

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

Para 4.7 Decision

MEETING NUMBER : 20/82-ALC4/2007 MEETING DATE : 18.09.2007

1	Case No.:1/6/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/00389/AM04/	RLA File : 09/24/040/00068/AM04/	Lic.No/Date:0910015288 05.08.2003	Defer Date: 16.10.2007
Decision :Committee considered case as per agenda for ratification of norms for export product N,N-Dimethyl Amino Ethoxy Benzyl Amino (DEBA) under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.				

2	Case No.:2/6/82-ALC4/2007	Party Name:HINDUSTAN ANTIBIOTICS LTD	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Rejected
	HQ File : 01/82/050/00432/AM04/	RLA File : 31/80/040/00163/AM04/	Lic.No/Date:3110012090 08.08.2003	
Decision : Committee considered case as per agenda for ratification of norms for export product Tablets i.e. Potassium Phenoxymethyl Pencillin Tablets BP 250mg under para 4.7 of HBP. Committee observed that copy of application alongwith a report was called from RA vide letter dated 25.06.2007, but same has not been received. Due to non-co-operative attitude of RA, Committee decided to reject the case. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.				

3	Case No.:2/35/82-ALC1/2004	Party Name:MADHUR PHARMA & RESEARCH LABORATORIES PVT.LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
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HQ File : 01/82/050/01467/AM05/	RLA File : 07/24/040/00492/AM05/	Lic.No/Date:07100342 46 23.11.2004	Defer Date: 16.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Herpasil Capsules and Stimmune Capsules under para 4.7 of HBP. Committee noted that technical comments were called for from Deptt. of Ayush, but same have not been received. Committee, therefore, decided to remind Deptt. of Ayush demi-officially at the level of DGFT. Accordingly, case was deferred for four weeks.			

Case No.:5/37/82-ALC1/2005	Party Name:FDC LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
HQ File : 01/82/050/00946/AM06/	RLA File : 03/94/040/00798/AM06/	Lic.No/Date:03103562 18 22.11.2005	Defer Date: 16.10.2007
4	Decision : Committee considered case as per agenda for ratification of norms for export product Econazole Nitrate BP/JP/USP under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.		

5	Case No.:1/35/83-ALC1/2006	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
	HQ File : 01/83/050/00557/AM07/	RLA File : 09/24/040/00190/AM07/	Lic.No/Date:09100272 54 22.08.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Bicalutamide under para 4.7 of HBP. Committee in light of its earlier decision taken in its 25/87 meeting held on 28.09.2005 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Bicalutamide-----1Kg. Import items: 1. N-[4-Cyano-3-(trifluoromethyl)phenyl]-2-methyloxirane Carboxamide--- 1.11kg/kg 2. 4-fluorobenzenethiol-----			

0.53kg/kg

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

6	Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	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 case as per agenda for ratification of norms for export product Terbinafine Hydrochloride under para 4.7 of HBP. Committee decided to call for copy of relevant DML from firm. Accordingly, case was deferred for three weeks.			

7	Case No.:11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/87/050/00566/AM07/	RLA File : 02/24/040/00189/AM07/	Lic.No/Date:0210094006 25.09.2006	Defer Date: 16.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Senega Soft Extract under para 4.7 of HBP. Committee noted that technical comments were called for from Deptt. of Ayush, but same have not been received. Committee, therefore, decided to remind Deptt. of Ayush demi-officially at the level of DGFT. Accordingly, case was deferred for four weeks.			

8	Case No.:23/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Rejected
	HQ File : 01/82/050/01100/AM07/	RLA File : 03/94/040/00702/AM07/	Lic.No/Date:0310402829 06.10.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 1-Phenyl Propanolamine Hcl (L-Norephedrine Hcl) under para 4.7 of HBP. Committee observed that firm was requested to furnish technical details as per Appendix 33 but same has not been received. Committee, therefore, decided			

to reject case.

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

9	Case No.:24/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Rejected
	HQ File : 01/82/050/01101/AM07/	RLA File : 03/94/040/00703/AM07/	Lic.No/Date:0310402830 06.10.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product L-Norephedrine Base under para 4.7 of HBP. Committee observed that firm was requested to furnish technical details as per Appendix 33 but same has not been received. Committee, therefore, decided to reject case. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.				

10	Case No.:4/43/83-ALC1/2006	Party Name:SREENIVASA PHRAMA PVT LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
	HQ File : 01/83/050/00942/AM07/	RLA File : 09/24/040/00163/AM07/	Lic.No/Date:0910028292 21.11.2006	
Decision : Committee considered 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. Committee in light of written comments forwarded by PI Division vide U.O. No.35011/68/2007 PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Cis-2-Bromo Methyl)-2-(2,4-Dichloro Phenyl)-4-Methane Sulphonyl methyl-1,3-dioxalane (Cis-Bromo mesylate)-----1Kg. Import items: 1. 2,4 Dichloro Acetophenone-----1.65kg/kg 2. Benzoyl chloride-----1.35kg/kg 3. Toluene-----5.28kg/kg 4. Methanol-----2.84kg/kg 5. Methane Sulfonyl chloride-----0.42kg/kg				

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

11	Case No.:3/47/80-ALC2/2006	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
	HQ File : 01/80/050/01016/AM07/	RLA File : 09/24/040/00324/AM07/	Lic.No/Date:09100285 24 06.12.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Benzyl (S)-(-)-1,2,3,4-Tetrahydro-3-Isoquinoline Carboxylate-para-toluene sulfonic acid salt under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/72/2007-PI-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Benzyl (S)-(-)-1,2,3,4-Tetrahydro-3-Isoquinoline Carboxylate-para-toluene sulfonic acid salt-----1kg. Import item: L-Phenyl Alanine-----0.64kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of norms Committee.			

12	Case No.:11/44/82-ALC1/2006	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/01409/AM07/	RLA File : 09/24/040/00374/AM07/	Lic.No/Date:09100285 36 07.12.2006	Defer Date: 16.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Lisinopril under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.			

13	Case No.:3/47/87-ALC1/2006	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Rejected
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HQ File : 01/87/050/00826/AM07/	RLA File : 09/24/040/00323/AM07/	Lic.No/Date:09100286 60 18.12.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product Ritonavir under para 4.7 of HBP. Committee observed that firm was request to furnish certain information, but same has not been received so far. Committee, therefore, decided to reject the case. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

Case No.:6/50/87-ALC1/2006	Party Name:ALKEM LABORATORIES LTD.,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
HQ File : 01/87/050/00967/AM07/	RLA File : 03/94/040/01200/AM07/	Lic.No/Date:03104187 37 07.02.2007	Defer Date: 04.10.2007
14	Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin and Clavulanate Potassium Tablets 375mg, 625mg and 1000mg under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee, accordingly decided to defer case for two weeks.		

Case No.:3/10/83-ALC1/2007	Party Name:WANKSONS CHEMICAL INDUSTRIES PVT.LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
HQ File : 01/83/050/01262/AM07/	RLA File : 03/95/040/01284/AM07/	Lic.No/Date:03104202 13 20.02.2007	Defer Date 30.10.2007 :
15	Decision : Committee considered case as per agenda for ratification of norms for export product Metachololpropioiphenone under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.		

16	Case No.:3/9/83-ALC1/2007	Party Name:VITAL HEALTHCARE PVT.LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:03104210	Defer

01/83/050/01284/AM07/	03/95/040/01405/AM07/	71 27.02.2007	Date: 16.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Dihydroartemisinin under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.			

Case No.:4/10/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
HQ File : 01/83/050/01288/AM07/	RLA File : 09/24/040/00448/AM07/	Lic.No/Date:0910029459 27.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Dibenzosuberone under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/77/2007-Pi-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. 17 Export product: Dibenzosuberone-----1kg. Import items: 1. Methanol-----0.627kg/kg 2. Acetonitrile-----0.75kg/kg 3. Phosphorous Pentaoxide-----0.758kg/kg 4. Phosphoric acid-----0.523kg/kg 5. Tetrahydrofuran-----0.25kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

18 Case No.:1/20/82-ALC4/2007	Party Name:MACRO POLYMERS P. LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Transferred
HQ File : 01/82/050/01805/AM07/	RLA File : 08/24/040/00348/AM07/	Lic.No/Date:0810063607 14.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product under para 4.7 of HBP.			

Committee decided to transfer case to DES-IV as export product pertains to Plastic Sector.

19	Case No.:5/10/82-ALC4/2007	Party Name:GLAXOSMITHKLINE PHARMACEUTICALS LIMITED,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/01887/AM07/	RLA File : 03/94/040/00324/AM06/	Lic.No/Date:03104246 28 27.03.2007	Defer Date: 30.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Betamethasone Di-Sodium Phosphate BP/USP under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.				

20	Case No.:8/12/82-ALC4/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
	HQ File : 01/82/050/01898/AM07/	RLA File : 09/24/040/00524/AM07/	Lic.No/Date:09100298 41 29.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Methyl(E)-2-[3(S)-[3-[2-[(7-Chloro-2-Quinoliny)Ethenyl]Phenyl]-3-Hydroxy Propyl]Benzoate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/72/2007-PI-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Methyl(E)-2-[3(S)-[3-[2-(7-chloro-2-Quinoliny)Ethenyl]Phenyl]-3-Hydroxypropyl]benzoate-----1Kg. Import items: 1. 7-chloro quinaldine-----1.43kg/kg 2. Isophthaldehyde-----1.70kg/kg 3. Vinyl magnesium bromide-----5.28kg/kg 4. Methyl-2-Iodobenzoate-----1.32kg/kg 5. Ammonium acetate-----1.13kg/kg 6. Palladium acetate-----0.0125kg/kg				

7. Dichloromethane-----14.29kg/kg
 8. (-)Diisopino camphenyl chloro borane-----1.47kg/kg

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

Case No.:2/8/83-ALC1/2007	Party Name:AARTI INDUSTRIES LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
HQ File : 01/83/050/00110/AM08/	RLA File : 03/94/040/01210/AM07/	Lic.No/Date:0310426693 13.04.2007	
21			
Decision : Committee considered case as per agenda for ratification of norms for export product Budesonide under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/93/2006-PI-III dated 19.09.2007 decided to ratify norms as per details below or as applied by firm whichever is lower.			
Export product: Budesonide-----1Kg.			
Import items: 1. Prednisolone-----2.69kg/kg 2. Triethyl Orthoformate-----2.61kg/kg			
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

22			
Case No.:6/12/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
HQ File : 01/83/050/00170/AM08/	RLA File : 03/94/040/00041/AM08/	Lic.No/Date:0310427432 20.04.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Metformin Hcl under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/178/2006-PI-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.			
Export product: Metformin Hcl-----1Kg.			

Import items:

1. Dicyandiamide-----0.567kg/kg
2. Mix Xylene-----0.40kg/kg
3. Methanol-----0.352kg/kg
4. Dimethylamine Hcl-----060kg/kg

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

23	Case No.:16/12/83-ALC1/2007	Party Name:HONEST BIO-VET PVT. LTD	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/83/050/00272/AM08/	RLA File : 08/24/040/00032/AM08/	Lic.No/Date:0810064691 07.05.2007	Defer Date: 16.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Menadione Dimethyl Pyrimidinol Bisulphite (MPB 50%) under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.				

24	Case No.:6/4/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/00031/AM08/	RLA File : 03/95/040/00095/AM08/	Lic.No/Date:0310428999 10.05.2007	Defer Date: 16.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Diprosone Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.				

25	Case No.:9/11/83-ALC1/2007	Party Name:RICHY GOLD INTERNATIONAL	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Approved
	HQ File : 01/83/050/00341/AM08/	RLA File : 03/95/040/00069/AM08/	Lic.No/Date:0310429618 16.05.2007	
Decision : Committee considered case as per agenda for ratification of norms				

for export product Methyl Dopa Tablets 250mg. under para 4.7 of HBP.

The Committee in the light of its earlier decision taken in 10/08 meeting held on 10.07.2007 vide case No.A-287 decided to ratify the norms under para 4.7 of HBP as per details below or as applied for by the firm whichever is lower.

Export Product:
Methyl Dopa tablets 250 mg.

Import item:
Methyl Dopa-----288.15 kgm/1 million tablets.

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

26	Case No.:3/16/82-ALC4/2007	Party Name:NIRAYU PRIVATE LIMITED,	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/00050/AM08/	RLA File : 34/24/040/00034/AM08/	Lic.No/Date:34100188 53 28.05.2007	Defer Date: 16.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Dihydrate (Micronised) under para 4.7 of HBP. Committee observed that firm has been requested to furnish complete specification of import and export items and manufacturing activity involved, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.			

27	Case No.:35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00051/AM08/	RLA File : 34/24/040/00035/AM08/	Lic.No/Date:34100188 54 28.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Step-3 under para 4.7 of HBP. Committee decided to withdraw the case as same has already been considered in NC Meeting No.19/08 dated 11.09.2007.			

28	Case No.:11/12/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Rejected
	HQ File : 01/82/050/00064/AM08/	RLA File : 34/24/040/00045/AM08/	Lic.No/Date:3410018932 07.06.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Step-4 under para 4.7 of HBP. Committee observed that firm was requested to furnish complete chemical description of export product, but same has not been received. Committee, therefore, decided to reject the case. RA concerned may take further necessary action including cancellation of Advance Authorisation under para 4.7 of HBP as per above decision of Norms Committee.			

29	Case No.:12/12/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/00069/AM08/	RLA File : 34/24/040/00047/AM08/	Lic.No/Date:3410018988 15.06.2007	Defer Date: 16.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Dihydrate (Micronized) under para 4.7 of HBP. Committee observed that firm was requested to furnish complete specification of import and export items and manufacturing activity involved, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.			

30	Case No.:2/20/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
	HQ File : 01/82/050/00081/AM08/	RLA File : 03/95/040/00033/AM08/	Lic.No/Date:0310433129 19.06.2007	Defer Date: 16.10.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Betasol Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.			

31	Case No.:2/14/82-	Party Name:NECTAR	Meet No/Date:20/82-	Status:Ca
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ALC4/2007	LIFESCIENCES LIMITED,	ALC4/2007 18.09.2007	se Deferred
HQ File : 01/82/050/00116/AM08/	RLA File : 22/24/040/00018/AM08/	Lic.No/Date:22100068 97 17.07.2007	Defer Date: 16.10.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Cefdimir under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.			

Case No.:3/20/82- ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:20/82- ALC4/2007 18.09.2007	Status:Ca se Deferred
HQ File : 01/82/050/00146/AM08/	RLA File : 03/95/040/00277/AM08/	Lic.No/Date:03104375 31 26.07.2007	Defer Date: 16.10.2007
32	Decision : Committee considered case as per agenda for ratification of norms for export product Epiderm Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.		

33	Case No.:4/20/82- ALC4/2007	Party Name:WOCKHARDT LIMITED	Meet No/Date:20/82- ALC4/2007 18.09.2007	Status:Ca se Approved
	HQ File : 01/82/050/00148/AM08/	RLA File : 03/95/040/00425/AM08/	Lic.No/Date:03104389 63 09.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Flu Strength Hot Lemon Powders 5GM Sachet under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/84/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Flu Strength Hot Lemon Powder in 5gm. Sachet (each 5gm. Sachet contain Paracetamol Ph. Eur-1gm) Import item: Paracetamol Ph. EUR-----1.01 gm/5gm Sachet			

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

Case No.:5/20/82-ALC4/2007	Party Name:RICHY GOLD INTERNATIONAL	Meet No/Date:20/82-ALC4/2007 18.09.2007	Status:Case Deferred
HQ File : 01/82/050/00162/AM08/	RLA File : 03/95/040/00461/AM08/	Lic.No/Date:03104394 44 14.08.2007	Defer Date: 30.10.2007
34			
Decision : Committee considered case as per agenda for ratification of norms for export product Oral Rehydration Salt BP under para 4.7 of HBP.			
Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.			

Date:14.09.2007
Place:New Delhi

Shyam Lal
Foreign Trade Development Officer

Case No.A-660	M/S DSM Anti-Infectives India Ltd
NC Meeting No.20/08	F.No.01/83/50/912/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/27/AM08
Adv.Lic. No.2210006952 dated 07.08.2007	
Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Pen G Route under para 4.7 of HBP. Committee observed that SION for export product Amoxycillin Trihydrate Pen G Route has already been published at Sl.No.A-58 vide Public Notice No.58 dated 26.09.2006, while RA, Chandigarh has issued Advance Authorisation to the firm for the same export product on 07.08.2007 under para 4.7 of HBP. Committee, therefore, decided to seek clarification from RA, Chandigarh as to why Advance Authorisation has been issued under para 4.7 of HBP when SION for export product has already been published on 26.09.2006. Committee also decided to ratify norms under para 4.7 of HBP as per SION at Sl.No.A-58 published vide Public Notice No.58 dated 26.09.2006. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.A-661	M/S DSM Anti-Infectives India Ltd
NC Meeting No.20/08	F.No.01/83/50/914/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/28/AM08
Adv.Lic. No.2210006954 dated 07.08.2007	
Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Pen G Route under para 4.7 of HBP. Committee observed that SION for export product Amoxycillin Trihydrate Pen G Route has already been published at Sl.No.A-58 vide Public Notice No.58 dated 26.09.2006, while RA, Chandigarh has issued Advance Authorisation to the firm for the same export product on 07.08.2007 under para 4.7 of HBP. Committee, therefore, decided to seek clarification from RA, Chandigarh as to why Advance Authorisation has been issued under para 4.7 of HBP when SION for export product has already been published on 26.09.2006. Committee also decided to ratify norms under para 4.7 of HBP as per SION at Sl.No.A-58 published vide Public Notice No.58 dated 26.09.2006.	

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

Case No.A-662	M/S DSM Anti-Infectives India Ltd
NC Meeting No.20/08	F.No.01/83/50/913/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/25/AM08
Adv.Lic. No.2210006953 dated 07.08.2007	
Committee considered case as per agenda for ratification of norms for export product Cloxacillin Sodium Pen G Route under para 4.7 of HBP. Committee decided to ratify norms under para 4.7 of HBP as per SION at Sl.No.A-152 published vide Public Notice No.45 dated 06.09.2007. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-663	M/S DSM Anti-Infectives India Ltd
NC Meeting No.20/08	F.No.01/83/50/869/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/20/AM08
Adv.Lic. No.2210006928 dated 31.07.2007	
Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Pen G Route under para 4.7 of HBP. Committee observed that SION for export product Amoxycillin Trihydrate Pen G Route has already been published at Sl.No.A-58 vide Public Notice No.58 dated 26.09.2006, while RA, Chandigarh has issued Advance Authorisation to the firm for the same export product on 07.08.2007 under para 4.7 of HBP. Committee, therefore, decided to seek clarification from RA, Chandigarh as to why Advance Authorisation has been issued under para 4.7 of HBP when SION for export product has already been published on 26.09.2006. Committee also decided to ratify norms under para 4.7 of HBP as per SION at Sl.No.A-58 published vide Public Notice No.58 dated 26.09.2006. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.A-664	M/S Vivin Laboratories Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/273/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/444/AM07
Adv.Lic. No.0910030207 dated 08.05.2007	
Committee considered case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-665	M/S Vivin Laboratories Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/275/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/39/AM08
Adv.Lic. No.0910030209 dated 18.05.2007	
Committee considered case as per agenda for ratification of norms for export product 5-O-Benzoyl-3-Mesyl-2,2 Anhydro-5-Methyl Uridine under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-666	M/S Vivin Laboratories Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/274/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/43/AM08
Adv.Lic. No.0910030208 dated 08.05.2007	
Committee considered case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-667	M/S Smilax Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/1268/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/478/AM07
Adv.Lic. No.0910039428 dated 22.02.2007	
Committee considered case as per agenda for ratification of norms for export product {3-5[Bromo-1-(fluorophenyl)(1,3-dihydro isobenzofuranyl)]propyl]dimehylamine oxalate under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-668	M/S Smilax Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/1203/AM07
Meeting date: 18.09.2007	RLA F.No.09/24/40/466/AM07
Adv.Lic. No.0910029229 dated 07.02.2007	
Committee considered case as per agenda for ratification of norms for export product 5-Methoxy-2-((4-Methoxy-3,5-Dimethyl-2Pyridinyl) methyl]Thio-1H-Benzimidazole under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-669	M/S Wockhardt Ltd.
NC Meeting No.20/08	F.No.01/82/50/155/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/44/AM08
Adv.Lic. No.0310427335 dated 19.04.2007	
Committee considered case as per agenda for ratification of norms for export product Hydroxocobalamin Acetate/Hcl under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/84/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.	

Export product:
Hydroxocobalamin Acetate/Hcl-----1kg

Import item:
Cyanocobalamin-----1.088kg/kg

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

Case No.A-670	M/S Cadila Healthcare Ltd.
NC Meeting No.20/08	F.No.01/82/50/132/AM08
Meeting date: 18.09.2007	RLA F.No.08/24/40/90/AM08
Adv.Lic. No.0810065759 dated 04.07.2007	
Committee considered case as per agenda for ratification of norms for export product Atenolol 25mg, 50mg and 100mg tablets under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-671	M/S Aurobindo Pharma Ltd.	
NC Meeting No.20/08	F.No.01/87/50/985/AM07	
Meeting date: 18.09.2007	RLA F.No.09/24/40/261/AM07	
Adv.Lic. No.0910029298 dated 12.02.2007		
Committee considered case as per agenda for ratification of norms for export product Nelfinavir Mesylate (From PHIQ route) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Nelfinavir Mesylate-----1Kg. Import items:		
Sl.No.	Description of import items	Quantity allowed
1.	Cis-2-Butene-1,4-Diol	1.061kg/kg
2.	2,2 Dimethoxy Propane	2.507kg/kg

3.	3-Acetoxy-2-Methylbenzoic Acid	0.448kg/kg
4.	Acetone	3.14kg/kg
5.	Acetonitrile	0.43kg/kg
6.	Carbon Enoanticromos (Activated carbon)	0.090kg/kg
7.	Isopropyl Alcohol	3.74kg/kg
8.	Methane Sulfonyl Chloride	0.649kg/kg
9.	Methanol	4.26kg/kg
10.	Methylene choride	7.93kg/kg
11.	Methyl Isobutyl Ketone	4.58kg/kg
12.	(S)-N-T-Butyl Decahydro Iso Quinoline Carboxamide	0.801kg/kg
13.	Thiophenol (Benzene Thiol)	0.479kg/kg
14.	Toluene	7.57kg/kg

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

Case No.A-672	M/S Cadila Healthcare Ltd.
NC Meeting No.20/08	F.No.01/82/50/133/AM08
Meeting date: 18.09.2007	RLA F.No.08/24/40/91/AM08
Adv.Lic. No.0810065758 dated 04.07.2007	
Committee considered case as per agenda for ratification of norms for export product Carvedilol 3.125mg, 6.25mg, 12.5mg and 25mg Tablets under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-673	M/S Acacia Life Sciences Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/1086/AM07
Meeting date: 18.09.2007	RLA F.No.09/24/40/492/AM07
Adv.Lic. No.0910029581 dated 08.03.2007	
Committee considered case as per agenda for ratification of norms for export product (3Z)-4-(Aminomethyl)-3-Pyrrolidinone-O-Methyloxime Hcl under para 4.7 of HBP. Committee perused application of firm and observed that firm has sought different quantities of inputs in their application. Committee, therefore, decided to seek clarification from RA.	

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/76/2007 PI-III dated 06.09.2007 also decided to call for following information from firm.

- i) Whereas the firm has applied BOC Anhydride @17.85kg/kg and O-Methoxy Hydroxylamine Hcl @1.85kg/kg under Appendix 11-A, the total requirement has been shown as 2000kg and 225kg respectively against the export of 200kg i.e. per unit norms of 10.00 kg/kg and 1.125 kg/kg respectively for the above two inputs.
- ii) Even the value addition have been shown as 66.7% and 1253% at two places.
- iii) The firm has neither given complete chemical reaction, molecular weight, molar requirement of inputs nor the percentage yield on molar basis for each step of chemical reactions.

Accordingly, case was deferred for six weeks.

Case No.A-674	M/S Astrix Laboratories Ltd
NC Meeting No.20/08	F.No.01/82/50/972/AM07
Meeting date: 18.09.2007	RLA F.No.09/24/40/440/AM07
Adv.Lic. No.0910029251 dated 08.02.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivudine (Cyclohexyl Ester Route) under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-675	M/S Envee Drugs Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/143/AM08
Meeting date: 18.09.2007	RLA F.No.34/24/40/296/AM07
Adv.Lic. No.3410018601 dated 18.04.2007	
Committee considered case as per agenda for ratification of norms for export product Betamethasone Valerate BP/USP under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-676	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/82/50/127/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/469/AM08
Adv.Lic. No.0910030086 dated 24.04.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Sllbactam Sodium (2:1) under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-677	M/S Medrieck Ltd.
NC Meeting No.20/08	F.No.01/82/50/1790/AM07
Meeting date: 18.09.2007	RLA F.No.07/24/40/718/AM07
Adv.Lic. No.0710049763 dated 24.01.2007	
Committee considered case as per agenda for ratification of norms for export product 1. Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 45mg + Codeine Phosphate 10mg Tablets, 2. Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 50mg + Codeine Phosphate 10mg Tablets and Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 30mg + Codeine Phosphate 10mg Tablets under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-678	M/S Mangalam Drugs & Organics Ltd.
NC Meeting No.20/08	F.No.01/83/50/825/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/362/AM08
Adv.Lic. No.0310437194 dated 23.07.2007	

Committee considered case as per agenda for ratification of norms for export product Amodiaquine Base under para 4.7 of HBP.

Committee observed that SION for the export product was deleted in 2005. Committee, therefore, decided to call for All Industry Data in respect of export product for revision of norms from Pharmexcil. Accordingly, case was deferred for six weeks.

Case No.A-679	M/S NGL Fine Chem Ltd.
NC Meeting No.20/08	F.No.01/83/162/449/AM07
Meeting date: 18.09.2007	RLA F.No.03/95/40/573/AM07
Para 4.4.2	
Committee considered case as per agenda for ratification of norms for export product Isometamidium Chloride Hcl under para 4.4.2 of HBP. Committee observed that firm was requested vide letter dated 02.08.2007 to furnish consumption data duly certified by Central Excise Authority, but same has not been received. Committee, therefore, decided to reject the case. RLA concerned may take further necessary action including cancellation of licence under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-680	M/S Makson Industries Pvt. Ltd.						
NC Meeting No.20/08	F.No.01/82/50/744/AM06						
Meeting date: 18.09.2007	RLA F.No.03/95/40/812/AM06						
Adv.Lic. No.0310350412 dated 05.10.2005							
Committee considered case as per agenda for ratification of norms for export product Vicks Veporub 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 firm whichever is lower. Export product: Vicks Veporub-----100kg. Import items: <table><tr><th>Sl.No.</th><th>Description of import items</th><th>Quantity allowed</th></tr><tr><td>1.</td><td>White Petrolactum (White Soft Paradin)</td><td>82.29kg/100kg</td></tr></table>		Sl.No.	Description of import items	Quantity allowed	1.	White Petrolactum (White Soft Paradin)	82.29kg/100kg
Sl.No.	Description of import items	Quantity allowed					
1.	White Petrolactum (White Soft Paradin)	82.29kg/100kg					

2.	Camphor USP	5.365kg/100kg
3.	Eucalyptus Oil	1.356kg/100kg
4.	Nutmeg Oil	0.703kg/100kg
5.	Cedar Leaf Oil	0.448kg/100kg
6.	Turpentine Oil	4.77kg/100kg
7.	Thymol	0.0916kg/100kg

RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee. The export product is for the limited purpose for Philippines, Malaysia, Thailand, Australia and New Zealand.

Case No.A-681	M/S Prachi Pharmaceuticals Pvt. Ltd.
NC Meeting No.20/08	F.No.01/83/50/709/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/308/AM08
Adv.Lic. No.0310435714 dated 11.07.2007	

Committee considered case as per agenda for ratification of norms for export product Thiamine Hcl BP/USP under para 4.7 of HBP.

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

Case No.A-682	M/S Neuland Laboratories Ltd.
NC Meeting No.20/08	F.No.01/83/50/1047/AM07
Meeting date: 18.09.2007	RLA F.No.09/24/40/361/AM07
Adv.Lic. No.0910028737 dated 21.12.2006	

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

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

Case No.A-683	M/S Lupin Ltd.
NC Meeting No.20/08	F.No.01/82/50/119/AM08

Meeting date: 18.09.2007	RLA F.No.03/95/40/293/AM08
Adv.Lic. No.0310433980 dated 26.06.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium 1mg/2mg/250mg Injection under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-684	M/S Lupin Ltd.
NC Meeting No.20/08	F.No.01/83/50/742/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/276/AM08
Adv.Lic. No.0310433502 dated 22.06.2007	
Committee considered case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-685	M/S Matrix Ltd.
NC Meeting No.20/08	F.No.01/82/50/125/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/445/AM08
Adv.Lic. No.0910030195 dated 07.05.2007	
Committee considered case as per agenda for ratification of norms for export product Nelfinavir Mesylate under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.A-686	M/S Nicholas Piramal India Ltd.
NC Meeting No.20/08	F.No.01/82/61/2/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/244/AM08

Case under para 4.4.2 of HBP	
Committee considered case as per agenda for ratification of norms for export product Oxysept Tablets under para 4.7 of HBP. Committee observed that firm has given wrong declaration that the application does not involve export and/or import of Biotechnology items and hence there is no need to submit NOC from Department of Biotechnology. Technical comments have been received from Department of Biotechnology according to which Export Product is a Biotechnology item. As such the declaration given by them is wrong and Committee decided to reject the case. RA concerned may take further necessary action including cancellation of licence as per above decision of Norms Committee.	

Case No.A-687	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/83/50/520/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/96/AM08
Adv.Lic. No.0910030542 dated 13.06.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Finasteride-----1kg.

Import items:

Sl.No	Description of import items	Quantity allowed
1.	Azandrostande Carboxamide (Androst-4-aza-3-one-17Beta-N-Tert. Butyl Carboxamide)	2.20kg/kg
2.	4-Dimethylaminopyridine (DMAP)	1.00kg/kg
3.	2,3-Dichloro-5,6-Dicyano-1,4-Benzoquinone (DDQ)	0.86kg/kg
4.	Bis-(Trimethylsilyl) Trifluoro-Acetamide (BSTFA)	1.47kg/kg
5.	Acetic Acid	13.31kg/kg
6.	Methanol	7.23kg/kg
7.	Methylene chloride	7.95kg/kg
8.	Tetrahydroduran	4.82kg/kg

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

Case No.A-688	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/83/50/878/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/182/AM08
Adv.Lic. No.0910031049 dated 06.08.2007	

Committee considered case as per agenda for ratification of norms for export product Benazepril Hcl under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Benazepril Hcl-----1kg.

Import items:

Sl.No	Description of import items	Quantity allowed
1.	Tert-buty(S)-3-Aminocaprolactam	0.8873kg/kg
2.	®-2-Hydroxy-4-Phenyl butanoic acid ethyl ester (HDPE)	0.9091kg/kg
3.	Methylene chloride	17.54kg/kg
4.	Trifluoro methansulphonic anhydride (Trifilic Anhydride)	1.43kg/kg
5.	Activated carbon	0.100kg/kg
6.	Potassium Carbonate	0.0909kg/kg

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

Case No.A-689	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/83/50/831/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/446/AM07
Adv.Lic. No.0910030991 dated 24.07.2007	
Committee considered case as per agenda for ratification of norms for export product Didanosine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Didanosine-----1kg.	

Import items:

Sl.No	Description of import items	Quantity allowed
1.	Inosine	3.82kg/kg
2.	2-Acetoxy Isobutyryl Bromide	7.84kg/kg
3.	Ethylene Diamine Tetra Acetic Acid Disodium Salt Dihydrate	4.20kg/kg
4.	Activated Carbon	0.100kg/kg
5.	N,N Dimethyl Formamide	2.14kg/kg
6.	Methylene chloride	4.49kg/kg
7.	Acetonitrile	7.68kg/kg
8.	Methanol	6.21kg/kg

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

Case No.A-690	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/83/50/823/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/159/AM08
Adv.Lic. No.0910030974 dated 23.07.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Efavirenz-----1kg.

Import items:

Sl.No	Description of import items	Quantity allowed
1.	Isopropyl Alcohol	6.00kg/kg
2.	Trifluoroethanol (2,2,2-Trifluoro Ethanol)	0.642kg/kg
3.	Tetra Hydro Furan	6.00kg/kg
4.	2-Trifluoromethylcarbonyl-4-Chloroaniline (Ketoaniline Free Base)	1.19kg/kg
5.	Cyclopropyl Acetylene	0.524kg/kg
6.	Triphosgene	0.498kg/kg
7.	Diethyl Zinc (60% in Hexane)	1.47kg/kg
8.	Potassium Carbonate	0.428kg/kg
9.	n-Hexane	6.03kg/kg
10.	(1R,2S)-PyrrilidinyI Norephedrine (L phenyl proferol	0.185kg/kg

amine Hcl)	
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-691	M/S Astrix Laboratories Ltd.
NC Meeting No.20/08	F.No.01/83/50/717/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/119/AM09
Adv.Lic. No.0910030868 dated 12.07.2007	
Committee considered case as per agenda for ratification of norms for export product Ritonavir under para 4.7 of HBP. Committee noted that firm was requested to furnish certain technical details vide letter dated 14.08.2007, but same has not been received. Committee, therefore, decided to reject case. RLA concerned may take further necessary action including cancellation of licence under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-692	M/Astrix Laboratories Ltd.
NC Meeting No.20/08	F.No.01/83/50/718/AM08
Meeting date: 18.09.2007	RLA F.No.09/24/40/118/AM08
Adv.Lic. No.0910030869 dated 12.07.2007	
Committee considered case as per agenda for ratification of norms for export product Lopinavir under para 4.7 of HBP. Committee observed that in another case of firm for same export product, firm was requested to furnish certain technical information vide letter dated 07.08.2007, but same has not been received. That case has been considered in NC Meeting No.19/08 dated 11.09.2007 and it has been decided to await reply of firm and defer case to be re-listed on 04.10.2007. Committee, therefore, decided to defer this case and to re-list on 04.10.2007 alongwith the other similar case.	

Case No.A-693	M/S Arvee Chem Pharma Pvt. Ltd.
NC Meeting No.20/08	F.No.01/82/50/297/AM08
Meeting date: 18.09.2007	RLA F.No.07/24/40/84/AM08
Adv.Lic. No.0710051589 dated	

10.05.2007	
Committee considered case as per agenda for ratification of norms for export product Dibenzosuberone Chemical Product under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/77/2007-PI-III dated 06.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Dibenzosuberone-----1kg. Import item: Tetrahydroduran-----1.627kg/kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee.	

Case No.A-694	M/S Wockhardt Ltd.
NC Meeting No.20/08	F.No.01/83/50/995/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/239/AM08
Adv.Lic. No.0310439955 dated 17.08.2007	
Committee considered case as per agenda for ratification of norms for export product Vitamin B12 (Cyanocobalamin) USP under para 4.7 of HBP. The Committee in light of earlier decision taken in its 13/08 meeting held on 31.07.2007 vide Case No.A-359 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: Vitamin B12 (Cyanocobalamin) USP Micronised-----1Kg. As per particle size A) Minimum 80% Less than 125 Microns B) Minimum 98% Less than 150 Microns Import item: Vitamin B12 (Cyanocobalamin)-----1.01Kg/Kg As per particle size A) Not more than 66% less than 125 Microns B) Not more than 77% less than 150 Microns RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-695	M/S Ranbaxy Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/107/AM08
Meeting date: 18.09.2007	RLA F.No.05/24/40/17/AM08
Adv.Lic. No.0510202504 dated 13.04.2007	
Committee considered case as per agenda for ratification of norms for export product Isotretinoin under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-696	M/S Vijay Perfumes Pvt. Ltd
NC Meeting No.20/08	F.No.01/83/50/854/AM08
Meeting date: 18.09.2007	RLA F.No.03/95/40/422/AM08
Adv.Lic. No.0310437769 dated 30.07.2007	

Committee considered case as per agenda for ratification of norms for export product N-Methyl Benzothiazene Methyl Ester under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/52/2006-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower;

Export product:
N-Methyl Benzothiazene Methyl Ester-----1kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	Sodium Saccarine	1.29kg/kg
2.	Dimethyl Formamide	0.50kg/kg
3.	Sodium Metal	0.337kg/kg
4.	Methyl Alcohol	1.55kg/kg
5.	Acetone	0.645kg/kg
6.	Xylene	0.645kg/kg
7.	Methyl Chloro Acetate	0.98kg/kg

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

Case No.A-697	M/S DSM Anti-Infectives India Ltd.
NC Meeting No.20/08	F.No.01/83/50/984/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/35/AM08
Adv.Lic. No.2210006969 dated 17.08.2007	
Committee considered case as per agenda for ratification of norms for export product Cloxacillin Sodium Pen G Route under para 4.7 of HBP. Committee decided to ratify norms under para 4.7 of HBP as per SION at SI.No.A-152 published vide Public Notice No.45 dated 06.09.2007. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-698	M/S Ranbaxy Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/758/AM08
Meeting date: 18.09.2007	RLA F.No.05/24/40/285/AM08
Adv.Lic. No.0910030869 dated 12.07.2007	
Committee considered case as per agenda for ratification of norms for export product Atorvastatin Calcium under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.A-699	M/S Surya Pharmaceutical Ltd.
NC Meeting No.20/08	F.No.01/83/50/1007/AM08
Meeting date: 18.09.2007	RLA F.No.22/24/40/34/AM08
Adv.Lic. No.2210006991 dated 21.08.2007	
Committee considered case as per agenda for ratification of norms for export product Cefprozil under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly decided to defer case for six weeks.	

Case No.B-277	M/S Alchem International Ltd.
NC Meeting No.20/08	F.No.01/87/50/1374/AM05
Meeting date: 18.09.2007	RLA F.No.05/24/40/542/AM05
Adv.Lic. No.0510148830 dated 17.01.2005	
Committee considered case as per agenda for ratification of norms for export product Hyocine-n-Butyl Bromide under para 4.7 of HBP. Committee observed that there are several cases of firm for same export product. Committee, therefore, decided to re-list all the cases of firm on 04.10.2007.	

Case No.B-278	M/S Cipla Ltd
NC Meeting No.20/08	F.No.01/82/50/124/AM08
Meeting date: 18.09.2007	RLA F.No.03/94/40/263/AM08
Adv.Lic. No.0310432617 dated 14.06.2007	

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

Committee in consultation with technical authorities present in meeting decided to amend description of import items No. 2 to 4 as per details below;

Sl.No.	Description of import item as per earlier decision of NC	Description amended
2.	Vials 10ml amber coloured glass (component)	63mcl Aerolol Valves
3.	Pump Vol.0.05ml 20mm crimp (component)	19ml Aluminium Can
4.	Applicator Nasal Spray EGS (Component)	Actuators with Dust Covers/Caps Fitting to 19ml Aluminium Can

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

Case No.B-279	M/S Anuh Pharma Ltd.
NC Meeting No.20/08	F.No.01/82/50/1430/AM08
Meeting date: 18.09.2007	RLA F.No.03/81/39/3/AM07
Adv.Lic. No.0310404537 dated 17.10.2006	

Committee considered case as per agenda for amendment in the description of export product under para 4.7 of HBP.

Committee in consultation with technical authorities present in meeting decided to allow amendment in description of export product to read as "Erythromycin Propionate".

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

Case No.B-280	M/S Glenmark Pharmaceuticals Ltd
NC Meeting No.20/08	F.No.01/82/50/574/AM06
Meeting date: 18.09.2007	RLA F.No.03/94/40/509/AM06
Adv.Lic. No.0310345199 dated 30.08.2005	
Committee considered case as per agenda for amendment in the description of export product under para 4.7 of HBP. Committee in consultation with technical authorities present in meeting decided to allow amendment in description of export product to read as "Glimepiride". RA concerned may take further necessary action as a per above decision of Norms Committee.	

Case No.B-281	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/87/50/421/AM07
Meeting date: 18.09.2007	RLA F.No.09/21/40/85/AM06
Adv.Lic. No.0910023252 dated 23.06.2005	
Committee considered case as per agenda for carry forward the export obligation under Advance licence to 100% EOU. Committee decided to advise firm to approach Regional Authority in terms of para 6.37.1 of HBP (Vol.I).	

Case No.B-282	M/S Alkem Laboratories Ltd.
NC Meeting No.20/08	F.No.01/83/50/409/AM08

Meeting date: 18.09.2007	RLA F.No.03/94/40/187/AM08
Adv.Lic. No.0310430680 dated 25.05.2007	
Committee considered case as per agenda for ratification of norms for export product Sucralose USP under para 4.7 of HBP. Committee decided to forward a copy of application to PI Division and defer case for four weeks.	

Case No.B-283	M/S Aurobindo Pharma Ltd.
NC Meeting No.20/08	F.No.01/87/50/917/AM08
Meeting date: 18.09.2007	RLA F.No.03/94/40/263/AM06
Adv.Lic. No.0910024429 dated 26.10.2005	

Committee considered case as per agenda for modification of norms fixed in its meeting No.37/05 dated 04.01.2006 for export product 7-Amino-3-Vinyl Cephalosporanic Acid under para 4.7 of HBP.

Committee in consultation with representative of PI Division present in meeting decided to modify import items as per details below;

Export product:
7-Amino-3-Vinyl Cephalosporanic Acid -----1kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	GCLE (7-Phenyl Acetamide-3-Chloro methyl Cephalosporanic)	3.808kg/kg
2.	Butyl Acetate/DMF	4.06kg/kg
3.	Methylene Chloride/Methanol	10.70kg/kg
4.	Activated Carbon	0.100kg/kg
5.	Phenol	6.1347kg/kg

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

Case No.B-284	M/S Glenmark Pharmaceuticals Ltd.
NC Meeting No.20/08	F.No.01/82/162/207/AM08
Meeting date: 18.09.2007	RLA F.No.03/24/40/789/AM04
Adv.Lic. No.0310217859 dated 11.08.2003	

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

Committee observed that advance authorization was issued on 11.08.2003 and firm has made representation now for ratification of norms. Committee decided to reject case as it appears to be time barred.

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

Case No.B-285	M/S Glenmark Pharmaceuticals Ltd.
NC Meeting No.20/08	F.No.01/82/162/154/AM08
Meeting date: 18.09.2007	RLA F.No.03/24/40/1857/AM04
Adv.Lic. No.0310241497 dated 11.12.2003	
Committee considered case as per agenda for ratification of norms for export product Amiodrone under para 4.7 of HBP. Committee observed that advance authorization was issued on 11.12.2003 and firm has made representation now for ratification of norms Committee decided to reject case as it appears to be time barred. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-286	M/S Ind Swift Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/1131/AM07
Meeting date: 18.09.2007	RLA F.No.22/24/40/261/AM07
Adv.Lic. No.2210006123 dated 11.10.2006	
Committee considered case as per agenda for allowing import of L(+)Tartaric Acid under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/192/2006 PI-III dated 24.04.2007 in case of M/S Arch Pharmababs Ltd	

decided to allow import of additional item as per details below.

Import item:

L+Tartaric acid-----0.70kg/kg

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

Case No.B-287	M/S Lupin Ltd.
NC Meeting No.20/08	F.No.01/82/50/1604/AM07
Meeting date: 18.09.2007	RLA F.No.03/95/40/1237/AM07
Adv.Lic. No.0310415404 dated 10.01.2007	
Committee considered case as per agenda for amendment in the description of import item under para 4.7 of HBP. Committee in consultation with representative of PI Division present in meeting decided to allow amendment in description of import item No.2 to read as "E.D.T.A. disodium" and import item No.9 to read as "Dimethyl Aniline" without any change in quantity. RLA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-288	M/S Ind-Swift Laboratories Ltd.
NC Meeting No.20/08	F.No.01/82/50/179/AM07
Meeting date: 18.09.2007	RLA F.No.22/24/40/18/AM07
Adv.Lic. No.2210005501 dated 04.05.2006	
Committee considered case as per agenda for modification of norms for export product Clopidogrel Hydrogen Sulphate under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.	

Case No.B-289	M/S Lupin Ltd.
NC Meeting No.20/08	F.No.01/82/50/1458/AM07
Meeting date: 18.09.2007	RLA F.No.03/95/40/1145/AM07
Adv.Lic. No.0310412637 dated	

19.12.2006	
Committee considered case as per agenda for amendment in the description of import item under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/46/2007-PI-III dated 24.04.2007 decided to allow amendment in the description of import item No.12 to read as "Dimethyl Aniline". RLA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-290	M/S Shalina Laboratories Pvt. Ltd.
NC Meeting No.20/08	F.No.01/83/50/1083/AM07
Meeting date: 18.09.2007	RLA F.No.03/95/40/1164/AM07
Adv.Lic. No.0310414237 dated 02.01.2007	
Committee considered case as per agenda for ratification of norms for export product Epiderm Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.B-291	M/S Shalina Laboratories Pvt. Ltd.
NC Meeting No.20/08	F.No.01/83/50/1084/AM07
Meeting date: 18.09.2007	RLA F.No.03/95/40/1163/AM07
Adv.Lic. No.0310414239 dated 02.01.2007	
Committee considered case as per agenda for ratification of norms for export product Betasol Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly decided to defer case for four weeks.	

Case No.B-292	M/S Wockhardt Ltd.
NC Meeting No.20/08	F.No.01/82/162/549/AM'07
Meeting date: 19.09.2007	

Committee considered case as per agenda for fixation of value addition for revision of DEPB rate in respect of export product 'Dextromethorphan Hydrobromide'.

Committee observed that there are five inputs allowed under SION at Sl.No.A-173 out of which, firm has given data for four items. As regards 5th item namely Cyclohexenyl Ethyl Amino", firm has furnished International data wherein it has been mentioned that Zeeland, USA the sole manufacturer in the world have stopped manufacturing of this product since 2002. The item is being manufactured in India by 02 Manufacturers. Hence no imports done for this item and no import price available since 2002.

Committee decided to call for All Industry Data for above input from Pharmexcil. Case was accordingly deferred for four weeks.

Case No.C-11	M/S IPCA Labs. Ltd.
NC Meeting No.20/08	F.No.01/82/50/1004/AM07/DES-III
Meeting date 19.09.2007	
Committee considered case as per agenda for amendment in description of export product in SION at Sl.No.A-373. Committee in consultation with technical authorities present in meeting decided to allow amendment in description of export product in SION A-373 to read as "Propranolol Hydrochloride" instead of "Propanolol Hydrochloride". Necessary steps may be taken to amend the description of export product through Public Notice.	