

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

Para 4.7 Officewise Statement

MEETING NUMBER : 19/82-ALC4/2007 **MEETING DATE** : 11.09.2007

1	Case No.: 10/20/87-ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Deferred
	HQ File :01/87/050/00429/AM06/	RLA File : 02/24/040/00081/AM06/	Lic.No/Date:0210080076 15.07.2005	DeferDate: 09.10.2007
	Decision :Committee considered the case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. Committee observed that technical comments in the matter has been called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for their comments. Accordingly, the case was deferred for four weeks.			
2	Case No.: 8/10/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. Committee observed that technical comments in the matter has been called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for their comments. Accordingly, the case was deferred for four weeks.			
3	Case No.: 39/9/82-ALC1/2006	Party Name:KDL BIOTECH LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 25.09.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Flu-Cloxacillin Sodium under para 4.7 of HBP. Committee observed that firm as well as Pharmexcil have been requested to furnish Excise Data for revision of norms but the same has not been received. Committee, therefore, decided to await data and also to defer the case for two weeks.			

4	Case No.:4/14/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Withdrawn
	HQ File :01/82/050/00215/AM07/	RLA File : 09/24/040/00511/AM06/	Lic.No/Date:0910026249 11.05.2006	
	Decision : Withdrawn as the case has already been approved in NC Meeting No.16/08 dated 21.08.2007.			

5	Case No.:1/23/87-ALC1/2006	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Silymarine Extract under para 4.7 of HBP. Committee observed that technical comments in the matter has been called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for their comments. Accordingly, the case was deferred for four weeks.			

6	Case No.:2/34/82-ALC1/2006	Party Name:DISHMAN PHARMACEUTICALS & CHEMICALS LTD	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/00593/AM07/	RLA File : 08/24/040/00247/AM06/	Lic.No/Date:0810058323 24.07.2006	Defer Date: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 1-Carbethoxy Ethylidene Triphenyl Phosphorane under para 4.7 of HBP. Committee observed that in the meeting No.15/08 dated 14.08.2007, it was decided to call for End use of the export product alongwith supporting technical literature from the firm, but letter could not be issued. Committee, therefore, decided to issue letter to the firm for sending the required information. Accordingly, the case was deferred for four weeks. The DES Divn. should issue letters in all pending cases and report compilation by 21 st September, 2007.			

7	Case No.:16/27/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Kola Extract under para 4.7 of HBP. Committee observed that technical comments in the matter has been called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for their comments. Accordingly, the case was deferred for four weeks.			

8	Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Terbinafine Hydrochloride Tablets 250mg under para 4.7 of HBP .Committee decided to call for copy of DML for the relevant export product from the firm. Accordingly, case was deferred for four weeks.			

9	Case No.:8/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Withdrawn
	HQ File :01/82/050/00998/AM07/	RLA File : 09/24/040/00214/AM07/	Lic.No/Date:0910027658 25.09.2006	
	Decision : Withdrawn as the case has already been approved in NC Meeting No.16/08 dated 21.08.2007.			

10	Case No.:9/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	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 NC Meeting No.16/08 dated 21.08.2007..			

11	Case No.:31/34/87-ALC1/2006	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 25.09.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 1—Methoxy Imino Stilbene 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.			

12	Case No.:2/46/87-ALC1/2006	Party Name:AVON ORGANICS LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007

Decision : Committee considered the case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidazolone (AABZ) or 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP.

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

13	Case No.: 3/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Deffered and Re-indexed
	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 : Committee considered the case as per agenda for ratification of norms for export product Fexofenadine Hcl under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, accordingly, decided to defer the case for four weeks.				

14	Case No.: 4/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Withdrawn
	HQ File :01/82/050/01215/AM07/	RLA File : 09/24/040/00194/AM07/	Lic.No/Date:0910028005 31.10.2006	
Decision : Withdrawn as case has already been rejected in NC Meeting No.17/08 dated 28.08.2007.				

15	Case No.: 17/37/87-ALC1/2006	Party Name:AVENTIS PHARMA LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 25.09.2007
Decision : Committee considered the case as per agenda for ratification of norms for 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 and he sought deferment for two weeks. The Committee, accordingly, decided to defer the case for two weeks.				

16	Case No.: 37/36/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Deferred
	HQ File :01/83/050/00874/AM07/	RLA File : 09/24/040/00307/AM07/	Lic.No/Date:0910028137 07.11.2006	Defer Date: 25.09.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Lamotrigine 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.			

17	Case No.: 12/45/87-ALC1/2006	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Salbactam Sodium (2:1) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, accordingly, decided to defer the case for four weeks.			

18	Case No.: 8/44/82-ALC1/2006	Party Name:M/S.ENAL DRUGS PVT LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Withdrawn
	HQ File :01/82/050/01307/AM07/	RLA File : 09/24/040/00237/AM07/	Lic.No/Date:0910028243 17.11.2006	
	Decision : Withdrawn as the case has already been approved in NC Meeting No.16/08 dated 21.08.2007.			

19	Case No.: 4/43/83-ALC1/2006	Party Name:SREENIVASA PHRAMA PVT LTD.	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 25.09.2007
	Decision : Committee considered the case as per agenda for ratification of 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. 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.			

20	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/01441/AM07/	RLA File : 09/24/040/00390/AM07/	Lic.No/Date:0910028634 13.12.2006	Defer Date: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-Lysine-Praline (Lyspro (Isolated) under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, accordingly, decided to defer the case for four weeks.			

21	Case No.:4/47/87-ALC1/2006	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 04.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Lopinavir under para 4.7 of HBP. Committee noted that the firm was requested to furnish certain technical information, but the same has not been received. Committee, therefore, decided to await reply of the firm. Accordingly, case was deferred for three weeks.			

22	Case No.:5/9/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/01646/AM07/	RLA File : 05/24/040/00937/AM07/	Lic.No/Date:0510199268 09.02.2007	Defer Date: 23.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product 3,4 Dihydroxy-4-Oxo-6Acetoxy-7Methoxyquinazole under para 4.7 of HBP. Committee decided to call for complete technical details as per Appendix 33 alongwith end use of export product from the firm. Accordingly, case was deferred for six weeks.			

23	Case No.:1/19/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Approved
	HQ File :01/82/050/01643/AM07/	RLA File : 03/94/040/01265/AM07/	Lic.No/Date:0310419579 14.02.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Rangtetra Bolus 600mg/Tetramisole Bolus 600mg under para 4.7 of HBP. Committee observed that firm has furnished DML for export product and in consultation			

with technical authorities present in the meeting decided to ratify norms under para 4.7 of HBP as per SION at Sl. No. A-412 with 2% wastage.

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

24	Case No.:4/9/82-ALC4/2007	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/01644/AM07/	RLA File : 03/94/040/01206/AM07/	Lic.No/Date:0310419586 14.02.2007	Defer Date: 23.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Losartan Potassium 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, accordingly, decided to defer the case for six weeks.			

25	Case No.:2/19/82-ALC4/2007	Party Name:KAJARIA CERAMICS LTD	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Transferred
	HQ File :01/82/050/01662/AM07/	RLA File : 05/24/040/00806/AM07/	Lic.No/Date:0510199743 20.02.2007	
	Decision : Committee decided to transfer the case to DES-IV as the export product pertains to Chemical Sector.			

26	Case No.:3/19/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/01663/AM07/	RLA File : 05/24/040/00951/AM07/	Lic.No/Date:0510199828 21.02.2007	Defer Date: 23.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Nalidixic 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, accordingly, decided to defer the case for six weeks.			

27	Case No.:4/3/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/83/050/01267/AM07/	RLA File : 03/95/040/01424/AM07/	Lic.No/Date:0310420407 21.02.2007	Defer Date: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export			

product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.

Committee decided to call for following information from firm and to defer the case for four weeks.

1. Percentage yield on molar basis for each step of manufacturing process.
2. Technical literature in support of the yields envisaged in the application.
3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%.
4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated.
5. In the process flow char export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended.
6. Copy of valid DML for above export product.

28	Case No.:1/11/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP. Committee observed that firm was requested to furnish certain technical information, but the same have not been received. Committee, therefore, decided to remind firm to furnish required information. Accordingly, case was deferred for four weeks.				

29	Case No.:6/9/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/01728/AM07/	RLA File : 09/24/040/00488/AM07/	Lic.No/Date:0910029504 01.03.2007	Defer Date: 09.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, accordingly, decided to defer the case for four weeks.				

30	Case No.:7/9/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Approved
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HQ File :01/82/050/01730/AM07/	RLA File : 03/94/040/01369/AM07/	Lic.No/Date:0310421609 01.03.2007	
Decision : Committee considered the case as per agenda for ratification of norms for export product Rangtetra Bolus 600mg/Tetramisole Bolus 600mg under para 4.7 of HBP. Committee observed that firm has furnished DML for export product and in consultation with technical authorities present in the meeting decided to ratify norms under para 4.7 of HBP as per SION at Sl. No. A-412 with 2% wastage. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

31	Case No.:7/7/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/83/050/01378/AM07/	RLA File : 03/95/040/01605/AM07/	Lic.No/Date:0310424623 27.03.2007	Defer Date: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee decided to call for following information from firm and to defer the case for four weeks. 1. Percentage yield on molar basis for each step of manufacturing process. 2. Technical literature in support of the yields envisaged in the application. 3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%. 4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated. 5. In the process flow char export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended. 6. Copy of valid DML for above export product.			

32	Case No.:23/9/82-ALC4/2007	Party Name:LUPIN LIMITED	Meet No/Date:19/82- ALC4/2007 11.09.2007	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: 09.10.2007

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

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.

33	Case No.: 6/11/82-ALC4/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Cyclopentacecanolide (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, accordingly, decided to defer the case for four weeks.			

34	Case No.: 2/3/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Azithromycin Crude under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee, accordingly, decided to defer the case for four weeks.			

35	Case No.: 25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 23.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Allylestrenol 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 six weeks.			

36	Case No.: 26/9/82-ALC4/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Deferred
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HQ File :01/82/050/00010/AM08/	RLA File : 09/24/040/00555/AM07/	Lic.No/Date:0910029933 10.04.2007	Defer Date: 23.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product 2-Chloro methyl-3-methyl-4-(2,2,2-trifluoro ethoxy)pyridine Hcl (Lansoprazole-Chloro Intermediate) 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.:6/13/82-ALC4/2007	Party Name:MEDREICH LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Deferred
HQ File :01/82/050/00022/AM08/	RLA File : 07/24/040/00072/AM08/	Lic.No/Date:0710051478 01.05.2007	Defer Date: 25.09.2007
37	Decision : Committee considered the case as per agenda for ratification of norms for export product Doxycycline Tablets 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 two weeks. The Committee, accordingly, decided to defer the case for two weeks.		

Case No.:1/13/82-ALC4/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Approved
HQ File :01/82/050/00023/AM08/	RLA File : 07/24/040/00066/AM08/	Lic.No/Date:0710051485 03.05.2007	
38	Decision : Committee considered the case as per agenda for ratification of norms for 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.35011/135/2006-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Gemcitabine-----1kg. Import item: 4-Amino-1-(3,3-difluoro-4-hydroxy-5-(Hydroxymethyl) Tetrahydrofuran-2-yl)-1H-Pyrimidine-2-one-----0.97kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.		

39	Case No.:29/9/82-ALC4/2007	Party Name:S.M. HERBALS	Meet No/Date:19/82-	Status:Case
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		PVT.LTD.	ALC4/2007 11.09.2007	Deferred
	HQ File :01/82/050/00039/AM08/	RLA File : 05/24/040/01075/AM07/	Lic.No/Date:0510203751 16.05.2007	Defer Date: 09.10.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP. Committee observed that technical comments in the matter has been called for from Department of Ayush, but the same has not been received. Committee, therefore, decided to remind Department of Ayush for their comments. Accordingly, the case was deferred for four weeks.				

	Case No.:8/13/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/00038/AM08/	RLA File : 34/24/040/00028/AM08/	Lic.No/Date:3410018760 17.05.2007	Defer Date: 23.10.2007
40	Decision : Committee considered the case as per agenda for ratification of norms for export product Clarithromycin under para 4.7 of HBP. Committee observed that the firm was requested to furnish complete specification of export product and import item No.1, but the same has not been received. Committee, therefore, decided to remind the firm to furnish required information. Accordingly, case was deferred for six weeks.			

	Case No.:31/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/00042/AM08/	RLA File : 34/24/040/00031/AM08/	Lic.No/Date:3410018811 21.05.2007	Defer Date: 23.10.2007
41	Decision : Committee considered the case as per agenda for ratification of norms for export product Cefepime 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.			

42	Case No.:34/9/82-ALC4/2007	Party Name:AGIO PHARMACEUTICALS LTD	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Approved
	HQ File :01/82/050/00045/AM08/	RLA File : 03/94/040/00082/AM08/	Lic.No/Date:0310430135 22.05.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for export product Prednisolone Solution for Injection 30mg/1ml under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O.			

No.35011/183/2005-PI-III dated 20.07.2007 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:

Prednisolone Sodium Phosphate Injection BP, 30mg/1ml vial
Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone base

Import item:

Prednisolone Sodium Phosphate-----42.628mg./vial

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

43	Case No.: 35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	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: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Azithromycin Step-3 under para 4.7 of HBP. Committee observed that firm was requested to furnish complete chemical description of the export product, but the same has not been received. Committee, therefore, decided to await reply of the firm. Accordingly, case was deferred for four weeks.			

44	Case No.: 38/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Deferred
	HQ File :01/82/050/00061/AM08/	RLA File : 34/24/040/00039/AM08/	Lic.No/Date:3410018874 01.06.2007	Defer Date: 09.10.2007
	Decision : Committee considered the case as per agenda for ratification of norms for export product Clarithromycin USP under para 4.7 of HBP. Committee observed that firm was requested to furnish complete specification of import item No.1 and export product, but the same has not been received. Committee, therefore, decided to await reply of the firm. Accordingly, case was deferred for four weeks.			

45	Case No.: 8/11/82-ALC4/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status: Case Approved
	HQ File :01/82/050/00074/AM08/	RLA File : 07/24/040/00196/AM08/	Lic.No/Date:0710052106 22.06.2007	
	Decision : Committee considered the case as per agenda for ratification of norms for 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.35011/135/2006-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Gemcitabine-----1kg.

Import item:

4-Amino-1-(3,3-difluoro-4-hydroxy-5-(Hydroxymethyl)

Tetrahydrofuran-2-yl)-1H-Pyrimidine-2-one-----0.97kg/kg

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

Case No.:3/13/82-ALC4/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Case Approved
HQ File :01/82/050/00109/AM08/	RLA File : 07/24/040/00251/AM08/	Lic.No/Date:0710052404 10.07.2007	
Decision : Committee considered the case as per agenda for ratification of norms for 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.35011/135/2006-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Gemcitabine-----1kg. Import item: 4-Amino-1-(3,3-difluoro-4-hydroxy-5-(Hydroxymethyl) Tetrahydrofuran-2-yl)-1H-Pyrimidine-2-one-----0.97kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

47 Case No.:9/13/82-ALC4/2007	Party Name:FDC LTD.,	Meet No/Date:19/82-ALC4/2007 11.09.2007	Status:Deffered and Re-indexed
HQ File : 01/82/050/00110/AM08/	RLA File : 03/94/040/01489/AM07/	Lic.No/Date:0310435952 12.07.2007	Defer Date:11.09.2007
Decision : Committee considered the case as per agenda for ratification of norms for export product Chloramphenicol Eye Drops 0.5% W/V 10ml under para 4.7 of HBP.			

Committee observed that firm has given DML for export product and in consultation with the technical authorities present in the meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Chloramphenicol Eye Drops 0.5% W/V 10ml vial made out of LDPE

Import item:

1. Chloramphenicol-----As applied for
2. LDPE Granules-----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.:4/19/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:19/82- ALC4/2007 11.09.2007	Status:Case Deferred
	HQ File :01/82/050/00145/AM08/	RLA File : 03/95/040/00204/AM08/	Lic.No/Date:0310437530 26.07.2007	Defer Date: 09.10.2007
48	Decision : Committee considered the case as per agenda for ratification of norms for export product Betasol Lotion 30ml under para 4.7 of HBP. The representative of PI Division present in the meeting 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.			

Date:10.09.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Case No.A-631	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/698/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/274/AM'08
Adv.Lic.No.0510206046 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Fosinopril Sodium under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.A-632	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/699/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/278/AM'08
Adv.Lic.No.0510206047 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lisinopril under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.A-633	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/700/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/279/AM'08
Adv.Lic.No.0510206048 dated 11.07.2007	
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 accordingly decided to defer the case for four weeks.

Case No.A-634	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/882/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/354/AM'08
Adv.Lic.No.0510207161 dated 03.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 1-benzyl-3,4-dimethyl-2-(4-methoxy benzyl)-1,2,5,6-tetrahydropyridine Oxalate (Pentazocine Intermediate) 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-635	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/1280/AM'07/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/964/AM'07
Adv.Lic.No.0510200111 dated 27.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lisinopril Tablets 5mg, 10mg, 20mg and 2.5mg 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 four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.A-636	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/1279/AM'07/DES-III

Meeting Date: 11.09.2007	RLA F.No.05/24/40/975/AM'07
Adv.Lic.No.0510200110 dated 27.02.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Rampril 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-637	M/S Ranbaxy Laboratories Ltd.
Meeting No.19/08	F.No.01/82/50/755/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/286/AM'08
Adv.Lic.No.0510206321 dated 16.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Citalopram Hydrobromide under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.A-638	M/S Wockhardt Ltd.
Meeting No.19/08	F.No.01/82/50/711/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.03/95/40/336/AM'08
Adv.Lic.No.0310435809 dated 11.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Oxybutynin Chloride 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-639	M/S XL Laboratories Ltd
Meeting No.19/08	F.No.01/82/50/1151/AM'07/DES-III
Meeting Date: 11.09.2007	RLA F.No.05/24/40/785/AM'07
Adv.Lic.No.0510198209 dated 21.01.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Evirose-1000 Capsules, 100 Capsules and 400 Capsules 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 per SION at SI.No.A-412 with 2% wastage or as applied by 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-640	M/S R.L. Fine Chem.
Meeting No.19/08	F.No.01/82/50/681/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.07/24/40/246/AM'08
Adv.Lic.No.0710052366 dated 06.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Clomipramine Hcl under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for two weeks. The Committee accordingly decided to defer the case for two weeks.	

Case No.A-641	M/S Dr. Reddy's Lab Ltd.
Meeting No.19/08	F.No.01/82/162/245/AM'08/DES-III
Meeting Date: 11.09.2007	RLA F.No.09/24/40/18/AM'08
Adv.Lic.No.0910030194 dated 07.05.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Bendrofluazide Tablets BP 2.5 mg and 5mg under para 4.7 of	

HBP.

Committee in light of written comments forwarded by PI Division vide their U.O.No.35011/209/2005-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Bendrofluazide Tabs 2.5mg & 5mg.

Import items:

For export of 1 lakh tabs.

Sl.No.	Description of import items	Quantity allowed for 2.5mg Tablets	Quantity allowed for 5mg Tablets
1.	Bendrofluazide	0.25kg	0.50kg
2.	Lactose	4.04kg	8.08kg
3.	Maize Starch	0.682kg	1.364kg
4.	Pregelatinised Starch	0.328kg	0.656kg
5.	Sodium Starch Glycolate	0.1875kg	0.375kg
6.	Magnesium Stearate	0.0125kg	0.025kg

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

Case No.A-643	M/S Makson Inds. Pvt. Ltd.	
Meeting No.19/08	F.No.01/82/162/196/AM'08/DES-III	
Meeting Date: 11.09.2007	RLA F.No.03/95/40/409/AM'07	
Adv.Lic.No.0310390363 dated 20.07.2006		
The Committee considered the case as per agenda for ratification of norms for the export product Vicks Vaporub under para 4.7 of HBP.		
Committee in light of written comments forwarded by DC(SSi) vide their U.O. No.5(9)/2005-chem dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.		
Export product:		
Vicks Vaporub-----100kg.		
Import items:		
Sl.No.	Description of import items	Quantity allowed
1.	White Petrolactum (White Soft Parafin)	82.30kg
2.	Camphor U.S.P.	5.365kg
3.	Eucalyptus Oil	1.356kg
4.	Nutmeg Oil	0.703kg
5.	Cedar Leaf Oil	0.448kg
6.	Turpentine Oil	4.77kg
7.	Thymol	0.0918kg

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

Note: The export should be to Phillipines, Malaysia, Thailand, Australia & New Zealand as per the the DML.

Case No.A-645	M/S KDL Biotech Ltd
Meeting No.19/08	File No.01/83/50/348/AM'08/DES-III
Date: 11.09.2007	RLA F.No.03/94/40/1433/AM'07
Advance licence No.0310429686 Dated 17.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Immobilised Pencillin G Amidase (Enzyme) under para 4.7 of HBP. The Committee observed that firm has given declaration that the item of import and export are not biotechnology items while technical comments have been received from Department of Biotechnology. Committee decided that firm should be asked whether they had given wrong declaration that items not biotechnology items. Accordingly, case was deferred for four weeks. The Committee noted that as per last sub para of para 4.7 of HBP. Vol.I that "Where export and/or import of biotechnology items are involved, Authorisation under this paragraph shall be issued by RA only on submission of a "No objection Certificate" from Department of Biotechnology." There are many standardized Biological items in respect of which technology is freely available and such products are widely used/utilized as well. It was decided to seek inputs from DBT whether any amendment in last sub para of para 4.7 of HBP, Vol.I is called for.	

CASE NO. A- 646	M/S IPCA LABORATORIES LTD
M. No. 19/08	F.NO. 01/83/50/584/AM08
DATED 11.09.2007	RLA NO.03/94/40/192/AM08
	ADV. LIC.NO. 0310332927 DT. 7.6.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product TESTOSTERONE 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-647	M/S Om Shree Pharmachem Ltd
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Meeting No.19/08	File No.01/82/50/82/AM'08/DES-III
Date: 11.09.2007	RLA F.No.03/95/40/230/AM08
Advance licence No.0310432141 Dated 08.06.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Oso Sorbide-5 Monohydrate under para 4.7 of HBP. Committee decided to call for following information from firm and to defer the case for four weeks. 1. Percentage yield on molar basis for each step of manufacturing process. 2. Technical literature in support of the yields envisaged in the application. 3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%. 4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated. 5. In the process flow char export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended. 6. Copy of valid DML for above export product.	

CASE NO. A- 648	M/S IPCA LABORATORIES LTD
M. No. 19/08	F.NO. 01/83/50/590/AM08
DATED 11.09.2007	RLA NO.03/94/40/243/AM08
	ADV. LIC.NO. 0310432929 DT. 18.06.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product NORETHISTERONE under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for six weeks. The Committee accordingly decided to defer the case for six weeks.	

Case No.A-649	M/S Lupin Ltd
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Meeting No.19/08	File No.01/83/50/456/AM'08/DES-III
Date: 11.09.2007	RLA F.No.03/95/40/187/AM'08
Advance licence No.0310431079 Dated 30.05.2007	
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 accordingly decided to defer the case for four weeks.	

CASE NO. A- 650	M/S IPCA LABORATORIES LTD																											
M. No. 19/08	F.NO. 01/83/50/27/AM08																											
DATED 11.09.2007	RLA NO.03/94/40/1455/AM07																											
	ADV. LIC.NO. 0310425418 DT. 2.04.2007																											
The Committee considered this case as per agenda for ratification of Norms for the Export Product 6-METHOXY -2-NAPHTHALDEHYDE under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/125/2005-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: 6-Methoxy-20Naphthaldehyde-----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>Bromine</td><td>0.791kg/kg</td></tr><tr><td>2.</td><td>Tetra hydro furan</td><td>0.686kg/kg</td></tr><tr><td>3.</td><td>Ethylene dichloride</td><td>0.682kg/kg</td></tr><tr><td>4.</td><td>Isopropyl alcohol</td><td>0.453kg/kg</td></tr><tr><td>5.</td><td>Dimethyl formamide</td><td>1.52kg/kg</td></tr><tr><td>6.</td><td>Iodine</td><td>0.004kg/kg</td></tr><tr><td>7.</td><td>N-butanol</td><td>1.856kg/kg</td></tr><tr><td>8.</td><td>Beta Naphthol</td><td>1.50kg/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.	Bromine	0.791kg/kg	2.	Tetra hydro furan	0.686kg/kg	3.	Ethylene dichloride	0.682kg/kg	4.	Isopropyl alcohol	0.453kg/kg	5.	Dimethyl formamide	1.52kg/kg	6.	Iodine	0.004kg/kg	7.	N-butanol	1.856kg/kg	8.	Beta Naphthol	1.50kg/kg
Sl.No.	Description of import items	Quantity allowed																										
1.	Bromine	0.791kg/kg																										
2.	Tetra hydro furan	0.686kg/kg																										
3.	Ethylene dichloride	0.682kg/kg																										
4.	Isopropyl alcohol	0.453kg/kg																										
5.	Dimethyl formamide	1.52kg/kg																										
6.	Iodine	0.004kg/kg																										
7.	N-butanol	1.856kg/kg																										
8.	Beta Naphthol	1.50kg/kg																										

CASE NO. A-651	M/S MOREPEN LABORATORIES LTD
M. No. 19/08	F.NO. 01/83/50/239/AM08

DATED	11.09.2007	RLA NO.05/24/40/80/AM07
		ADV. LIC.NO. 0510203207 DT. 3.5.2007
The Committee considered this case as per agenda for ratification of Norms for the Export Product MONTELUKAST SODIUM MIN ASSAY 97% 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-652	M/S Medreich Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/48/AM08/DES-III
Meeting date: 11.09.2007	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. Committee decided to forward a copy of application alongwith copy of reply received from the firm to PI Division for their comments. Accordingly, case was deferred for two weeks.	

Case No.A-653	M/S Ind- Laboratories Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/2/AM08/DES-III
Meeting date: 11.09.2007	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 Ezetimibe under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.A-654	M/S Neuland Laboratories Ltd.
N.C. Meeting No.19/08	F.No.01/83/50/170/AM08/DES-III
Meeting date: 11.09.2007	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 accordingly decided to defer the case for four weeks.	

Case No.A-655	M/S Neuland Laboratories Ltd.
N.C. Meeting No.19/08	F.No.01/83/50/1337/AM07/DES-III
Meeting date: 11.09.2007	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 accordingly decided to defer the case for four weeks.	

Case No.A-656	M/S Cipla Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/155/AM08/DES-III
Meeting date: 11.09.2007	RLA F.No.03/94/40/473/AM08
Adv.Lic.No.0310438672 dated 07.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml 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-657	M/S Honest Bio Pvt. Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/1761/AM07/DES-III
Meeting date: 11.09.2007	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 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-658	M/S Intas Pharmeceuticals Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/381/AM08/DES-III
Meeting date: 11.09.2007	RLA F.No.08/24/40/123/AM08
Adv.Lic.No.0810066581 dated 14.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Gencitabine for 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 two weeks. The Committee accordingly decided to defer the case for two weeks.	

Case No.A-659	M/S Alliance Laboratories Pvt. Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/424/AM'08/DES-III
Meeting date: 11.09.2007	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.

Committee decided to call for following information from firm and to defer the case for four weeks.

1. Percentage yield on molar basis for each step of manufacturing process.
2. Technical literature in support of the yields envisaged in the application.
3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%.
4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated.
5. In the process flow char export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended.
6. Copy of valid DML for above export product.

It is seen that M/S Alliance Laboratories Pvt. Ltd had obtained Advance licence No. 0310430399 dated 23.05.2007 with following details;

Description of export product and its quantity	Fob value	Description of import item and its quantity	CIF value
Iso Sorbide-5-Mononitrate----- 2400kg	Rs.2,15,28,000/-	i) Sorbitol -----12,840kg ii) Sodium Bicarbonate--- 72kg. iii) Dioxabicyclo Octan----- 2112kg iv) Sodium Acetate----- 2.400kg v) Nitric Acid----- 1200kg vi) CHCL3----- 5256Ltr vii) Carbon----- 2.400kg viii) Toluene----- 216kg ix) Cyclo Hexane----- 13848kg x) MeCL2----- 2304kg xi) Pharmotose 200m Lactose----- 1488kg	Rs.1,18,59,794/

Similarly M/S Om Shree Pharmachem Pvt. Ltd. had obtained Advance licences No.0310420407 dated 21.02.2007 with the same details as mentioned

above.

It is great co-incidence that two firms may obtain licences with same FOB value , CIF value and same quantity.

It was also decided to write to Zonal Jt. DGFT, Mumbai for verification of the existence of M/S Om Shree Pharma Chem Ltd, Mumbai and this firm. Relevant documents submitted by these firms while applying for issue of Authorisations may also be got verified and report submitted to Hqrs.

Case No.B-268	M/S Shilpa Medicare Ltd.
N.C. Meeting No.19/08	F.No.01/87/50/1517/AM'06/DES-III
Meeting date: 11.09.2007	RLA F.No.07/24/40/1025/AM06
Adv.Lic.No.0710043911 dated 23.03.2006	
The Committee considered the case as per agenda for ratification of norms for the export product N-[B-D-Ribofuranasy]-5-Hydroxyimidiazole-4-Carboxamide Technical Grade 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-269	M/S Medreich Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/795/AM'06/DES-III
Meeting date: 11.09.2007	RLA F.No.07/24/40/553/AM06
Adv.Lic.No.0710040930 dated 18.10.2005	
The Committee considered the case as per agenda for ratification of norms for the export product Iodine 20mg+Peptone 75mg+Rutin 1mg Tablets under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for two weeks. The Committee accordingly decided to defer the case for two weeks.	

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Case No.B-270	M/S Cipla Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/927/AM'06/DES-III
Meeting date: 11.09.2007	RLA F.No.03/94/40/904/AM06
Adv.Lic.No.0310355734 dated 17.11.2005	

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

Committee observed that firm was requested to furnish certain technical information vide DGFT letter dated 3/7.8.2006. As per the details furnished, yield shown by them is 29.76% in step I, 87% in Step-II and 60% in Step III with an overall yield of 17%. On considering the details given by the firm it is noted that the information given appears to be incorrect since there is no linkage between the applied quantity and quantity which may arise based on the technical inputs supplied now by party. Committee, therefore, decided to remind the firm and defer the case for six weeks.

Case No.B-271	M/S Aurobindo Pharma Ltd.
N.C. Meeting No.19/08	F.No.01/87/50/953/AM'07/DES-III
Meeting date: 11.09.2007	RLA F.No.09/24/40/429/AM07
Adv.Lic.No.0910029197 dated 05.02.2006	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/22/2007-PI-III dated 11.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export Product:
Simvastatin-----1Kg.

Import Items:

1. Lavastatin-----1.736Kg/Kg.

2. Acetic Acid-----1.116Kg/Kg.
3. Carbon DC Enoaniticromos (activated carbon)-0.035Kg/Kg.
4. Cyclohexane-----5.27Kg/Kg.
5. Methanol-----13.64Kg/Kg.
6. Methyl Iodide-----0.61Kg/Kg.
7. Methylene Chloride-----3.04Kg/Kg.
8. N,N-Dimethylformamide-----1.71Kg/Kg.
9. N-Butyllithium in Hexanes-----0.988Kg/Kg.
10. Pyrrolidine-----1.208Kg/Kg.
11. Tert Butyldimethylsilyl chloride-----1.62Kg/Kg.
12. THF-----8.09Kg/Kg.
13. Imidazole-----0.700kg/kg

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

Case No.B-272	M/S Cipla Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/722/AM'07/DES-III
Meeting date: 11.09.2007	RLA F.No.03/94/40/519/AM07
Adv.Lic.No.0310394029 dated 10.08.2006	
Committee considered the case as per agenda for amendment in the description of inputs under para 4.7 of HBP. Committee decided to examine the case on file. Accordingly, case was deferred for four weeks.	

Case No.B-273	M/S Agio Pharmaceuticals Ltd
N.C. Meeting No.19/08	F.No.01/87/50/925/AM'06/DES-III F.No.01/87/50/182/AM07/DES-III F.No.01/87/50/1118/AM07/DES-III F.No.01/87/50/63/AM07/DES-III F.No.01/87/50/267/AM07/DES-III
Meeting date: 11.09.2007	RLA F.No.03/94/40/703/AM06 RLA F.No.03/94/40/133/AM07 RLA F.No.03/94/40/1267/AM07 RLA F.No.03/94/40/02/AM07

	RLA F.No.03/94/40/294/AM07
Adv.Lic.No.0310353471 dated 25.10.2005 Adv.Lic.No.0310381026 dated 19.05.2006 Adv.Lic.No.0310423444 dated 16.03.2007 Adv.Lic.No.0310376482 dated 19.04.2006 Adv.Lic. No.0310385834 dated 21.06.2006	
The Committee considered the cases as per agenda for ratification of norms for the export product Prednisolone Sodium Phosphate injection BP, 30mg/1ml vial and Prednisolon Sodium Phosphate injection USP, 30mg/1ml vial under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/183/2005-PI-III dated 20.07.2007 decided to ratify norms as per details below or as applied by firm whichever is lower. <u>Adv.Lic.No.0310353471 dated 25.10.2005</u> Export product: Predmisolone Sodium Phosphate Injection BP, 30mg/1ml vial Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone base Import item: Prednisolone Sodium phosphate-----42.628mg/vial <u>Adv.Lic.No. 0310381026 dated 19.05.2006</u> Predmisolone Sodium Phosphate Injection USP, 30mg/1ml vial Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone phosphate Import item: Prednisolone Sodium phosphate-----36.297mg/vial <u>Adv.Lic.No.0310423444 dated 16.03.2007</u> Export product: Predmisolone Sodium Phosphate Injection BP, 30mg/1ml vial Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone base Import item: Prednisolone Sodium phosphate-----42.628mg/vial <u>Adv.Lic.No.0310376482 dated 19.04.2006</u>	

Export product:

Prednisolone Sodium Phosphate Injection BP, 30mg/1ml vial

Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone base

Import item:

Prednisolone Sodium phosphate-----42.628mg/vial

Adv.Lic. No.0310385834 dated 21.06.2006

Export product:

Prednisolone Sodium Phosphate Injection BP, 30mg/1ml vial

Each ml. contains Prednisolone Sodium Phosphate equivalent to 30mg of Prednisolone base

Import item:

Prednisolone Sodium phosphate-----42.628mg/vial

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

Case No.B-274	M/S Kudos Chemie Ltd
N.C. Meeting No.19/08	F.No.01/82/162/335/AM'08/DES-III
Meeting date: 11.09.2007	
Committee considered the case as per agenda for clarification regarding applicability of DEBP rate on export of Caffeine (Anhydrous) Synthetic under Sl.No.62/19. Committee decided to refer the case to DEPB Committee.	

Case No.B-275	M/S Dr. Reddys Laboratories Ltd.
N.C. Meeting No.19/08	F.No.01/83/50/501/AM'07/DES-III
Meeting date: 11.09.2007	RLA F.No.09/24/40/112/AM07
Adv.Lic.No.0910026737 dated 05.07.2006	

Committee considered the case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/16/2007-PI-III dated 11.09.2007 decided to ratify norms as per details below or as applied by firm whichever is lower.

Export product:

Sertraline Hcl-----1kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	N-(4-(3,4-Dichlorophenyl)-3,4-dihydro-1(2H)-Naphthalenylidene) methalanime	3.27kg/kg
2.	Hexane	5.75kg/kg
3.	D(-)Mandalic acid	0.392kg/kg
4.	Ethyl Acetate	5.57kg/kg
5.	Sodium Borohydride	0.331kg/kg

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

Committee also decided to delete Sion at Sl.No.A-97 and A-420.

Case No.B-276	CBI
N.C. Meeting No.19/08	F.No.01/82/162/332/AM'08/DES-III
Meeting date: 11.09.2007	
Committee considered the case as per agenda for amendment in the description of inputs under para 4.7 of HBP. Committee decided to give an interim reply to CBI based on the inputs received from Deptt. of C&PC (PI)	

Case No.B-276-A	M/S Lee Pharma Ltd.
N.C. Meeting No.19/08	F.No.01/82/50/1427/AM'03/DES-III
Meeting date: 11.09.2007	
Committee considered the case as per agenda for amendment in the	

description of inputs under para 4.7 of HBP.

Committee decided to amend the description of import item to read as '5-difluoromethoxy-2-mercapto-1H-benzimidazole after due verification.

Case No.B-276-B	Lupin Ltd.
N.C. Meeting No.19/08	F.No.01/83/50/533/AM'08/DES-III
Meeting date: 11.09.2007	RLA F.No.03/95/40/234/AM08 Adv.Lic.No.0310432279 dated 11.06.2007
Committee considered case as per agenda for correction in description of import items under para 4.7 of HBP.	
Committee decided to amend description of import items as given in agenda after due verification.	

Outside Agenda

NC Meeting No.19/08

Meeting date: 11.09.2007

Committee considered report forwarded by PI Division vide their U.O. No.35011/165/2006 PI-III dated 30.07.2007 and decided to fix SION at Sl.No.109 as per details below;

Sl.No.	Description of export product	Quantity	Sl.No.	Description of import items	Quantity allowed
1.	Cefadroxil Monohydrate from 7-ADCA stage	1KG	1.	7-ADCA	0.6430kg
			2.	Acetone	0.883kg
			3.	Methylene chloride	0.360kg
			4.	D(-) para hydroxy Phenyl glycine methyl/ethyl potassium dane salt	0.959kg
				OR	
			4(a)	D(-) para hydroxy Phenyl glycine base	0.5402kg
			4(b)	Methyl Aceto acetate	0.4113kg
			4©	Methanol	0.3370kg
			5.	Dimethyl formamide	2.051kg
			6.	Trimethyl chlorosilane	0.2180kg
			7.	Ethyl chloro formate	0.357kg
			8.	Pottassium carbonate	0.2418kg