of comments from Department of Ayush.			

11	Case No.:24/20/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/00533/AM07/	RLA File :07/24/040/00220/AM07/	Lic.No/Date:0710045973 11.07.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Magnesium Orotate (Dihydrate) under para 4.7 of HBP. The Committee noted that the export product is a Calcium Nutrient but not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

12	Case No.:25/20/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/00534/AM07/	RLA File :07/24/040/00145/AM07/	Lic.No/Date:0710045974 11.07.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Potassium Citrate, Calcium Citrate and Zinc Citrate under para 4.7 of HBP. The Committee noted that the export product is Nutrient but not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

13	Case No.:2/34/82-ALC1/2006	Party Name:DISHMAN PHARMACEUTICALS & CHEMICALS LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
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	HQ File :01/82/050/00593/AM07/	RLA File :08/24/040/00247/AM06/	Lic.No/Date:0810058323 24.07.2006	Defer Date: 11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 1-Carbethoxy Ethylidene Triphenyl Phosphorance under para 4.7 of HBP. The Committee decided to call for the End Use of the export product alongwith supporting technical literature from the firm. Accordingly, it was decided to defer the case for four weeks.			

14	Case No.:16/27/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00419/AM07/	RLA File :02/24/040/00123/AM07/	Lic.No/Date:0210092125 02.08.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Kola Extract under para 4.7 of HBP. The Committee decided to remind Deptt. of Ayush and defer the case for four weeks.			

15	Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	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:11.09.2007
	Decision : The Committee considered the case 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 the Committee that the case is under examination in their Department. The Committee, therefore, decided to defer the case for four weeks.			

16	Case No.:5/32/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/01096/AM07/	RLA File :07/24/040/00412/AM07/	Lic.No/Date:0710047697 05.10.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Calcium Levulinate under para 4.7 of HBP. The Committee observed that the firm themselves has declared that the export product can be used for the preparation of various organic mineral Salts and can be used as Mineral supplements. Hence the export product is not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

17	Case No.:24/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Withdrawn
	HQ File :01/82/050/01101/AM07/	RLA File :03/94/040/00703/AM07/	Lic.No/Date:0310402830 06.10.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product L-Norephedrine Base under para 4.7 of HBP. Withdrawn as the case has already been rejected by NC in its 8/08 meeting held on 28.06.2007.			

18	Case No.:10/32/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/01118/AM07/	RLA File :07/24/040/00413/AM07/	Lic.No/Date:0710047772 09.10.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Zinc Gluconate etc. under para 4.7 of HBP. The Committee noted that the export product is a Gluconate and Minerals but not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

19	Case No.:31/34/87-ALC1/2006	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00637/AM07/	RLA File :04/24/040/00252/AM07/	Lic.No/Date:0410084952 17.10.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 10-Methoxy Imino Stilbene 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. The Committee, therefore, decided to defer the case for four weeks.			

20	Case No.:2/46/87-ALC1/2006	Party Name:AVON ORGANICS LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00663/AM07/	RLA File :09/24/040/00271/AM07/	Lic.No/Date:0910027981 30.10.2006	Defer Date: 11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 5-Acetyl Amino Benzimidazolone (AABZ) or 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP.			

The Committee observed that NC-I has forwarded the copy of application to Department of Chemicals & Petrochem, while the export product is Pharmaceutical item. The application should have been forwarded to PI Division. The Committee, therefore decided to forward the application to PI Division for their comments. It was accordingly decided to defer the case for four weeks.

21	Case No.: 3/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01214/AM07/	RLA File :09/24/040/00174/AM07/	Lic.No/Date:0910028004 31.10.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Fexofenadine Hcl under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department. The Committee, therefore, decided to defer the case for four weeks.			

22	Case No.: 4/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01215/AM07/	RLA File :09/24/040/00194/AM07/	Lic.No/Date:0910028005 31.10.2006	Defer Date:28.08.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Sodium Cromo Glycate under para 4.7 of HBP. The Committee observed that the firm was requested to furnish End Use of the export product and copy of DML, but the same has not been received. The Committee therefore decided to await the reply and defer the case for two weeks.			

23	Case No.: 17/37/87-ALC1/2006	Party Name:AVENTIS PHARMA LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00684/AM07/	RLA File :03/94/040/00824/AM07/	Lic.No/Date:0310406387 02.11.2006	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Articaine 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. The Committee, therefore, decided to defer the case for four weeks.			

24	Case No.: 12/45/87-ALC1/2006	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/87/050/00747/AM07/	RLA File :09/24/040/00128/AM07/	Lic.No/Date:0910028249 17.11.2006	Defer Date:11.09.2007

Decision : The Committee considered the case as per agenda for ratification of norms for the export product Sterile Ampmicillin Sodium+Salbactam Sodium (2:1) under para 4.7 of HBP.

The Committee decided to call for the production and consumption date certified by the Central Excise Authority from firm and Pharmexcil for revision of SION at Sl.No.A-2114 and A-2121. The Committee also decided to defer this case for four weeks.

25	Case No.:8/44/82-ALC1/2006	Party Name:M/S.ENAL DRUGS PVT LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01307/AM07/	RLA File :09/24/040/00237/AM07/	Lic.No/Date:0910028243 17.11.2006	Defer Date:11.09.2007
	Decision : The 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. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department. The Committee, therefore, decided to defer the case for four weeks.			

26	Case No.:2/38/82-ALC1/2006	Party Name:CROPNOSYS (INDIA) PRIVATE LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/01322/AM07/	RLA File :03/94/040/00923/AM07/	Lic.No/Date:0310408850 21.11.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Fluazinam echnical Min 98% under para 4.7 of HBP. The Committee decided to transfer the case to DES-IV as the export product is from Chemical Sector.			

27	Case No.:23/36/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/01314/AM07/	RLA File :07/24/040/00565/AM07/	Lic.No/Date:0710048577 22.11.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Magnesium Orottate Dihtrate, Calcium Orotate Dihydrate, Potassium Orotate and Zinc Orotate Dihydrate under para 4.7 of HBP. The Committee noted that the export product is a Gluconate and Minerals but not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

28	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:15/82-ALC4/2007	Status:Case
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		14.08.2007	Deferred
HQ File :01/82/050/01441/AM07/	RLA File :09/24/040/00390/AM07/	Lic.No/Date:0910028634 13.12.2006	Defer Date:11.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product N-Trifluoro Acetyl-N-Lysine-Praline (Lyspro (Isolated) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department. The Committee, therefore, decided to defer the case for four weeks.			

29	Case No.: 4/47/87-ALC1/2006	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/87/050/00827/AM07/	RLA File :09/24/040/00359/AM07/	Lic.No/Date:0910028661 18.12.2006	Defer Date:28.08.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Lopinavir under para 4.7 of HBP. The Committee observed that the firm was requested to furnish some information, but the same has not been received. The Committee therefore decided to await the reply and defer the case for two weeks.			

30	Case No.: 14/43/82-ALC1/2006	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/82/050/01502/AM07/	RLA File :07/24/040/00655/AM07/	Lic.No/Date:0710049235 27.12.2006	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Calcium Levulinate under para 4.7 of HBP. The Committee noted that the export product is used as Minerals and Nutrients but not a bulk drug. Moreover, the copy of DML has not been received. The Committee, therefore, decided to transfer the case to DES-IV.			

31	Case No.: 18/46/82-ALC1/2006	Party Name:FLORALE (INDIA) PVT. LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/82/050/01580/AM07/	RLA File :07/24/040/00695/AM07/	Lic.No/Date:0710049625 18.01.2007	
	Decision : The Committee decided to transfer the case to DES-VI as the export product pertains to Food Product sector.			

32	Case No.: 16/49/82-ALC1/2006	Party Name:LUPIN LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01721/AM07/	RLA File :03/95/040/01297/AM07/	Lic.No/Date:0310416716	Defer

		22.01.2007	Date:25.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Sterile Ceftriazone Sodium-Non Infringing under para 4.7 of HBP.			
The Committee decided to call for the production and consumption data duly certified by the Central Excise Authority from the firm as firm has stated that it is prepared using non infringing process. Accordingly, the case was deferred for six weeks.			

33	Case No.:2/14/83-ALC1/2007	Party Name:SRI GAYATHRI DRUGS PVT LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/01204/AM07/	RLA File :09/24/040/00447/AM07/	Lic.No/Date:0910029230 07.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 4-(3,4-Dichlorophenyl)-3,4-dihydro-1(2H)-Naphthalenone (PID) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that earlier the firm was allowed input @0.95kg/kg, while in the present application, the firm has applied the input @0.943kg/kg. The Committee, therefore, decided to ratify the norms under para 4.7 of HBP as applied by the firm. RLA Concerned may take further necessary action as per above decision of NC.			

34	Case No.:3/4/82-ALC1/2007	Party Name:HETERO LABS LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01648/AM07/	RLA File :09/24/040/00482/AM07/	Lic.No/Date:0910029348 15.02.2007	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Osel Tamivir Phosphate 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.			

35	Case No.:1/11/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/83/050/01270/AM07/	RLA File :03/95/040/01095/AM07/	Lic.No/Date:0310420522 22.02.2007	Defer Date: 11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Sertraline Hcl under para 4.7 of HBP.			

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/221/20060PI-III dated 14.08.2007 decided to call for the following information from the firm and also decided to defer the case for four weeks:-

1. The firm have applied Alpha Naphthol @0.80kg/kg whereas the consumption co-efficient of Tetralone indicated @3.73 kg/kg. Technical justification alongwith complete working for the above may be furnished.
2. The firm has given chemical reactions. However molecular weight of each input and output, % yield on molar basis for each step is not given. The same may be furnished.
3. Requirement and recovery of solvents may be given for each step.
4. Molecular weight of Sertraline Hcl is shown as 341 whereas it is indicated as 342.70 in the literature. The discrepancy may be explained.

36	Case No.:6/16/83-ALC1/2007	Party Name:SODIUM METAL (P) LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/01275/AM07/	RLA File :34/24/040/00268/AM07/	Lic.No/Date:3410018173 26.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 1,1Cyclohexane Diacetic Acid Monoamide under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/187/2006-PI-III dated 08.08.2006 in the case of M/S Rampex Labs Pvt. Ltd, 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: 1,1Cyclohexane Diacetic Acid Monoamide-----1Kg. Import items: 1,1 Cyclohexane Diacetic Acid-----1.12kg/kg RLA concerned may take further necessary action as per above decision of NC.			

37	Case No.:22/50/83-ALC1/2006	Party Name:SEQUENT SCIENTIFIC LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/01286/AM07/	RLA File :03/95/040/01482/AM07/	Lic.No/Date:0310421169 27.02.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Chloropropiophenone under para 4.7 of HBP. The Committee observed that the complete description of the export is 3-Chloropropiophenone and SION for this product has been fixed at Sl.No.A-3405. The Committee, therefore decided to ratify the norms under para 4.7 of HBP as per SION at Sl.No.A-3405.			

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

38	Case No.: 3/1/87-ALC1/2007	Party Name:AVON ORGANICS LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/87/050/01107/AM07/	RLA File :09/24/040/00487/AM07/	Lic.No/Date:0910029668 14.03.2007	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 5-Aceto Acetyl Amino Benzimidazo 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.			

39	Case No.: 43/9/82-ALC4/2007	Party Name:KOPRAN LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01818/AM07/	RLA File :03/94/040/01416/AM07/	Lic.No/Date:0310423486 16.03.2007	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Clarithromycin EP/USP under para 4.7 of HBP. The Committee decided to defer the case for four weeks.			

40	Case No.: 1/15/82-ALC4/2007	Party Name:CHEMSHEL ENTERPRISES PVT.LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/82/050/01841/AM07/	RLA File :02/24/040/00357/AM07/	Lic.No/Date:0210099250 21.03.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Aleuritic Acid under para 4.7 of HBP. The Committee decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.			

41	Case No.: 17/9/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01837/AM07/	RLA File :03/94/040/01468/AM07/	Lic.No/Date:0310423777 21.03.2007	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Exemestane 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.

42	Case No.: 19/9/82-ALC4/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01846/AM07/	RLA File :09/24/040/00523/AM07/	Lic.No/Date:0910029739 22.03.2007	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Carvedilol 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.			

43	Case No.: 20/9/82-ALC4/2007	Party Name:CONCORD BIOTECH LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/01863/AM07/	RLA File :08/24/040/00356/AM07/	Lic.No/Date:0810063862 26.03.2007	Defer Date:25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Vamcomycin Hcl under para 4.7 of HBP. The Committee observed that the firm intends to import only consumables and not raw material. The Committee, therefore, decided to seek the comments of Policy Division. Accordingly, the case was deferred for six weeks.			

44	Case No.: 8/4/83-ALC1/2007	Party Name:SALVI CHEMICAL INDUSTRIES LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/83/050/01379/AM07/	RLA File :03/95/040/01615/AM07/	Lic.No/Date:0310424638 27.03.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 8-Quinolium under para 4.7 of HBP. The Committee observed that the application of the firm has been forwarded to Chemical Division by Norms Committee-1. The Committee, therefore, decided to transfer the case to DES-IV.			

45	Case No.: 9/4/83-ALC1/2007	Party Name:SALVI CHEMICAL INDUSTRIES LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Approved
	HQ File :01/83/050/01380/AM07/	RLA File :03/95/040/01614/AM07/	Lic.No/Date:0310424641 27.03.2007	

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

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2004-PI-III dated 14.08.2007 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:

Ferrous Fumarate USP, Purity not less than 97%-----1Kg.

Import items:

1. Furmeric Acid-----0.856kg/kg
2. Soda Ash-----0.944kg/kg
3. Ferrous Sulphate-----1.98kg/kg

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

46	Case No.:22/9/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/82/050/01894/AM07/	RLA File :03/94/040/01500/AM07/	Lic.No/Date:0310424681 28.03.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Tylocip Powder 20%/Tylosin Soluble Powder 20% w/w under para 4.7 of HBP. The Committee decided to ratify the norms under para 4.7 of HBP as per details below; Export product: 1. Tylocip Powder 20%/Tylosin Soluble Powder 20% w/w (Pack size of 100GM) Each 10gm contains Tylosin Tartarate BP (Vet) 2.00gm-----560 Packs 2. Tylocip Powder 50%/Tylosin Soluble Powder 50% w/w (Pack Size of 100GM) Each 10gm contains Tylosin Tartarate BP(Vet) 5.00gm-----200 Packs Import item: Tylosin Tartarate BP (Vet)-----21.41kg RLA concerned may take further necessary action as per above decision of NC.			

47	Case No.:2/4/82-ALC4/2007	Party Name:HERBERT BROWN PHARMACEUTICAL & RESEARCH LABS	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Transferred
	HQ File :01/82/050/01906/AM07/	RLA File :03/94/040/01515/AM07/	Lic.No/Date:0310424944 29.03.2007	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Unylinker Nittomar Solid Support Loaded Support under para 4.7 of HBP. The Committee decided to transfer the case to DES-IV as the export product is a Polymer item and not Pharmaceutical product.				

48	Case No.:23/9/82-ALC4/2007	Party Name:LUPIN LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01901/AM07/	RLA File :03/95/040/01622/AM07/	Lic.No/Date:0310424915 29.03.2007	Defer Date:11.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Cefpodoxime Proxetil under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, therefore, decided to defer the case for four weeks.				

49	Case No.:6/11/82-ALC4/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/01897/AM07/	RLA File :09/24/040/00529/AM07/	Lic.No/Date:0910029839 29.03.2007	Defer Date:11.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Cyclopentadecanolide (Recrystallised) 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.				

50	Case No.:2/3/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/82/050/00005/AM08/	RLA File :34/24/040/00301/AM07/	Lic.No/Date:3410018454 30.03.2007	Defer Date: 11.09.2007
Decision : 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.				

51	Case No.: 25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/83/050/00016/AM08/	RLA File :04/24/040/00501/AM07/	Lic.No/Date:0410088727 02.04.2007	Defer Date: 11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Allylestrenol 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.			

52	Case No.: 6/11/83-ALC1/2007	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Approved
	HQ File :01/83/050/00049/AM08/	RLA File :05/24/040/01067/AM07/	Lic.No/Date:0510202037 02.04.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Hyoscine-N-Butyl Bromide or Hyoscine Hydro Bromide under para 4.7 of HBP. The Committee in light of written comments forwarded by DC(SSI) vide their U.O. No.5(9)/2005-chem dated 18.12.2006 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: Hyoscine-N-Butyl Bromide or Hyoscine Hydro Bromide-----1Kg. Import items: 1. Dubosia Leaves-----85Kg 2. Methylene Chloride-----68.55Kg 3. Methanol-----26.34Kg RLA concerned may take further necessary action as per above decision of NC.			

53	Case No.: 9/9/83-ALC1/2007	Party Name:LACTOSE (INDIA) LTD.,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/83/050/00024/AM08/	RLA File :03/95/040/01500/AM07/	Lic.No/Date:0310425398 02.04.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Lactose Monohydrate BP under para 4.7 of HBP. The Committee decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.			

54	Case No.:13/7/83-ALC1/2007	Party Name:NEULAND LABORATORIES LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/83/050/00086/AM08/	RLA File :09/24/040/00544/AM07/	Lic.No/Date:0910029937 10.04.2007	Defer Date: 25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Ranitidine 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.			

55	Case No.:9/13/83-ALC1/2007	Party Name:KUMAR ORGANIC PRODUCTS LIMITED,	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Deferred
	HQ File :01/83/050/00105/AM08/	RLA File :07/24/040/00020/AM08/	Lic.No/Date:0710051216 13.04.2007	Defer Date: 25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Minoxidil 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.			

56	Case No.:21/16/83-ALC1/2007	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/00144/AM08/	RLA File :22/24/040/00004/AM08/	Lic.No/Date:2210006675 17.04.2007	
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Cefadroxil under para 4.7 of HBP. The Committee in light of Report forwarded by PI Division vide their U.O.35011/165/2006/PI-III dated 30.07.2007 decided to ratify the norms as per details below or as applied for by the firm whichever is lower. Export Product: Cefadroxil Monohydrate from Pen G Route-----1Kg. Import items: 1. Penicillin G Potassium 1st Crystal-----2.34BOU/Kg 2. Pyridine Hydrobromide-----0.320kg/kg OR Hydrobromic acid 48%-----0.375kg/kg			

3. Hydrogen Peroxide 60%-----0.363kg/kg
4. Acetic Acid-----0.933kg/kg
5. Trimethyl chloro silane-----2.7027kg/kg

OR

- 5(a). Bis trimethyl silyl urea-----1.543kg/kg
- 5(b). Hexamethyl disilazane-----0.3284kg/kg
6. Trimethyl chloro silane-----0.2180kg/kg
7. D(-)para hydroxy Phenyl glycine-----0.959kg/kg
Methyl/ethyl potassium dane salt

OR

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

57	Case No.:8/6/83-ALC1/2007	Party Name:R L FINE CHEM	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status:Case Approved
	HQ File :01/83/050/00123/AM08/	RLA File :07/24/040/00021/AM08/	Lic.No/Date:0710051273 17.04.2007	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Methane Sulfonate of 10,11,Dihydro-N,N Betatrimethyl 5H-Dibenzo (B,F)Azepine-5 Propanamine under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/49/2006-PI-III dated 14.08.2007 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:				

Methane Sulfonate of 10,11-Dihydro-N,N, Betarimethyul-5H-Dibenz(B,F) Azepine-5-Propanamine-----1Kg.

Import items:

1. 1 Bramo 3 chloro 2 methyl propane-----0.55kg/kg
2. Iminodibenzyl-----0.56kg/kg

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

58	Case No.: 18/7/83-ALC1/2007	Party Name:RESONANCE LABORATORIES PVT LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/83/050/00171/AM08/	RLA File :07/24/040/00048/AM08/	Lic.No/Date:0710051363 23.04.2007	Defer Date: 25.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product 1-[2,6 Dichloro-4(Trifluoromethyl) Phenyl]-5-[Pyridine-2-YL Methylene)Amino] 1H-Pyrazole-3-Carbonitrile (C-6900) under para 4.7 of HBP. The Committee decided to forward copy of application to PI Division for their comments. The Committee also decided to defer the case for six weeks.			

59	Case No.: 9/11/83-ALC1/2007	Party Name:RICHY GOLD INTERNATIONAL	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/83/050/00341/AM08/	RLA File :03/95/040/00069/AM08/	Lic.No/Date:0310429618 16.05.2007	Defer Date: 28.08.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Methyl Dopa Tablet 250MG under para 4.7 of HBP. The Committee decided to defer the case for two weeks for want of comments of PI Division.			

60	Case No.: 34/9/82-ALC4/2007	Party Name:AGIO PHARMACEUTICALS LTD	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/00045/AM08/	RLA File :03/94/040/00082/AM08/	Lic.No/Date:0310430135 22.05.2007	Defer Date:11.09.2007
	Decision : The Committee considered the case as per agenda for ratification of norms for the export product Prednisolone Solution for Injection 30mg/1ml under para 4.7 of HBP. The Committee decided to remind the firm to get the export product amended from RLA and to furnish documentary evidence in this regard. The Committee also decided to defer the case for four weeks.			

61	Case No.: 37/16/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/83/050/00385/AM08/	RLA File :03/94/040/00170/AM08/	Lic.No/Date:0310430424 23.05.2007	Defer Date: 25.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Niclosamide Piperazine Salt 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.				

62	Case No.: 35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/00051/AM08/	RLA File :34/24/040/00035/AM08/	Lic.No/Date:3410018854 28.05.2007	Defer Date: 11.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Azithromycin Step-3 under para 4.7 of HBP. The Committee observed that the firm has been requested to furnish complete chemical description of the export product which has not been received. The Committee, therefore, decided to await the reply of the firm and to defer the case for four weeks.				

63	Case No.: 2/15/82-ALC4/2007	Party Name:NICHIPLAST INDIA PVT LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Transferred
	HQ File :01/82/050/00063/AM08/	RLA File :05/24/040/00140/AM08/	Lic.No/Date:0510204505 05.06.2007	
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Dettol Medicated Fabric Plaster under para 4.7 of HBP. The Committee decided to transfer the case to DES-VIII as the export product pertains to Plastic Sector.				

64	Case No.: 3/15/82-ALC4/2007	Party Name:HARMAN FINOCHEM LTD.	Meet No/Date:15/82-ALC4/2007 14.08.2007	Status: Case Deferred
	HQ File :01/82/050/00103/AM08/	RLA File :03/94/040/00179/AM08/	Lic.No/Date:0310431949 07.06.2007	Defer Date: 25.09.2007
Decision : The Committee considered the case as per agenda for ratification of norms for the export product Phenobarbital (Phenobarbitone) 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:13.08.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Minutes of the Norms Committee Meeting No.15/08 held on 14.08.2007 under the Chairmanship of Shri Sanjay Rastogi, Export Commissioner.

The Committee first considered the minutes of the NC Meeting No.14/08 held on 07.08.2007 for confirmation and confirmed and adopted the same.

The Committee considered each case as per agenda.

Case No.A-460	M/S RA Chem Pharma Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/1335/AM'07/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/463/AM07
Adv.Lic.No.0910029658 dated 14.03.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 2,3,Dichloro Benzoyl Cyanide under para 4.7 of HBP.

The Committee in light of earlier decision of Norms Committee in its 14/08 meeting held on 07.08.2007 vide Case No.A-424 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-461	M/S Unimark Remedies Ltd
N.C. Meeting No.15/08	F.No.01/82/50/1206/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/502/AM07
Adv.Lic.No.0310416918 dated 23.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Cefprozil under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-462	M/S Unimark Remedies Ltd
N.C. Meeting No.15/08	F.No.01/82/50/1207/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/934/AM07
Adv.Lic.No.0310416945 dated 23.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ethyl-1,4 Dihydro-7-Methyl-4-one-1,8-Napthyridine-3-Carboxylate 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-463	M/S R.L. Fine Chem
N.C. Meeting No.15/08	F.No.01/82/50/176/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.07/24/40/18/AM08
Adv.Lic.No.0710051369 dated 23.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Oxo-6,11-Dihydro Dibenzo (B-E) Thiepine 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-464	M/S Rashmi Pharma Pvt. Ltd
N.C. Meeting No.15/08	F.No.01/82/50/1327/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/506/AM07
Adv.Lic.No.0910029625 dated 09.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Orlistat Pellets 50% (Tetrahydro Lipstatin Pellets 50%) Pellets (Anti-Obesity) under para 4.7 of HBP. The Committee in light of earlier decision taken in its 39/2006 meeting held on 10.01.2007 vide Case No.47/31/82 decided to ratify the norms under para 4.7 of HBP as per details below or as applied for whichever is lower. Export Product: Orlistat Pellets 50%-----1Kg.	

Import item:

Olistat-----0.505kg/kg

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

Case No.A-465	M/S Rantus Pharma Ltd
N.C. Meeting No.15/08	F.No.01/82/50/1235/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/401/AM07
Adv.Lic.No.0910029304 dated 12.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Tramadol Crude under para 4.7 of HBP. The Committee decided to call for complete specification of the export product from the firm. The case was accordingly deferred for six weeks.	

Case No.A-466	M/S Unichem Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/453/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/143/AM08
Adv.Lic.No.0310431069 dated 30.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Amlodipine Maleatate under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/232/2005-PI-III dated 14.08.2007 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:	

Amlodipine Maleate-----1Kg.

Import items:

1. Phthaloyl Amlodipine-----1.08kg/kg
2. Methylene chloride-----4.50kg/kg
3. Isopropyl alcohol-----2.40kg/kg

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

Case No.A-467	M/S Unichem Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/1388/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/1488/AM07
Adv.Lic.No.0310424905 dated 29.03.2007	

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

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/232/2005-PI-III dated 14.08.2007 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:

Amlodipine Maleate-----1Kg.

Import items:

4. Phthaloyl Amlodipine-----1.08kg/kg
5. Methylene chloride-----4.50kg/kg
6. Isopropyl alcohol-----2.40kg/kg

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

Case No.A-468	M/S Suven Life Science Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/84/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/541/AM07
Adv.Lic.No.0910029935 dated 10.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 5-Cyano Phthalide 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-469	M/S R.L. Fine Chem
N.C. Meeting No.15/08	F.No.01/83/50/365/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.07/24/40/16/AM08
Adv.Lic.No.0710051274 dated 17.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Nortriptyline 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-470	M/S Satya Deeptha Pharmaceuticals Ltd
N.C. Meeting No.15/08	F.No.01/82/50/1234/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/430/AM07
Adv.Lic.No.0910029303 dated 12.02.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 1,1-Cyclohexane Diacetic 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 six weeks. The Committee, therefore, decided to defer the case for six weeks.

Case No.A-471	M/S Shilpa Medicare Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/1382/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.07/24/40/879/AM07
Adv.Lic.No.0710050972 dated 29.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product N-[B-D-Ribofuranosyl]-5-Hydroxyimidazole-4-Carboxamide Technical Grade under para 4.7 of HBP. The Committee in the light of written comments forwarded by PI Division vide their U.O. No.35011/159/2006-PI-III dated 14.08.2007 decided to call for the following information from the firm and also decided to defer the case for six weeks:- 1. Percentage yield on molar basis. 2. Material balance for the entire process. 3. Requirement & recovery of solvents of each step.	

Case No.A-472	M/S Dalas Biotech Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/223/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.05/24/40/1078/AM07
Adv.Lic.No.0510203062 dated 27.04.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 7-Amino-3-Vinyl-3-Cephem-4-Carboxylic Acid Diphenyl Ester HCL (7AVCA) under para 4.7 of HBP.

The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/18/2007-PI-III dated 26.06.2007 in another case 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:

7AVCA (7Amino-3-vinyl-cephalosporanic acid-----1Kg.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	7-Phenylacetamido-3-chloromethyl cephalosporanic Acid Para Methoxybenzyl Ester (GCLE)	2.672kg/kg
2.	Triphenyl Phosphine	1.26kg/kg
3.	Methylene Chloride	10.31kg/kg

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

Case No.A-473	M/S DCM Shriram Industries Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/524/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.05/24/40/166/AM08
Adv.Lic.No.0510204918 dated 14.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product D(-) Para Hydroxy Phenyl Glycine Dane Salt 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-474	M/S Surya Pharmaceuticals Ltd
N.C. Meeting No.15/08	F.No.01/82/50/90/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.21/24/40/291/AM07
Adv.Lic.No.2210006400 dated 17.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Sultamicillin Tosylate under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-475	M/S PAB Organics Pvt. Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/1782/AM'07/DES-III
Meeting date: 14.08.2007	RLA F.No.34/24/40/299/AM07
Adv.Lic.No.3410018452 dated 30.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 2,3,Dichloro Benzoyl Cyanide under para 4.7 of HBP. The Committee in light of earlier decision of Norms Committee in its 14/08 meeting held on 07.08.2007 vide Case No.A-424 decided to ratify the norms under para 4.7 of HBP as applied by the firm, only 1 item of import is allowed. Export product: 2,3 Dichloro benzoyl cyanide-----1Kg. Import items: 1. 2,3 dichloro benzoyl chloride-----1.50kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-476	M/S Medreich Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/48/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.07/24/40/810/AM07
Adv.Lic.No0710050467 dated 06.03.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 45mg + Codeine Phosphate 10mg Tablets under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee, therefore, decided to defer the case for six weeks.	

Case No.A-477	M/S Neuland Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/1337/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/513/AM07
Adv.Lic.No.0910029660 dated 14.03.2007	
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 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-478	M/S KDL Biotech Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/77/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/94/40/1430/AM07
Adv.Lic.No.0310429938 dated 21.05.2007	

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

The Committee in light of Report forwarded by PI Division vide their U.O.35011/165/2006/PI-III dated 30.07.2007 decided to ratify the norms as per details below or as applied for by the firm whichever is lower.

Export Product:

Cefadroxil Monohydrate from Pen G Route-----1Kg.

Import items:

1. Penicillin G Potassium 1st Crystal-----2.34BOU/Kg
2. Pyridine Hydrobromide-----0.320kg/kg

OR

- Hydrobromic acid 48%-----0.375kg/kg
3. Hydrogen Peroxide 60%-----0.363kg/kg
4. Acetic Acid-----0.933kg/kg
5. Trimethyl chloro silane-----2.7027kg/kg

OR

- 5(a). Bis trimethyl silyl urea-----1.543kg/kg
- 5(b). Hexamethyl disilazane-----0.3284kg/kg
6. Trimethyl chloro silane-----0.2180kg/kg
7. D(-)para hydroxy Phenyl glycine-----0.959kg/kg
- Methyl/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.

Case No.A-479	M/S Nexuz Pharma Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/76/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/317/AM07
Adv.Lic.No.0810062842 dated 09.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Dexamethasone IP/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-480	M/S Lyka BDR Intl. Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/89/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/1309/AM07
Adv.Lic.No.0310419266 dated 12.02.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Clobetasole Propionate Cream 10mg 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-481	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/2/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.22/24/40/297/AM07
Adv.Lic.No.2210006382dated 13.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ezethimibe 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-482	M/S Neuland Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/170/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/378/AM07
Adv.Lic.No.0910029084 dated 18.01.2007	
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 four weeks. The Committee, therefore, decided to defer the case for four weeks.	

Case No.A-483	M/S Lepro Herbals Pvt. Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/469/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.05/24/40/155/AM08
Adv.Lic.No.0510204504 dated 05.06.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Griffonia Dry Extract under para 4.7 of HBP. The Committee decided to forward the copy of application to Department of Ayush for their comments. The case was accordingly deferred for six weeks.	

Case No.A-484	M/S Lupin Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/742/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/276/AM08
Adv.Lic.No.0310433502 dated 22.06.2007	
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, therefore, decided to defer the case for six weeks.	

Case No.A-485	M/S Parabolic Drugs Ltd
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N.C. Meeting No.15/08	F.No.01/83/50/1120/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.22/24/40/284/AM07
Adv.Lic.No.2210006368 dated 10.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Ampicillin Trihydrate under para 4.7 of HBP. The Committee decided to ratify the norms of the export product under para 4.7 of HBP. as per revised SION at SI.No.A-69 published vide Public Notice No.2 dated 19.04.2007 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-486	M/S Ind-Swift Laboratories Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/675/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.22/24/40/23/AM08
Adv.Lic.No.2210006857 dated 05.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Atorvastatin Calcium 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-487	M/S Ponalab
N.C. Meeting No.15/08	F.No.01/83/50/640/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.07/24/40/223/AM08
Adv.Lic.No.0710052285 dated 03.07.2007	

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

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

Case No.A-488	M/KDL Biotech Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/426/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/94/40/1431/AM07
Adv.Lic.No.0310430868 dated 29.05.2007	

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

The Committee in light of Report forwarded by PI Division vide their U.O.35011/165/2006/PI-III dated 30.07.2007 decided to ratify the norms as per details below or as applied for by the firm whichever is lower.

Export Product:

Cefadroxil Monohydrate from Pen G Route-----1Kg.

Import items:

1. Penicillin G Potassium 1st Crystal-----2.34BOU/Kg
2. Pyridine Hydrobromide-----0.320kg/kg

OR

- Hydrobromic acid 48%-----0.375kg/kg
3. Hydrogen Peroxide 60%-----0.363kg/kg
4. Acetic Acid-----0.933kg/kg
5. Trimethyl chloro silane-----2.7027kg/kg

OR

- 5(a). Bis trimethyl silyl urea-----1.543kg/kg
 5(b). Hexamethyl disilazane-----0.3284kg/kg
 6. Trimethyl chloro silane-----0.2180kg/kg
 7. D(-)para hydroxy Phenyl glycine-----0.959kg/kg
 Methyl/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.

Case No.A-489	M/S Lepro Herbals Pvt. Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/468/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.05/24/40/131/AM08
Adv.Lic.No.0510204503 dated 05.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Glycyrrhetic Acid (18 Beta Glycyrrhetic Acid) under para 4.7 of HBP.

The Committee in light of the written comments of the Deptt. of C&PC forwarded vide their U.O.No.35011/163/2006-PI-III dated 23.5.2007 decided to fix I/O Norms for

the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower.

Export product:

Glycyrrhetic acid (18 Beta Glycyrrhetic acid---1kg

Import item

Glycyrrhizic acid-----2.70kg/kg

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

Case No.A-490	M/Lupin Ltd.
N.C. Meeting No.15/08	F.No.01/83/50/743/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/95/40/254/AM08
Adv.Lic.No.0310433506 dated 22.06.2007	

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

The Committee in light of Report forwarded by PI Division vide their U.O.35011/165/2006/PI-III dated 30.07.2007 decided to ratify the norms as per details below or as applied for by the firm whichever is lower.

Export Product:

Cefadroxil Monohydrate from Pen G Route-----1Kg.

Import items:

1. Penicillin G Potassium 1st Crystal-----2.34BOU/Kg

2. Pyridine Hydrobromide-----0.320kg/kg

OR

Hydrobromic acid 48%-----0.375kg/kg

3. Hydrogen Peroxide 60%-----0.363kg/kg
4. Acetic Acid-----0.933kg/kg
5. Trimethyl chloro silane-----2.7027kg/kg

OR

- 5(a). Bis trimethyl silyl urea-----1.543kg/kg
- 5(b). Hexamethyl disilazane-----0.3284kg/kg
6. Trimethyl chloro silane-----0.2180kg/kg
7. D(-)para hydroxy Phenyl glycine-----0.959kg/kg
Methyl/ethyl potassium dane salt

OR

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

Case No.A-491	M/S Cipla Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/169/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.03/94/40/250/AM08
Adv.Lic.No.0310432136 dated 08.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Stavir 15mg, 20mg, 30mg, 40mg Capsules and Lamvir S-30, S-40 Tablets under para 4.7 of HBP.

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

Case No.A-492	M/S Honest Bio Pvt. Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/1761/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/304/AM07
Adv.Lic.No.0810062375 dated 12.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Chloroperoxybenzoic under para 4.7 of HBP. The Committee decided to forward the copy of application to PI Division for their comments. The case was accordingly deferred for four weeks.	

Case No.A-493	M/S Gulf Oil corporation.
N.C. Meeting No.15/08	F.No.01/82/50/47/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.09/24/40/538/AM07
Adv.Lic.No.0910028240 dated 17.11.2006	
The Committee considered the case as per agenda for ratification of norms for the export product Fexafenadine 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-494	M/S Cadila Healthcare Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/182/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/54/AM08
Adv.Lic.No.0810065287 dated 08.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Simvastatin 5mg, 10mg, 20mg, 40mg and 80mg Tablets under para 4.7 of HBP.

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

Export Product:

Sl.No.	Description of Export Product	Quantity
1.	Simvastatin 5mg tablets	94,95,640 Nos.
2.	Simvastatin 10mg tablets	4,03,58,000 Nos.
3.	Simvastatin 20mg tablets	13,30,98,000 Nos.
4.	Simvastatin 40mg tablets	11,98,87,000 Nos.
5.	Simvastatin 80mg tablets	3,19,42,250 Nos.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	Simvastatin	10,673.15kg
2.	Lactose anhydrous	76,530.69kg
3.	Citric acid Anhydrous	1,472.54kg
4.	Magnesium Stearate	999.05kg
5.	Bottles & Caps (a to c)	Relevant, As per packing policy.

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

Case No.A-495	M/S Cadila Healthcare Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/181/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/53/AM08
Adv.Lic.No.0810065288 dated 08.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Paroxetine 10mg, 20mg, 30mg and 40mg Tablets under para 4.7 of HBP.

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

Export Product:

Sl.No.	Description of Export Product	Quantity
1.	Paroxetine 10mg tablets	4,62,25,000 Nos.
2.	Paroxetine 20mg tablets	11,55,00,000 Nos.
3.	Paroxetine 30mg tablets	3,39,35,000 Nos.
4.	Paroxetine 40mg tablets	4,72,00,000 Nos.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	Paroxetine hcl. Hemihydrate	5,740.76 Kg.
2.	Lactose anhydrous NF	37,439.85
3.	Diabasic calcium phosphate anhydrous USP	13,163.80 Kg.
4.	Povidone K 30	2,495.97 Kg.
5.	Magnesium Stearate	623.94Kg.
6.	Bottles & Caps (a to c)	Relevant, As per packing policy

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

Case No.A-496	M/S Cadila Healthcare Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/187/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/355/AM07
Adv.Lic.No.0810063496 dated 09.03.2007	

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

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

Export Product:

Sl.No.	Description of Export Product	Quantity
1.	Atorvastatin Condensation product	1 Kg.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	Methyl Isobutyryl Acetate	0.970kg/kg
2.	4-Methy-5-Hydroxy ethyl Thiazole	0.120kg/kg
3.	(4R,Cis)-1,1-dimethyl ethyl-6-cyanomethyl-2,2-dimethyl-1,3-Dioxane-4-Acetate	0.635kg/kg
4.	Methanol	1.09kg/kg
5.	Cyclohexane	2.77kg/kg
6.	Tetrahydrofuran	0.53kg/kg
7.	Isopropyl alcohol	4.49kg/kg
8.	Toluene	1.62kg/kg

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

Case No.A-497	M/S Cadila Healthcare Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/186/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/269/AM07
Adv.Lic.No.0810064986 dated 22.05.2007	

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

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

Export Product:

Sl.No.	Description of Export Product	Quantity
1.	Lamivudine	1Kg.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	(1R,2S,5R)-Methyl-5(S)-Cytosin-1-YL-1,3-Oxathiolane,2R-Carboxylate	2.19kg/kg
2.	Sodium Borohydride	0.48kg/kg
3.	Salicylic Acid	0.8169kg/kg
4.	Methanol	3.23kg/kg

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

Case No.A-498	M/S Cadila Healthcare Ltd.
N.C. Meeting No.15/08	F.No.01/82/162/183/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/62/AM08
Adv.Lic.No.0810065364 dated 13.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Amlodipine Besylate 2.5mg, 5mg. & 10mg tablets under para 4.7 of HBP.

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

Export Product:

Sl.No.	Description of Export Product	Quantity
1.	Amlodipine Besylate 2.5 mg. tablets	1,74,46,570 Nos.
2.	Amlodipine Besylate 5 mg. tablets	12,97,30,200 Nos.
3.	Amlodipine Besylate 10 mg. tablets	11,70,79,490 Nos.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	Amlodipine Besylate	2,635.74kg/kg
2.	Microcrystalline cellulose	33,186.661kg/kg
3.	Magnesium starch	372.106kg/kg
4.	Bottles & Caps (a to e)	Relevant as per packing policy

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

Case No.A-499	M/S Ellpe Chemicals Pvt. Ltd.
N.C. Meeting No.15/08	F.No.01/82/50/388/AM07/DES-III
Meeting date: 14.08.2007	RLA F.No.03/94/40/1062/AM07
Adv.Lic.No.0310418988 dated 09.02.2007	

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

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

Case No.A-500	M/S Cadila Pharmaceuticals Ltd
N.C. Meeting No.15/08	F.No.01/82/162/185/AM08/DES-III
Meeting date: 14.08.2007	RLA F.No.08/24/40/27/AM07
Adv.Lic.No.0810064612 dated 04.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Carbetapentane Tannate under para 4.7 of HBP. The Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/21/2005-PI-III dated 14.08.2007 in the case of M/S Malladi Drugs & Pharma Pvt. Ltd. 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: Carbetapentane Tannate-----1Kg. Import items: 1. Carbetapentane Citrate-----0.86kg/kg 2. Tanic Acid-----0.73kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of NC.	

CASE NO. B-217	M/S MEDRIECH LTD
M. No. 11/08	F.NO. 01/82/50/795/AM06
DATED 17.7.2007	RLA NO.07/24/40/553/AM06

ADV. LIC.NO. 0710040930 DT. 18.10.05

The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product IODINE 20 MG+ PEPTONE 75 MG + RUTIN 1 MG 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. B-218	M/S AGIO PHARMACEUTICAL LTD
M. No. 15/08	F.NO. 01/87/50/925/AM06
DATED 14.08.2007	F.NO. 01/87/50/182/AM07
	F.NO. 01/87/50/1118/AM07
	F.NO. 01/87/50/63/AM07
	F.NO. 01/87/50/267/AM07
	ADV. LIC.NO. 0310353471 DT. 25.10.05
	ADV. LIC.NO. 0310381026 DT. 19.05.06
	ADV. LIC.NO. 0310423444 DT. 16.03.07
	ADV. LIC.NO. 0310376482 DT. 19.04.06
	ADV. LIC.NO. 0310385834 DT. 21.06.06
The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product PREDNISOLONE SODIUM PHOSPHATE INJECTION 30MG/ML VAIL under para 4.7 of HBP. The Committee decided to remind the firm to furnish the documents regarding amendment in the export product as per their DML from the office of Jt. DGFT, Mumbai. The case was accordingly deferred for four weeks.	

CASE NO. B-219	M/S Aarti Drugs Ltd.
M. No. 15/08	F.NO. 01/87/50/630/AM06

DATED 14.08.2007	RLA F.No.03/94/40/598/AM'06
Adv.Lic.No.0310345259 dated 30.08.2005	
The Committee considered this case as per agenda for modification of I/O Norms for the Export Product Diphenyl Methyl-(4-ISO Propyl Pyridine) Boronate 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. B-220	M/S Cipla Ltd.
M. No. 15/08	F.NO. 01/82/50/722/AM07
DATED 14.08.2007	RLA F.No.03/94/40/519/AM'07
Adv.Lic.No.0310394029 dated 10.08.2006	
The Committee considered this case as per agenda for amendment in the item of imports under para 4.7 of HBP. The Committee decided to defer the case for four weeks and link the earlier file.	

CASE NO. B-221	M/S CADILA PHARMA LTD
M. No. 15/08	F.NO. 01/82/50/1433/AM05
DATED 14.08.2007	RLA NO.08/24/40/95/AM05
	ADV. LIC.NO. 0810041718 DT. 6.09.2004
	ADV.LIC NO. 0810036678 DT. 05.03.2004
The Committee considered this case as per agenda for fixation of I/O Norms for the Export Product CARBINOXAMINE under para 4.7 of HBP.	

The Committee decided to examine the case on file.

CASE NO. C-08	M/S WOCKHARDT
M. No. 15/08	F.NO. 01/82/162/262/AM08
DATED 14.08.2007	
The Committee considered this case as per agenda for fixation of SION for vitamin B12 (Cyanocobalamin) USP (Micronised) Non Feed Grade. The Case was discussed in detail and it was noted that the SION for Vitamin B12 are already fixed from the basic stage. The Committee observed that in the present case, there is only minor operations for which Advance Authorisation can be considered under para 4.7 of HBP. The firm may be advised accordingly.	

Norms Committee Meeting No.15/08 dated 14.08.2007

Outside Agenda:

The Committee observed that as per para 4.7.1 of Current Hand Book of Procedures Vol.I, in cases where Norms Committee has already ratified norms for same export and import product in respect of an Authorisation obtained under para 4.7, such norms shall be valid for a period of six months reckoned from date of ratification. The RAs are authorized to issue Authorisations under "Adhoc Norms Fixed" Category and application copies need not be forwarded to NC for fixation/ratification of Norms.

It is observed that the RAs are not strictly adhering to the above provision with the result that the work load on Norms Committee has increased enormously.

The Committee deliberated the issue and decided to issue instructions to all the RAs to strictly adhere to the provisions of para 4.7.1 of Current HBP.