

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

Para 4.7 Decision

MEETING NUMBER : 30/82-ALC4/2007 MEETING DATE : 27.11.2007

Case No.B-414	M/S Kudos Chemie Ltd.
NC Meeting No.30/08	F.No.01/82/162/335/AM'08
Meeting Date: 27.11.2007	
Committee considered the case as per agenda for clarification as to whether the product Synthetic Caffeine (Anhydrous) is covered under DEPB Schedule against Sl.No.62/19 and SION No.A-97 under the product Head 'Caffeine'. Shri Jitendra Singh, Managing Director of the company appeared in personal hearing and explained the matter in detail. Committee noted that Natural Caffeine is found in tea and coffee. Thus the export product appearing at SION A-97 appears to be Synthetic Caffeine. They have stated that they are manufacturing and exporting Synthetic Caffeine (Anhydrous) which is Caffeine as per the Indian Pharmacopia. In support, the firm has submitted CA certificate for 2005-06 and 2006-07 supported with copies of shipping bills. The Committee also noted that in SION A-97, the inputs Theophylline and Activated Carbon are allowed which are being used by the applicant. Committee after detailed deliberation and in consultation with the representatives of Deptt. of C&PC present in the meeting came to the conclusion that the synthetic Caffeine (Anhydrous) exported by the firm should be eligible for DEPB benefits. Committee decided to recommend the case to DEPB Committee.	

Case No.B-415	M/S Agio Pharmaceuticals Ltd.
NC Meeting No.30/08	F.No.01/87/162/287/AM'07 F.No.01/87/50/287/AM07
Meeting Date: 27.11.2007	RLA F.No.03/94/40/294/AM07 RLA F.No.03/94/40/1267/AM07
Adv.Lic.No.0310423444 dated 16.03.2007 Adv.Lic.No.0310385834 dated 21.06.2006	
Committee considered case as per agenda for modification of norms for export product Prednisol Sodium 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 two weeks. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-872	M/S Cipla Ltd.
NC Meeting No.30/08	F.No.01/82/50/250/AM'08
Meeting Date: 27.11.2007	RLA F.No.03/94/40/749/AM08
Adv.Lic.No.0310447493 dated 23.10.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir HBV Tablets 100mg/Lamivudine 100mg Tablets under para 4.7 of HBP. Committee decided to defer case for 18.12.2007 as firm has been called for personal hearing before Norms Committee on the same date.	

Case No.A-873	M/S Cipla Ltd.
NC Meeting No.30/08	F.No.01/82/50/251/AM'08
Meeting Date: 27.11.2007	RLA F.No.03/94/40/747/AM08
Adv.Lic.No.0310447486 dated 23.10.2007	
Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP. Committee decided to defer case for 18.12.2007 as firm has been called for personal hearing before Norms Committee on the same date.	

Case No.A-874	M/S Gland Pharma Ltd.
NC Meeting No.30/08	F.No.01/82/50/254/AM'08
Meeting Date: 27.11.2007	RLA F.No.09/24/40/314/AM08
Adv.Lic.No.0910031800 dated 16.10.2007	
Committee considered case as per agenda for ratification of norms for export product Adenosine Injections USP Prefilled Syringe 3mg/ml, 2ml in a PFS 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-875	M/S Aurobindo Pharma Ltd.
NC Meeting No.30/08	F.No.01/82/50/253/AM'08
Meeting Date: 27.11.2007	RLA F.No.09/24/40/205/AM08
Adv.Lic.No.0910031156 dated 16.08.2007	
Committee considered case as per agenda for ratification of norms for export product Ceftiofur Sodium Sterile 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-876	M/S Cipla Ltd.
NC Meeting No.30/08	F.No.01/82/50/212/AM'08
Meeting Date: 27.11.2007	RLA F.No.03/94/40/590/AM08
Adv.Lic.No.0310442077 dated 06.09.2007	
Committee considered case as per agenda for ratification of norms for export product Terbinafine Hydrochloride 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-877	M/S Alembic Ltd.
NC Meeting No.30/08	F.No.01/82/50/218/AM'08
Meeting Date: 27.11.2007	RLA F.No.34/24/40/70/AM08
Adv.Lic.No.3410019349 dated 02.08.2007	
Committee considered case as per agenda for ratification of norms for export product Clarithromycin Coated Granules 28 to 31% and 38 to 44% under para 4.7 of HBP.	
Committee in consultation with technical authorities present in meeting	

observed that firm has proposed to export Clarithromycin Coated Granules (26 to 31% and 38 to 44%) while such range of export product is not covered in DML Committee, therefore, decided to close the case.

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

Case No.A-878	M/S Alembic Ltd.
NC Meeting No.30/08	F.No.01/82/50/37/AM'08
Meeting Date: 27.11.2007	RLA F.No.34/24/40/290/AM07
Adv.Lic.No.3410018404 dated 23.03.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 12.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Azithromycin Crude Purity NLT 94.5%-----1Kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	Erythromycin base	1.75kg/kg
2.	Acetone	6.45kg/kg
3.	Ethyl Alcohol	2.81kg/kg
4.	Hydroxylamine Hcl	0.91kg/kg
5.	Methane Sulfonyl chloride	0.72kg/kg
6.	Methanol	2.72kg/kg
7.	Platinum Catalyst with base of activated Carbon (5% Platinum on Carbon)	1.00gm/kg
8.	Hyflo	Not a raw material. Hence not allowed.

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

Case No.A-879	M/S Cadila Healthcare Ltd
NC Meeting No.30/08	F.No.01/82/50/161/AM'08
Meeting Date: 27.11.2007	RLA F.No.08/24/40/136/AM08
Adv.Lic.No.0810066915 dated 30.08.2007	
Committee considered case as per agenda for ratification of norms for export product 2-(2-Methoxyphenoxy)-Ethylamine Base Pharma Grade 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-880	M/S Brawn Laboratories Ltd.
NC Meeting No.30/08	F.No.01/82/50/154/AM'08
Meeting Date: 27.11.2007	RLA F.No.05/24/40/163/AM08
Adv.Lic.No.0510204890 dated 13.06.2007	
Committee considered case as per agenda for ratification of norms for export product Kanamycin Acid Sulphate Inj. BP 1gm and Lincomycin Capsules 500mg under para 4.7 of HBP. Committee observed that technical information was called for from firm vide letter dated 12.09.2007 followed by reminder dated 16.11.2007, but same has not been received. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.A-881	M/S Amoli Organics Pvt. Ltd.
NC Meeting No.30/08	F.No.01/87/50/606/AM'07
Meeting Date: 27.11.2007	RLA F.No.03/94/40/411/AM07
Adv.Lic.No.0310380982 dated 24.07.2006	
Committee considered case as per agenda for ratification of norms for export product Noscaphine Resin Complex under para 4.7 of HBP. Committee decided to hand over the file to representative of PI Division for examination of case and their comments. Accordingly, case was deferred for four weeks.	

1	Case No.:330/24/83-	Party Name:VASUDHA	Meet No/Date:30/82-	Status:Ca
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ALC1/2007	PHARMA CHEM LTD	ALC4/2007 27.11.2007	se Approved
HQ File : 01/83/050/00676/AM07/	RLA File : 09/21/040/00259/AM07/	Lic.No/Date:09100275 81 15.09.2006	
Decision :Committee considered case as per agenda for ratification of norms for export product Amitriptyline Crude under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/210/2005-PI-III dated 27.11.2005 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower. Export product: Amitriptyline Crude-----1kg. Import items: 1. Methanol-----0.423kg/kg 2. Acetonitrile-----0.333kg/kg 3. Phosphorus Pentaocide-----0.396kg/kg 4. Phosphoric Acid-----0.297kg/kg 5. Tetrahydrofuran-----0.477kg/kg 6. 1-bromo-3 chloropropane-----0.648kg/kg 7. Carbon-----0.043kg/kg 8. Methylene di chloride-----0.288kg/kg 9. Acetone-----0.072kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.:4/47/87- ALC1/2006	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:30/82- ALC4/2007 27.11.2007	Status:Ca se Deferred
HQ File : 01/87/050/00827/AM07/	RLA File : 09/24/040/00359/AM07/	Lic.No/Date:09100286 61 18.12.2006	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Lopinavir 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.:654/24/87-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
HQ File : 01/87/050/00987/AM07/	RLA File : 09/24/040/00451/AM07/	Lic.No/Date:0910029300 12.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Ampicillin Sodium Sterile under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 26.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. 3 Export product: Ampicillin Sodium Sterile-----1kg. Import items: 1. Ampicillin Anhydrous-----1.04kg/kg 2. Diethylamine-----0.2525kg/kg 3. Sodium Thiocyanate-----0.3075kg/kg 4. Acetonitrile-----1.41kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

4 Case No.:756/24/87-ALC1/2007	Party Name:AVIGNON EXIM PVT.LTD.,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Rejected
HQ File : 01/87/050/01102/AM07/	RLA File : 03/94/040/01374/AM07/	Lic.No/Date:0310422847 13.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Niacinamide BP/USP under para 4.7 of HBP. Committee observed that firm was requested to furnish technical information vide MSME letter No.5(9)/2005-chem dated 15.11.2007, but firm has refused to provide required information vide their letter dated 21.11.2007. Committee, therefore, decided to close the case.			

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

5	Case No.:43/9/82-ALC4/2007	Party Name:KOPRAN LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01818/AM07/	RLA File : 03/94/040/01416/AM07/	Lic.No/Date:03104234 86 16.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin EP/USP under para 4.7 of HBP. Committee observed that firm has not submitted technical details as per Appendix 33 alongwith their application for Advance Authorisation. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.			

6	Case No.:4/12/82-ALC4/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01861/AM07/	RLA File : 09/24/040/00500/AM07/	Lic.No/Date:09100297 49 23.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Fluoro Lactone under para 4.7 of HBP. Committee observed that firm was requested to furnish technical information vide letter dated 08.10.2007, but same has not been received. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.			

7	Case No.:5/10/82-ALC4/2007	Party Name:GLAXOSMITHKLINE PHARMACEUTICALS LIMITED,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/82/050/01887/AM07/	RLA File : 03/94/040/00324/AM06/	Lic.No/Date:03104246 28 27.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Betamethanone Di-Sodium Phosphate BP/USP			

under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/42/2006-PI-III dated 27.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower.

Export product:

Betamethasone Sodium Phosphate-----1kg.

Import item:

9:11 Epoxide (DBXI or 17-Alpha, 21-Dihydroxy-16-Beta-Methyl-9-Beta-11-Beta-Epoxypregna-1,4-Diene-3,20-Dione)-----0.993kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

8	Case No.:474/24/83-ALC1/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01382/AM07/	RLA File : 07/24/040/00879/AM07/	Lic.No/Date:0710050972 29.03.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product N-[B-D-Ribofuranosyl]-5-Hydroxyimidazole-4-Carboxamide Grade 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.			

9	Case No.:508/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00084/AM08/	RLA File : 09/24/040/00541/AM07/	Lic.No/Date:0910029935 10.04.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 5-Cyano Phthalide 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.

10	Case No.:530/24/83-ALC1/2007	Party Name:ENVEE DRUGS PVT LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00143/AM08/	RLA File : 34/24/040/00296/AM07/	Lic.No/Date:3410018601 18.04.2007	Defer Date: 26.12.2007
	Decision : 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 four weeks. Committee, accordingly, decided to defer case for four weeks.			

11	Case No.:543/24/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Rejected
	HQ File : 01/83/050/00169/AM08/	RLA File : 03/94/040/00046/AM08/	Lic.No/Date:0310427426 20.04.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Diclofenac Sodium under para 4.7 of HBP. Committee observed that firm and Pharmexcil were requested to furnish Central Excise certified production and consumption data vide letter dated 14.09.2007, but same has not been received. In absence of data, it is not possible for Committee to fix norms. Committee, therefore, decided to close case. RA concerned may take further necessary action as per above decision of Norms Committee.			

12	Case No.:550/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00188/AM08/	RLA File : 09/24/040/00526/AM07/	Lic.No/Date:0910030104 25.04.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Propafenone Hydrochloride 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.:15/18/83-ALC1/2007	Party Name:GRANULES INDIA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00252/AM08/	RLA File : 09/24/040/00023/AM08/	Lic.No/Date:0910030174 04.05.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Oso Metheptene Mucate under para 4.7 of HBP. Committee observed that firm has been requested to furnish technical information as per Appendix 33 vide letter dated 29.10.2007, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.				

14	Case No.:627/24/83-ALC1/2007	Party Name:SIRIS IMPEX,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/83/050/00396/AM08/	RLA File : 09/24/040/00562/AM07/	Lic.No/Date:0910030342 25.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Griffonia Simplicifolia Dry Extract 95% under para 4.7 of HBP. Committee in light of its earlier decision taken in its 2/87meeting held on 13.04.2005 vide Case No.4/19/87 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Griffonia Simplicifolia Extract-----1kg. Import item: Griffonia Simplicifolia Dried seeds Containing 10% 5HTP by HPLC-----2.40kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision				

of Norms Committee.

15	Case No.:636/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00412/AM08/	RLA File : 09/24/040/00531/AM07/	Lic.No/Date:09100303 65 28.05.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Cyclohexyl Ester 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.				
16	Case No.:635/24/83-ALC1/2007	Party Name:JUPITER BIOSCIENCE LIMITED,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00411/AM08/	RLA File : 09/24/040/00045/AM08/	Lic.No/Date:09100303 62 28.05.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product N-T-Boc-L-Phenylalanine 99% Purity 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.				
17	Case No.:645/24/83-ALC1/2007	Party Name:AYURSIDDHA INC.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00438/AM08/	RLA File : 05/24/040/00105/AM08/	Lic.No/Date:05102042 54 30.05.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Blockbuster All Clear Capsules made of Citrolive under para 4.7 of HBP. Representative of MSME present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				
18	Case No.:647/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:30/82-ALC4/2007	Status:Case

		27.11.2007	Approved
HQ File : 01/83/050/00441/AM08/	RLA File : 09/24/040/00015/AM08/	Lic.No/Date:09100304 01 31.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Doxofylline under para 4.7 of HBP. Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide Case No.455/24/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: Doxofylline-----1kg. Import items: 1. Theophylline-----1.17kg/kg 2. Chloro acetaldehyde dimethyl acetal-----0.81kg/kg 3. Potassium carbonate-----0.89kg/kg 4. Methanol-----0.63kg/kg 5. Dimethyl formamide-----0.56kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

19	Case No.:674/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/83/050/00512/AM08/	RLA File : 09/24/040/00063/AM08/	Lic.No/Date:09100305 26 13.06.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Doxofylline under para 4.7 of HBP. Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide Case No.455/24/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.				

Export product:
Doxofylline-----1kg.

Import items:

1. Theophylline-----1.17kg/kg
2. Chloro acetaldehyde dimethyl acetal-----0.81kg/kg
3. Potassium carbonate-----0.89kg/kg
4. Methanol-----0.63kg/kg
5. Dimethyl formamide-----0.56kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

	Case No.:680/24/83-ALC1/2007	Party Name:DCM SHRIRAM INDUSTRIES LTD,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00524/AM08/	RLA File : 05/24/040/00166/AM08/	Lic.No/Date:05102049 18 14.06.2007	Defer Date: 26.12.2007
20	Decision : Committee considered case as per agenda for ratification of norms for export product D(-)Para Hydroxy Phenyl Glycine Dane Salt 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.			

21	Case No.:655/24/83-ALC1/2007	Party Name:CADILA PHARMACEUTICALS LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00530/AM08/	RLA File : 08/24/040/00066/AM08/	Lic.No/Date:08100654 23 15.06.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Methscopolamine Tannete under para 4.7 of HBP. Representative of PI Division present in 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.			

22	Case No.:730/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00623/AM08/	RLA File : 09/24/040/00120/AM08/	Lic.No/Date:0910030686 29.06.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product (S)-3-Hydroxy-N-Benzyl Pyrrolidine 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.				

23	Case No.:737/24/83-ALC1/2007	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Transferred
	HQ File : 01/83/050/00638/AM08/	RLA File : 09/24/040/00004/AM08/	Lic.No/Date:0910030723 03.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Etocrylene under para 4.7 of HBP. Committee observed that firm has stated about export product being used as Photo anti oxidant. Therefore it pertains to Chemical Sector. It was decided to transfer case to DES-IV.				

24	Case No.:19/23/83-ALC1/2007	Party Name:SEQUENT SCIENTIFIC LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00655/AM08/	RLA File : 07/24/040/00234/AM08/	Lic.No/Date:0710052301 04.07.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product L-(+)-Selenomethionine 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.:798/24/83-ALC1/2007	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File :	RLA File :	Lic.No/Date:05102063	

01/83/050/00756/AM08/	05/24/040/00241/AM08/	28 16.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Mica Ester under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/67/2007-PI-III dated 23.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Mica Ester-----1kg. Import items: 1. Mica Acid-----0.83kg/kg 2. Triphenyl Phosphine-----0.911kg/kg 3. Methanol-----0.525kg/kg 4. Triethylamine-----0.322kg/kg 5. Acetonitrile-----1.44kg/kg 6. MBTS-----1.157kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

26	Case No.:799/24/83-ALC1/2007 HQ File : 01/83/050/00757/AM08/	Party Name:SURYA PHARMACEUTICAL LTD RLA File : 05/24/040/00240/AM08/	Meet No/Date:30/82- ALC4/2007 27.11.2007 Lic.No/Date:05102063 31 16.07.2007	Status:Case Approved
Decision : Committee considered case as per agenda for ratification of norms for export product 7AVNA under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/67/2007-PI-III dated 23.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: 7 AVNA-----1kg.				

Import items:

1. 7-Phenylacetamideo-3-chloromethyl
Cephalosporanic Acid Para methoxy
Benzyl Ester (GCLE)-----2.672kg/kg
2. Triphenyl Phospine-----1.26kg/kg
3. Methanol-----8.48kg/kg
4. Acetone-----1.95kg/kg
5. Acetic acid-----0.022kg/kg
6. Methylene chloride-----8.20kg/kg
7. Sodium iodide-----0.828kg/kg
8. N,N,Dimethyl Formamide-----0.54kg/kg
9. Phenol-----0.933kg/kg
10. N-Butyl Acetate-----5.54kg/kg
11. Carbon-----0.100kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

27	Case No.:2/14/82-ALC4/2007	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:30/82- ALC4/2007 27.11.2007	Status:Case 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: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefdinir 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.			

28	Case No.:851/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:30/82- ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/83/050/00851/AM08/	RLA File : 05/24/040/00313/AM08/	Lic.No/Date:05102066 70 24.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Midazolam under para 4.7 of HBP.			
	Committee in light of written comments forwarded by PI Division vide			

their U.O. No.35011/85/2007-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Midazolam-----1Kg.

Import items:

1. 2-Amino-5Chloro2-Fluoro Benzophenone-----5.223kg/kg
2. CADMA (Chloro Acetaldehyde Dimethyl Acetal-----3.90kg/kg
3. Dimethyl Sulphoxide-----6.40kg/kg
4. Lithium Amide-----0.85kg/kg
5. Nitromethane-----1.88kg/kg
6. Tetrahydrofuran-----8.40kg/kg
7. Triethyl Ortho Acetate-----3.42kg/kg
8. Activated Carbon-----0.100kg/kg
9. Isopropyl Alcohol-----4.40kg/kg
10. Methylene Chloride-----5.26kg/kg
11. Methanol-----5.00kg/kg
12. Toluene-----5.00kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

	Case No.:897/24/83-ALC1/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00905/AM08/	RLA File : 05/24/040/00287/AM08/	Lic.No/Date:05102073 00 07.08.2007	Defer Date: 26.12.2007
29	Decision : Committee considered case as per agenda for ratification of norms for export product Captothecin under para 4.7 of HBP. Committee observed that application has been forwarded to MSME vide U.O. dated 19.11.2007, but comments have not been received. Committee decided to await comments from MSME. Accordingly, case was deferred for four weeks.			
30	Case No.:894/24/83-ALC1/2007	Party Name:DOCTORSORGANIC CHEMICALS LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred

HQ File : 01/83/050/00902/AM08/	RLA File : 26/24/040/00001/AM08/	Lic.No/Date:26100063 18 07.08.2007	Defer Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Clopidogrel Hydrogen Sulfate Solid 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.:16/25/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/83/050/01041/AM08/	RLA File : 03/94/040/00516/AM08/	Lic.No/Date:03104397 36 16.08.2007	Defer Date: 26.12.2007
31	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium 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.:999/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/83/050/01017/AM08/	RLA File : 09/24/040/00154/AM08/	Lic.No/Date:09100312 00 24.08.2007	Defer Date: 26.12.2007
32	Decision : Committee considered case as per agenda for ratification of norms for export product [1S,4R]-4-[(2-Amino-6-Chloro-5-Formamido-4-Pyrimidinyl)Amino]-2-Cyclopentene-1-Methanol (An Intermediate of Abacavir) 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.:8/27/83-ALC1/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/83/050/01082/AM08/	RLA File : 05/24/040/00439/AM08/	Lic.No/Date:05102084 08 31.08.2007	Defer Date: 26.12.2007
33	Decision : Committee considered case as per agenda for ratification of		

norms for export product Captothecin under para 4.7 of HBP.

Committee observed that application has been forwarded to MSME vide U.O. dated 19.11.2007, but comments have not been received. Committee decided to await comments from MSME. Accordingly, case was deferred for four weeks.

Case No.:4/22/82-ALC4/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/82/050/00174/AM08/	RLA File : 09/24/040/00207/AM07/	Lic.No/Date:09100313 28 31.08.2007	Defer Date: 26.12.2007

34 **Decision :** Committee considered case as per agenda for ratification of norms for export product Cefoperazone Sodium Sterile USP/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 four weeks. Committee, accordingly, decided to defer case for four weeks.

Case No.:28/27/83-ALC1/2007	Party Name:GLOBAL CALCIUM PRIVATE LIMITED,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Transferred
HQ File : 01/83/050/01102/AM08/	RLA File : 07/24/040/00172/AM08/	Lic.No/Date:07100531 50 03.09.2007	

35 **Decision :** Committee considered case as per agenda for ratification of norms for export product Calcium Levulinate under para 4.7 of HBP.

Representative of PI Division present in meeting pointed out that norms for above export product has been fixed in DES-IV Section. Committee, accordingly, decided to transfer this case to DES-IV Section.

Case No.:23/27/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
HQ File : 01/83/050/01097/AM08/	RLA File : 09/24/040/00209/AM08/	Lic.No/Date:09100313 82 03.09.2007	

36 **Decision :** Committee considered case as per agenda for ratification of norms for export product Amitriptyline Crude under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide

their U.O. No.35011/210/2005-PI-III dated 27.11.2005 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower.

Export product:

Amitriptyline Crude-----1kg.

Import items:

1. Methanol-----0.423kg/kg
2. Acetonitrile-----0.333kg/kg
3. Phosphorus Pentaocide-----0.396kg/kg
4. Phosphoric Acid-----0.297kg/kg
5. Tetrahydrofuran-----0.477kg/kg
6. 1-bromo-3 chloropropane-----0.648kg/kg
7. Carbon-----0.043kg/kg
8. Methylene di chloride-----0.288kg/kg
9. Acetone-----0.072kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

37	Case No.:32/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01106/AM08/	RLA File : 09/24/040/00388/AM07/	Lic.No/Date:0910031402 05.09.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP. Representative of PI Division present in 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.			

38	Case No.:31/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01105/AM08/	RLA File : 09/24/040/00470/AM07/	Lic.No/Date:0910031401 05.09.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of			

norms for export product Pivmecillinam hydrochloride 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.:39/27/83-ALC1/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
HQ File : 01/83/050/01113/AM08/	RLA File : 22/24/040/00039/AM08/	Lic.No/Date:22100070 31 06.09.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product 6-Amino Penicillanic Acid Pen G Route under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/165/2006-PI-III dated 27.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

39 Export product:
6-Amino Penicillanic acid (6 APA)-----1kg.

Import items:

1. Pencillin G Potassium 1st Crystal-----2.92BOU/kg
2. Penicillin G Amidase Enzyme-----0.096kg/kg
3. Boric Acid-----0.055kg/kg
4. Methanol-----0.04kg/kg
5. Butyl acetate-----0.214kg/kg
6. P.T. Resin-----0.004kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

40	Case No.:41/27/83-ALC1/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File :	RLA File :	Lic.No/Date:22100070	

01/83/050/01115/AM08/	22/24/040/00036/AM08/	33 06.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Pen G Route Through Enzymatic Route under para 4.7 of HBP. Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide case No.902/24/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower. Export product: Amoxycillin Trihydrate enzymatic route-----1kg. Import items: 1. Penicillin G Pot. 1st crystal-----1.664 BOU/Kg 2. D(-) Para hydroxy phenyl glycine methyl ester-----0.608Kg 3. Oxilasa enzyme-----5.0gm. 4. Penicillin G Amidase enzyme-----0.852gm. 5. Methanol-----0.0215Kg 6. Butyl Acetate-----0.122Kg 7. Boric acid-----0.032Kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

41	Case No.:40/27/83-ALC1/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/83/050/01114/AM08/	RLA File : 22/24/040/00037/AM08/	Lic.No/Date:22100070 32 06.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Pen G Route Through Enzymatic Route under para 4.7 of HBP. Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide case No.902/24/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm				

whichever is lower.

Export product:

Amoxycillin Trihydrate enzymatic route-----1kg.

Import items:

1. Penicillin G Pot. 1st crystal-----1.664 BOU/Kg
2. D(-) Para hydroxy phenyl glycine methyl ester-----0.608Kg
3. Oxilasa enzyme-----5.0gm.
4. Penicillin G Amidase enzyme-----0.852gm.
5. Methanol-----0.0215Kg
6. Butyl Acetate-----0.122Kg
7. Boric acid-----0.032Kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

42	Case No.:82/27/83-ALC1/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
	HQ File : 01/83/050/01156/AM08/	RLA File : 07/24/040/00422/AM08/	Lic.No/Date:0710053281 11.09.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/231/2006-PI-III dated 27.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Ambroxol Hcl-----1kg.

Import items:

1. Liquid Bromine-----1.32kg/kg
2. Trans Para Amino Cyclohexanol----0.80kg/kg
3. Sodium Borohydride-----0.583kg/kg
4. Tetra Hydrofuran-----2.15kg/kg
5. Methanol-----2.58kg/kg

6. Methylene dichloride-----3.225kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

43	Case No.:98/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01172/AM08/	RLA File : 09/24/040/00258/AM08/	Lic.No/Date:09100315 11 14.09.2007	Defer Date: 26.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumerate 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.			

44	Case No.:13/22/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00183/AM08/	RLA File : 13/24/040/00018/AM08/	Lic.No/Date:13100250 51 21.09.2007	Defer Date: 08.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Biotin Granules under para 4.7 of HBP. Committee perused file of firm and observed that copy of Advance Authorisation has been furnished for export product Biotin Granules while the application has been furnished for export product Alpha Lipoic Acid Granules 95%. Moreover, copy of DML has not been furnished. Committee, therefore, decided to call for copy of application for export product Biotin Granules alongwith a copy of relevant DML form firm. RA may be asked to furnish reasons for above lapse. Accordingly, case was deferred for six weeks.			

45	Case No.:14/22/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:13100250	Defer

01/82/050/00184/AM08/	13/24/040/00017/AM08/	52 21.09.2007	Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Vitamin B12 Granules under para 4.7 of HBP. Committee decided to call for a copy of relevant DML from firm. Accordingly, case was deferred for six weeks.			

Case No.:16/22/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/82/050/00186/AM08/	RLA File : 03/95/040/00574/AM08/	Lic.No/Date:03104440 49 24.09.2007	Defer Date: 26.12.2007
46	Decision : Committee considered case as per agenda for ratification of norms for export product Diprosone Lotion (30ml) under para 4.7 of HBP. Committee observed that the export product Diprosone Lotion 30ml is based on Betamethasone Dipropionate whereas the firm has applied for import of Betamethasone base. Committee after detailed deliberations decided to call for clarification from firm since import item is not tallying with DML and technical justification has also not been given. Accordingly, case was deferred for four weeks.		

Case No.:154/27/83-ALC1/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/83/050/01228/AM08/	RLA File : 34/24/040/00140/AM08/	Lic.No/Date:34100196 98 25.09.2007	Defer Date: 08.01.2008
47	Decision : Committee considered case as per agenda for ratification of norms for export product Venlafaxine Hydrochloride Extended Release Pellets Stage under para 4.7 of HBP. Committee observed that description of export product is not clear. Committee, therefore, decided to call for specific description of export product alongwith copy of relevant DML. Accordingly, case was deferred for six weeks.		

48	Case No.:33/29/83-ALC1/2007	Party Name:AUCTUS PHARMA PRIVATE LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:09100317	Defer

01/83/050/01298/AM08/	09/24/040/00244/AM08/	13 05.10.2007	Date: 26.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product {1R,2S,5R}-Methyl-5S-(Cytosine-1-YL)-1,3-Oxathiolane-2R-Carboxylae/CME Compound 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.:57/29/83-ALC1/2007	Party Name:VITAL HEALTHCARE PVT.LTD.	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
HQ File : 01/83/050/01322/AM08/	RLA File : 03/95/040/00633/AM08/	Lic.No/Date:03104457 26 09.10.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Artesunate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/182/2006-PI-III dated 27.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Artesunate-----1kg Import item: Artemisinin-----0.9259kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

50	Case No.:2/26/82-ALC4/2007	Party Name:CIRON DRUGS & PHARMACEUTICALS P. LTD.,	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00220/AM08/	RLA File : 03/94/040/00755/AM08/	Lic.No/Date:03104473 19 22.10.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of				

norms for export product Drugs Formulations Drops Namely Fecistil Drops under para 4.7 of HBP.

Committee decided to call for a copy of relevant DML from firm. Accordingly, case was deferred for six weeks.

Case No.:3/26/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Approved
HQ File : 01/82/050/00221/AM08/	RLA File : 03/94/040/00751/AM08/	Lic.No/Date:03104473 34 22.10.2007	Defer Date:27.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Sulfacox Powder (per pack 1 Kg.) under para 4.7 of HBP.

Committee in consultation with technical authorities present in 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:

51 Sulfacox Powder-----1kg.

Each pack of 1kg Sulfacox Powder containing 860 gms Sulphadimerazine and 105 gms. Diaveridine

Import items:

1. Sulphadimerazine-----868.60gms/kg
2. Diaveridine-----106.05gms/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

52 Case No.:28/30/83-ALC1/2007	Party Name:AUCTUS PHARMA PRIVATE LIMITED	Meet No/Date:30/82-ALC4/2007 27.11.2007	Status:Case Deferred
HQ File : 01/83/050/01397/AM08/	RLA File : 09/24/040/00291/AM08/	Lic.No/Date:09100318 44 23.10.2007	Defer Date: 26.12.2007

Decision : Committee considered case as per agenda for ratification of norms for export product {1'R,2'S,5'R}-Methyl-5S(Cytosine-1'-YL)-1-3-

Oxathiolane-2R-Carboxylate/CME Compound 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.:76/32/83-ALC1/2007

Party Name:VIVIN
LABORATORIES PRIVATE
LIMITED

Meet No/Date:30/82-
ALC4/2007
27.11.2007

**Status:Case
Approved**

HQ File :
01/83/050/01498/AM08/

RLA File :
09/24/040/00249/AM08/

Lic.No/Date:09100319
43
02.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Menthyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lmuvudine Intermediate Stage-III under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/108/2007-PI-III dated 30.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Menthyl-5 S-Cytosine-1YL-1,3-

53 Oxathiolane-2R Carboxalate
(Lamivudine intermediate State 3)-----1Kg.

Import items:

1. Menthol-----0.87kg/kg
2. Glyoxalic acid 50%-----0.90kg/kg
3. 2,5 Dihydroxy-1,4 dithiane-----0.37kg/kg
4. Triethylamine-----0.67kg/kg
5. Cytosine-----0.475kg/kg
6. Hexamethyl disilazane-----0.75kg/kg
7. Dimethyl formamide-----0.31kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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

54 **Case No.:1/30/82-ALC4/2007**

Party Name:NESTOR
PHARMACEUTICALS LTD.

Meet No/Date:30/82-
ALC4/2007
27.11.2007

**Status:Case
Approved**

HQ File :
01/82/050/00249/AM08/

RLA File :
05/24/040/00627/AM08/

Lic.No/Date:05102118
66
08.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Paracetamol Granules under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 8/82 meeting held on 28.06.2007 vide case No.22/32/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Paracetamol Granules containing Paracetamol 860gms.-----1Kg.

Import items:

1. Paracetamol-----0.8686kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.

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