

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

Para 4.7 Decision

MEETING NUMBER : 2/82-ALC4/2008 MEETING DATE : 08.04.2008

The Meeting No.02/09 in the year 2008-09 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2004-09 pertaining to products falling in Chapter 29 and 30 was held on **08.04.2008** under the Chairmanship of Export Commissioner, Shri Sanjay Rastogi.

Following members were present:-

1. Shri Jasbir Singh, IA, Chemical Division, C & PC.
2. Shri D.N. Mathur, Dy. IA, PI Division, C & PC.
3. Shri Rajinder Pal Singh, Dy. DGFT.
4. Shri Shyam Lal, FTDO

At the outset minutes of Norms Committee Meeting No.47/08 dated 25.03.2008 and 01/09 meeting held on 01.04.2008 were ratified by the Committee.

Case No.B-5	M/S Madaus Pharma Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/201/AM08
Meeting Date:08.04.2008	RLA F.No.17/24/40/68/AM08
Adv.Lic.No.1710001775 dated 09.10.2007	
Committee considered case as per agenda for enhancement in the quantity of inputs. Committee observed that norms were ratified in its 37/82 meeting held on 15.01.2008 as per details below:- Export product: Agiolax (bulk granules laxative formulation)-----1kg. Import items: 1. Iron Oxide Red E 172-----0.0035kg/kg 2. Iron Oxide Yellow E 172-----0.00145kg/kg 3. Iron Oxide Black E 172-----0.00169kg/kg 4. Caraway Oil Dab Type III-----0.00040kg/kg 5. Sage oil type 90745 Dacl-----0.00040kg/kg	

6. Peppermint oil-----0.00110kg/kg
7. ACACIA-----0.01570kg/kg
8. Hard Paraffin-----0.00127kg/kg
9. Liquid Paraffin-----0.00276kg/kg

Representative of PI Division present in meeting informed Committee that revised norms have been given in NC Meeting No.1/82 held on 09.05.2007 (copy of decision enclosed with agenda). Committee, therefore, in consultation with representative of PI Division decided to revise norms as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Agiolax (bulk granules laxative formulation)	1 Kg.	1.	Iron Oxide Red E 172	0.0035 kg/kg
		2.	Iron Oxide Yellow E 172	0.00145 kg/kg
		3.	Iron Oxide Black E 172	0.00169 kg/kg
		4.	Caraway Oil Dab Type III	0.00052 kg/kg
		5.	Sage oil type 90745 Dacl	0.00052 kg/kg
		6.	Peppermint oil	0.00110 kg/kg
		7.	ACACIA	0.01570 kg/kg
		8.	Hard Paraffin	0.00127 kg/kg
		9.	Liquid Paraffin	0.00276 kg/kg

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

Case No.B-6	M/S Pab Organics Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/1256/AM07
Meeting Date:08.04.2008	RLA F.No.34/24/40/259/AM07
Adv.Lic.No.3410018108 dated 19.02.2007	

Committee considered case as per agenda for correction in the quantity of inputs.

Committee in light of written corrected comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 21.01.2008 decided to correct norms ratified in its 35/08 meeting held on 08.01.2008 as per details below:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
5-Bromo Phthalide	1 Kg.	1.	Hydrobromic Acid 48%	3.35 kg/kg
		2.	5-Amino Phthalide	0.87 kg/kg

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

Case No.B-7	M/S Pab Organics Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/799/AM08
Meeting Date:08.04.2008	RLA F.No.34/24/40/76/AM08
Adv.Lic.No.3410019236 dated 19.07.2007	
Committee considered case as per agenda for enhancement in the quantity of inputs. Committee observed that firm vide their letter dated 07.04.2008 have requested for personal hearing before NC to explain their case. Committee, therefore, decided to grant personal hearing on 13.05.2008. Accordingly, case was deferred.	

Case No.B-8	M/S Om Shree Pharma Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/83/50/1378/AM07
Meeting Date:08.04.2008	RLA F.No.03/95/40/1605/AM07
Adv.Lic.No.0310424623 dated 27.03.2007	
Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-9	M/S Om Shree Pharma Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/83/50/1267/AM07
Meeting Date:08.04.2008	RLA F.No.03/95/40/1424/AM07
Adv.Lic.No.0310420407 dated 21.02.2007	
Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-10	M/S Om Shree Pharma Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/83/50/725/AM08
Meeting Date:08.04.2008	RLA F.No.03/95/40/230/AM08
Adv.Lic.No.03104321412 dated 08.06.2007	
Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-11	M/S SMS Pharmaceuticals Ltd
Norms Committee Meeting No.2/09	F.No.01/83/162/424/AM07
Meeting Date:08.04.2008	RLA F.No.09/24/40/02/AM06
Adv.Lic.No.0910023407 dated 05.07.2005	
Committee considered case as per agenda for revision of norms for export product (D-erythro.d-threo)-2-Deoxy-2,2-difluoro pentafuluramos-1-ulose-3,5 dibenzoate para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/15/2006-PI-III dated 24.03.2008 decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-	

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(D-erythro.d-thero)-2-Deoxy-2,2-difluoro penta furanos-1-ulose-3,5 dibenzoate	1kg.	1.	2,2 Dimethoxy Propane	3.34 kg/kg
		2.	Dimethyl sulfoxide	1.33 kg/kg
		3.	Sodium meta peraodate	3.06 kg/kg
		4.	Tetrahydrofuran	2.50 kg/kg
		5.	Trimethyl silyl chloride	0.100 kg/kg
		6.	Ethyl bromo difluoro acetate	1.51 kg/kg
		7.	Trifluoro acetic acid	0.400 kg/kg
		8.	Dimethyl amino pyridine	0.125 kg/kg
		9.	Methylene chloride	3.64 kg/kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.B-12	M/S SMS Pharmaceuticals Ltd			
Norms Committee Meeting No.2/09	F.No.01/83/162/425/AM07			
Meeting Date:08.04.2008	RLA F.No.09/24/40/377/AM06			
Adv.Lic.No.0910025027 dated 28.11.2005				
Committee considered case as per agenda for revision of norms for export product (D-erythro.d-threo)-2-Deoxy-2,2-difluoro pentafuramos-1-ulose-3,5 dibenzoate para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/15/2006-PI-III dated 24.03.2008 decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(D-erythro.d-threo)-2-Deoxy-2,2-difluoro pentafuranos-1-ulose-3,5 dibenzoate	1kg.	1.	2,2 Dimethoxy Propane	3.34 kg/kg
		2.	Dimethyl sulfoxide	1.33 kg/kg
		3.	Sodium meta peroate	3.06 kg/kg
		4.	Tetrahydrofuran	2.50 kg/kg

		5.	Trimethyl silyl chloride	0.100 kg/kg
		6.	Ethyl bromo difluoro acetate	1.51 kg/kg
		7.	Trifluoro acetic acid	0.400 kg/kg
		8.	Dimethyl amino pyridine	0.125 kg/kg
		9.	Methylene chloride	3.64 kg/kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.B-13	M/S Vasudha Pharma Ltd.
Norms Committee Meeting No.2/09	F.No.01/83/50/1097/AM07
Meeting Date:08.04.2008	RLA F.No.09/24/40/209/AM08
Adv.Lic.No.0910031382 dated 03.09.2007	

Committee considered case as per agenda for revision 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.35011/94/2007-PI-III dated 31.03.2008 decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Amitriptyline crude	1 Kg.	1.	Pthalic Anhydride	0.823 kg/kg
		2.	Toluene	1.49 kg/kg
		3.	Methanol	0.423 kg/kg
		4.	Phosphorus Pentaoxide	0.396 kg/kg
		5.	Phosphoric Acid	0.297 kg/kg
		6.	Tetrahydrofuran	0.477 kg/kg
		7.	1-bromo-3 chloropropane	0.648 kg/kg
		8.	Carbon	0.043 kg/kg
		9.	Methylene di chloride	0.288 kg/kg
		10.	Acetone	0.072 kg/kg

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

Case No.B-14	M/S Vasudha Pharma Ltd.			
Norms Committee Meeting No.2/09	F.No.01/83/50/1098/AM08			
Meeting Date:08.04.2008	RLA F.No.09/24/40/226/AM08			
Adv.Lic.No.0910031383 dated 03.09.2007				
Committee considered case as per agenda for revision of norms for export product Dibenzosuberone para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 31.03.2008 decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Dibenzosuberone	1 Kg.	1.	Pthalic Anhydride	1.17 kg/kg
		2.	Methanol	0.627 kg/kg
		3.	Toluene	0.503 kg/kg
		4.	Phosphorus Pentaoxide	0.758 kg/kg
		5.	Phosphoric Acid	0.523 kg/kg
		6.	Tetrahydrofuran	0.250 kg/kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.B-15	M/S Smilax Laboratories Ltd.
Norms Committee Meeting No.2/09	F.No.01/83/50/1203/AM07
Meeting Date:08.04.2008	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-iH-BenzimidaZole under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/97/2007-PI-III dated 31.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
5-[[4-Methoxy-3,5-Dimethyl-2 pyridinyl] methyl]thio-iH-Benzimidazole (Omeprazole sulphide)	1 Kg.	1.	3,5 Lutidine	1.456 kg/kg
		2.	Hydrogen peroxide	1.26 kg/kg
		3.	Methanol	2.16 kg/kg
		4.	Ammonium Persulphate	2.00 kg/kg
		5.	2-Mercapto-5-Methoxy Benzimidazole	0.70 kg/kg
		6.	Thionyl chloride	0.75 kg/kg
		7.	Toluene	3.45 kg/kg

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

Case No.B-16	M/S Smilax Laboratories Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/10/AM08
Meeting Date:08.04.2008	RLA F.No.09/24/40/555/AM07
Adv.Lic.No.0910029933 dated 10.01.2007	

Committee considered case as per agenda for ratification of norms for export product 2-Chloro methyl-3-methyl-4-(2,2,2-trifluoro ethoxy) pyridine Hcl (Lansoprazole-Chloro intermediate) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/97/2007-PI-III dated 31.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
2-chloro methyl-3-methyl-4-(2,2,2-trifluoroethoxy)pyridine Hcl (Lansoprazole-chloro intermediate)	1 Kg.	1.	2,3-Lutidine	0.79 kg/kg
		2.	Hydrogen Peroxide	1.25 kg/kg
		3.	Methylene Dichloride	1.68 kg/kg
		4.	Isopropyl alcohol	0.18 kg/kg
		5.	2,2,2 Trifluoro Ethanol	0.936 kg/kg
		6.	Potassium Carbonate	0.96 kg/kg
		7.	Methyl Isobutyl Keton	0.38 kg/kg
		8.	Toluene	0.80 kg/kg

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

Case No.B-17	M/S Shalina Laboratories Pvt. Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/146/AM08
Meeting Date:08.04.2008	RLA F.No.03/95/40/277/AM08
Adv.Lic.No.0310437531 dated 26.07.2007	
Committee considered case as per agenda for revision of norms for export product Epiderm Lotion 30ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that quantity of inputs has already been allowed correctly and hence there is no scope for enhancement in the quantity of inputs. Committee, accordingly decided to maintain status quo.	

Case No.B-18	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/1484/AM06
Meeting Date:08.04.2008	RLA F.No.03/94/40/1347/AM06
Adv.Lic.No.0310372003 dated 17.03.2006	

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

Committee decided to defer case for four weeks for comments of PI Division.

Case No.B-19	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/162/285/AM08
Meeting Date:08.04.2008	RLA F.No.03/24/40/1485/AM05
Adv.Lic.No.0310295800 dated 07.10.2004	
Committee considered case as per agenda for ratification of norms for export product Cilazapril under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-20	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/1159/AM05
Meeting Date:08.04.2008	RLA F.No.03/24/40/1482/AM05
Adv.Lic.No.0310295800 dated 07.10.2004	
Committee considered case as per agenda for ratification of norms for export product Cilazapril under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-21	M/S Advy Chemical
Norms Committee Meeting No.2/09	F.No.01/87/50/313/AM07
Meeting Date:08.04.2008	RLA F.No.03/94/40/310/AM07

Committee considered case as per agenda for ratification of norms for export product HBsAG Subtypes ad Reagent (4000mgs) (Hepatitis B Surface Antigen-Subtypes ad) under para 4.7 of HBP.

Committee in light of written comments forwarded by Department of Bio-technology vide their O.M. No.BT/IL/05/231/06/2006-PID dated 03.04.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
HBsAg Subtypes and Reagent (4000mgs) (Hepatitis-B surface antigen-subtypes ad)	1000 mg (1gm)	1.	Hepatitis B Positive Plasma	100,000 m (100 ltrs) (200ml bag X 50)/1000mg (1 gm)
		2.	Trizma base	24kg/1000 mg (1 gm)
		3.	Sucrose	10 kg/1000mg (1 gm)
		4.	Dextran Sulphate	125 gm/1000mg (1 gm)
		5.	Polyethylene Glycol	18 kg/1000 mg (1 gm)

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

Case No.B-22	M/S Shalina Laboratories Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/288/AM08
Meeting Date:08.04.2008	RLA F.No.03/95/40/841/AM08
Adv.Lic.No.0310452338 dated 03.12.2007	

Committee considered case as per agenda for revision of norms for export product Diproson Lotion 30ml under para 4.7 of HBP.

Representative of PI Division present in meeting informed Committee that quantity of inputs has already been allowed correctly and hence there is no scope for enhancement in the quantity of inputs. Committee, accordingly decided to maintain status quo.

Case No.B-23	M/S Shalina Laboratories Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/31/AM08
Meeting Date:08.04.2008	RLA F.No.03/95/40/95/AM08
Adv.Lic.No.0310428999 dated 10.05.2007	
Committee considered case as per agenda for revision of norms for export product Diprosol Lotion under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that quantity of inputs has already been allowed correctly and hence there is no scope for enhancement in the quantity of inputs. Committee, accordingly decided to maintain status quo.	

Case No.B-24	M/S Shalina Laboratories Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/186/AM08
Meeting Date:08.04.2008	RLA F.No.03/95/40/574/AM08
Adv.Lic.No.0310444049 dated 24.09.2007	
Committee considered case as per agenda for revision of norms for export product Diprosol Lotion under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that quantity of inputs has already been allowed correctly and hence there is no scope for enhancement in the quantity of inputs. Committee, accordingly decided to maintain status quo.	

Case No.A-18	M/S Cipla Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/274/AM08

Meeting Date:08.04.2008		RLA F.No.03/94/40/895/AM08		
Adv.Lic.No.0310451841 dated 28.11.2007				
Committee considered case as per agenda for ratification of norms for export product Efavir Capsule 200mg/Efavirenz 200mg Capsules and Efavir 600mg Tablets/Efavirenz 600mg Tablets under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export Product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Efavirenz Capsules 200mg [Efavirenz 204 mg/Capsule]	1No.	1.	(S)-5-chloro-alpha-(cyclopropyl ethyl)-2-amino-alpha-(trifluoro methyl) benzene methanol	1.092 kg/kg of Efavirenz
Efavirenz Tablets 600mg [Efavirenz 612 mg/tablet]	1 No.			
RA concerned may take further necessary action as per above decision of NC.				

Case No.A-19	M/S Bal Pharma Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/333/AM08
Meeting Date:08.04.2008	RLA F.No.07/24/40/721/AM08
Adv.Lic.No.0710055464 dated 16.01.2008	
Committee considered case as per agenda for ratification of norms for export product Amiloride Hcl under para 4.7 of HBP.	

Committee decided to defer case for four weeks for comments of PI Division.

Case No.A-20	M/S Bal Pharma Ltd.
Norms Committee Meeting No.2/09	F.No.01/82/50/277/AM08
Meeting Date:08.04.2008	RLA F.No.07/24/40/617/AM08
Adv.Lic.No.0710054687 dated 28.11.2007	
Committee considered case as per agenda for ratification of norms for export product Amiloride Hcl under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-21	M/s Codexis Laboratories (I) Ltd
M.No.2/09	F.No.01/82/50/332/AM 08
Meeting Date 08.04.2008	RLA F. No. 05/24/40/725/AM08
Adv. Lic. No. 0510214137 dt. 28.12 .2007	

The Committee considered the case as per agenda for ratification of norms for the export product (4R-CIS)-1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1-3-Dioxane –4-Acetate(Pharma Grade)NLT99% under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/20/2007-PI-III dated 24.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl ®-4-cyno-3-Hydroxy Butanoate	1.00 kg/kg
		2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg
		3.	Tertiary Butyl Acetate	2.11 kg/kg
		4.	Tetra Hydro Furan	5.63 kg/kg
		5.	2,2-Dimethoxy propane	2.79 kg/kg
		6.	Ketroreducate YDH/KRED	0.013 kg/kg
		7.	Glucose Dehydrogenase Enzyme GDH	0.0045 kg/kg
		8.	B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)	0.90 gm/kg

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

Case No.A-22	M/s Aarti Drugs Ltd.
M.No.2/09	F.No.01/82/50/341/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/753/AM08
Adv. Lic. No. 0310455126 dated 26.12.2007	

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

Committee decided to defer case for four weeks for comments of PI Division.

Case No.A-23	M/S Global Calcium Pvt. Ltd.
M.No.2/09	F.No.01/83/162/1033/AM 08
Meeting Date 08.04.2008	RLA F. No. 07/24/40/53/AM08
Adv. Lic. No. 0710051439 dated 26.04.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Calcium Gluconate Injectable Grade, Calcium Lactate Gluconate, Calcium Glubionate and Calcium Borogluconate under para 4.7 of HBP. Committee decided to defer case for three weeks for comments of Chemical Division.	

Case No.A-24	M/s Gland Pharma Ltd.			
M.No.2/09	F.No.01/82/50/254/AM 08			
Meeting Date 08.04.2008	RLA F. No. 09/24/40/314/AM08			
Adv. Lic. No. 0910031800 dated 16.10.2007				
The Committee considered the case as per agenda for ratification of norms for the export product Adenosine Injection USP Prefilled Syringe 3mg/ml, 2ml in a PFS under para 4.7 of HBP.				
Committee perused written comments forwarded by PI Division vide their U.O. No.35011/2007/2006-PI-III dated 08.04.2008 as per details below:-				
Export product	Export Qty.	Sl.No.	Import items	Qty. recommended per unit of export product
Adenosine Injection USP prefilled syringes	1 unit of 2ml PFS	1.	Adenosine	0.0066 gm/unit
		2.	Glass barrel syringes	1.25 Nos./unit
		3.	V-OVS 10.6 tip caps	1.25 Nos./unit
		4.	Plunger stoppers	1.25 Nos./unit

2ml in a PFS		5.	Plunger Rods	1.10 Nos./unit
		6.	Filter	0.00025 Nos./unit
		7.	Tubing	0.00025 Nos./unit
		8.	Reference standard	0.00010 Nos./unit
Adenosine Injection USP prefilled syringes 4ml in PFS	1 unit of 4ml PFS	1.	Adenosine	0.0132 gm/unit
		2.	Glass barrel syringes	1.25 Nos./unit
		3.	V-OVS 10.6 tip caps	1.25 Nos./unit
		4.	Plunger stoppers	1.25 Nos./unit
		5.	Plunger Rods	1.10 Nos./unit
		6.	Filter	0.00025 Nos./unit
		7.	Tubing	0.00050 Nos./unit
		8.	Reference standard	0.00020 Nos./unit

Committee decided to call for production and consumption data duly certified by Central Excise Authority and to verify the above norms with the Central Excise Data on file. Accordingly, case was deferred for six weeks.

Case No.A-25	M/S Global Calcium Pvt. Ltd.
M.No.2/09	F.No.01/83/50/1077/AM 08
Meeting Date 08.04.2008	RLA F. No. 07/24/40/861/AM07
Adv. Lic. No. 0710051390 dated 24.04.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Zinc Gluconate, Magnesium Gluconate, Potassium Gluconate, Ferrous Gluconate, Manganese Gluconate, Calcium Magnesium Lactate Gluconate, Magnesium Lactate Gluconate, Cobalt Gluconate and Copper Gluconate under para 4.7 of HBP.

Committee decided to defer case for three weeks for comments of Chemical Division.

Case No.A-26	M/S Emami Ltd.
M.No.2/09	F.No.01/83/162/1069/AM 08
Meeting Date 08.04.2008	RLA F. No. 02/24/40/183/AM08
Adv. Lic. No. 0210106154 dated 19.11.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Himani (Fast Relief) Pain Relief Ointment (HFRO) under para 4.7 of HBP. Committee observed that Drug Manufacturing Licence submitted by firm has been issued from Directorate of ISM Drug Control, Kolkata. Committee, therefore, decided to seek the comments from Department Ayush/DC(MSME). Accordingly, case was deferred for four weeks.	

Case No.A-27	M/S Arch Pharma Labs Ltd.
M.No.2/09	F.No.01/82/50/269/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/713/AM08
Adv. Lic. No. 0310451128 dated 22.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product (1'R,2'S,5'R)-Methyl-5S-(Cytosine-1-YL)-1,3-Oxathiolane-2R-Carboxylate under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 07.04.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(1'R,2'S,5'R)-Methyl-5S-(Cytosine-1-YL)-1,3-Oxathiolane-2R-Carboxylate	1kg.	1.	Menthol	0.81 kg/kg
		2.	2,5-Dihydroxy-1,4-Diethane	0.348 kg/kg
		3.	Cytosine	0.455 kg/kg
		4.	Cyclohexane	1.535 kg/kg
		5.	Toluene	3.023 kg/kg
		6.	N-Hexane	3.728 kg/kg
		7.	Ethyl Acetate	0.920 kg/kg

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

Case No.A-28	M/s Cipla Ltd.
M.No.2/09	F.No.01/82/50/251/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/747/AM08
Adv. Lic. No. 0310447486 dated 23.10.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200mg Tablets/Nevirapine 200mg tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune (per pack 100mg) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Nevirapine 200mg tablet [Nevirapine 204 mg/tablet]	1 No.	1.	3-(2-Chloro-3-pyridine-carbonyl)-amino-2-chloro-4-methyl pyridine/(NVP(II) compound)	1.428 kg/kg of Nevirapine
		2.	Cyclopropylamine	0.57 kg/kg of Nevirapine
Nevirapine Oral solution 50 mg/5ml, 100ml bottle [Nevirapine 1020 mg/100 ml bottle]	1 No.	3.	Diglyme	2.76 kg/kg of Nevirapine

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

Case No.A-29	M/s Cipla Ltd.
M.No.2/09	F.No.01/82/50/160/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/524/AM08
Adv. Lic. No. 0310440273 dated 21.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Irinotecan Hydrochloride Injection 40mg/2ml and Irinotecan Hydrochloride Injection 100mg/5ml under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.	

Case No.A-30	M/S Cipla Ltd.
M.No.2/09	F.No.01/82/50/255/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/798/AM08
Adv. Lic. No. 0310448930 dated 02.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Lamivir 150mg Tablets/Lamivudine Tablets 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets/Lamivudine and Stavudine Tablets, Lamivir S Baby Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 100mh/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamivudine, Zidovudine and Nevirapine Tablets/Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Lamivudine 150mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	1.	(1'R,2'S,5'R)- Menthyl-5S- (Cytosine-1''- YL)-1,3Oxathiolane- 2R- carboxylate/CME compound	2.19 kg/kg of Lamivudine
Lamivudine 150mg + Stavudine 30mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Stavudine 40mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	2.	Sodium Borohydride	0.48 kg/kg of Lamivudine
Lamivudine 60mg + Stavudine 12mg tablet [Lamivudine 61.2 mg/tablet]	1 No.			
Lamivudine 30mg + Stavudine 3mg Tables	1 No.			

[Lamivudine 30.6 mg/tablet				
Lamivudine 100mg tablet [Lamivudine 102.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg + Nevirapine 200mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Triomune 30/Lamivudine, Stavudine and Nevirapine Tablet [DML not given] Hence not allowed.	1 No.		Not allowed	
RA concerned may take further necessary action as per above decision of NC.				

Case No.A-31	M/S Cipla Ltd.
M.No.2/09	F.No.01/82/50/152/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/437/AM08
Adv. Lic. No. 0310437618 dated 27.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Triomune30/Lamivudine, Stavudine and Nevirapine Tablets and Triomune 40/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee decided to call for a copy of Drug Manufacturing Licence from firm. Accordingly, case was deferred for six weeks.	

Case No.A-32	M/S Cipla Ltd.
M.No.2/09	F.No.01/82/50/153/AM 08

Meeting Date 08.04.2008		RLA F. No. 03/94/40/485/AM08		
Adv. Lic. No. 0310439033 dated 09.08.2007				
The Committee considered the case as per agenda for ratification of norms for the export product Gemcitabine Okasa Pharma (Gemcicross) 1g Injection/Gemcitabine Hydrochloride Injection 1000mg/Oncogem 100mg Injection and Gemcitabnine 200mg Injection/Gemcitabine Hydrochloride Injection 200mg/Oncogem 200 Injection under para 4.7 of HBP.				
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export Product	Export Qty.	Sl.No.	Import items	Quantity allowed per unit of export product
Gemcitabine 1 gm. Injection, 50ml Vial [Gencitanine Hcl 1.05 gm/Vial]	1 No.	1.	2-Deoxy-3,5-Dibenzoyl-2,2-Difluoro-D-Erythropento Furano-1-Ulose	8.10 kg/kg of Gencitabine Hcl
		2.	Sodium Dihydro Bil (2-Methoxy Ethoxy Aluminate-70% Active in Toluene) [Vitrade]	3.05 kg/kg of Gemcitabine Hcl
		3.	Tetrahydrofuran	14.175 kg/kg of Gemcitabine Hcl
Gemcitabine 200 mg Injection, 10 ml Vial [Gemcitabine Hcl 210 mg/Vial]	1 No.	4.	4-amino 2-hydroxypyrimidine [Cytosine]	5.10 kg/kg of Gemcitabine Hcl
RA concerned may take further necessary action as per above decision of NC.				

Case No.A-33	M/S Cipla Ltd.

M.No.2/09	F.No.01/82/50/213/AM 08			
Meeting Date 08.04.2008	RLA F. No. 03/94/40/534/AM08			
Adv. Lic. No. 0310440647 dated 23.08.2007				
The Committee considered the case as per agenda for ratification of norms for the export product Efavir Capsule 200mg/Efavirenz 200mg Capsules and Efavir 600mg Tablets/Efavirenz 600 mg tahlets under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export Product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Efavirenz Capsules 200mg [Efavirenz 204 mg/Capsule]	1No.	1.	(S)-5-chloro-alpha-(cyclopropyl ethyl)-2-amino-alpha-(trifluoro methyl) benzene methanol	1.092 kg/kg of Efavirenz
Efavirenz Tablets 600mg [Efavirenz 612 mg/tablet]	1 No.			
RA concerned may take further necessary action as per above decision of NC.				

Case No.A-34	M/S Cipla Ltd.
M.No.2/09	F.No.01/82/50/250/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/749/AM08
Adv. Lic. No. 0310447493 dated 23.10.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lamivir 150mg Tablets/Lamivudine Tablets 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets/Lamivudine and Stavudine Tablets, Lamivir S Baby Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 100mh/Lamivudine 100mg Tablets, Lamivudine and Zidovudine	

Tablets/Duovir/Bivir, Lamivudine, Zidovudine and Nevirapine Tablets/Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Lamivudine 150mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	1.	(1'R,2'S,5'R)- Menthyl-5S- (Cytosine-1''- YL)-1,3Oxathiolane- 2R-carboxylate/CME compound	2.19 kg/kg of Lamivudine
Lamivudine 150mg + Stavudine 30mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Stavudine 40mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	2.	Sodium Borohydride	0.48 kg/kg of Lamivudine
Lamivudine 60mg + Stavudine 12mg tablet [Lamivudine 61.2 mg/tablet]	1 No.			
Lamivudine 30mg + Stavudine 3mg tablets [Lamivudine 30.6mg/tablet]				
Lamivudine 100mg tablet [Lamivudine 102.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg + Nevirapine 200mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Triomune 30/Lamivudine, Stavudine and Nevirapine Tablet	1 No.			
			Not allowed	

[DML not given. Hence not allowed.]

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

Case No.A-35	M/S Cipla Ltd.
M.No.2/09	F.No.01/82/50/215/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/621/AM08
Adv. Lic. No. 0310443538 dated 18.09.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Lamivir 150mg Tablets/Lamivudine Tablets 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets/Lamivudine and Stavudine Tablets, Lamivir S Baby Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 100mh/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamivudine, Zidovudine and Nevirapine Tablets/Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Lamivudine 150mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	1.	(1'R,2'S,5'R)- Menthyl-5S- (Cytosine-1''- YL)-1,3Oxathiolane- 2R- carboxylate/CME compound	2.19 kg/kg of Lamivudine
Lamivudine 150mg + Stavudine 30mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Stavudine 40mg tablet [Lamivudine 153.0 mg/tablet]	1 No.	2.	Sodium Borohydride	0.48 kg/kg of Lamivudine
Lamivudine 60mg + Stavudine 12mg	1 No.			

tablet [Lamivudine 61.2 mg/tablet]				
Lamivudine 30mg + Stavudine 3mg tablets [Lamivudine 30.6 mg/tablet]				
Lamivudine 100mg tablet [Lamivudine 102.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg tablet [Lamivudine 153.0 mg/tablet]	1 No.			
Lamivudine 150mg + Zidovudine 300mg + Nevirapine 200mg tablet [Lamivudine 153.0 mg/tablet]	1 No.		Not allowed	
Triomune 30/Lamivudine, Stavudine and Nevirapine Tablet [DML not given. Hence not allowed]	1 No.			
RA concerned may take further necessary action as per above decision of NC.				

Case No.A-36	M/S Cadila Healthcare Ltd.			
M.No.2/09	F.No.01/82/50/278/AM 08			
Meeting Date 08.04.2008	RLA F. No. 08/24/40/203/AM08			
Adv. Lic. No. 0810068702 dated 28.11.2007				
The Committee considered the case as per agenda for ratification of norms for the export product Warfarin 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg,, 7.5mg and 10mg tablets under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/73/2007-PI-III dated 17.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product	Export Qty.	Sl.No.	Items of import	Qty. allowed per unit of export product
Warfarin tablets 1	1 million	1.	Warfarin Sodium Clathrate	1.09 kg/million

mg.			USP	tablets
		2.	Hydroxypropyl Cellulose	3.67 kg/million tablets
		3.	Lactose monohydrate	168.08 kg/million tablets
		4.	Magnesium Stearate	1.37 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 2 mg.	1 million	1.	Warfarin Sodium Clathrate USP	2.18 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.66 kg/million tablets
		3.	Lactose monohydrate	167.12 kg/million tablets
		4.	Magnesium Stearate	1.38 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 2.5 mg.	1 million	1.	Warfarin Sodium Clathrate USP	2.725 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.68 kg/million tablets
		3.	Lactose monohydrate	166.98 kg/million tablets
		4.	Magnesium Stearate	1.38 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 3.0	1 million	1.	Warfarin Sodium	3.27 kg/million

mg.			Clathrate USP	tablets
		2.	Hydroxypropyl Cellulose	3.66 kg/million tablets
		3.	Lactose monohydrate	165.53 kg/million tablets
		4.	Magnesium Stearate	1.37 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 4.0 mg.	1 million	1.	Warfarin Sodium Clathrate USP	4.36 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.67 kg/million tablets
		3.	Lactose monohydrate	165.12 kg/million tablets
		4.	Magnesium Stearate	1.38 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 5.0 mg.	1 million	1.	Warfarin Sodium Clathrate USP	5.45 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.67 kg/million tablets
		3.	Lactose monohydrate	159.50 kg/million tablets
		4.	Magnesium Stearate	1.38 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy

Warfarin tablets 6.0 mg.	1 million	1.	Warfarin Sodium Clathrate USP	6.54 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.66 kg/million tablets
		3.	Lactose monohydrate	156.07 kg/million tablets
		4.	Magnesium Stearate	1.37 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 7.5 mg.	1 million	1.	Warfarin Sodium Clathrate USP	8.175 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.66 kg/million tablets
		3.	Lactose monohydrate	156.87 kg/million tablets
		4.	Magnesium Stearate	1.37 kg/million tablets
		5.	Bottle 60CC Bottle 400CC Closure 33mm CR Closure 53mm NCR	As per packing policy
Warfarin tablets 10 mg.	1 million	1.	Warfarin Sodium Clathrate USP	10.90 kg/million tablets
		2.	Hydroxypropyl Cellulose	3.66 kg/million tablets
		3.	Lactose monohydrate	154.67 kg/million tablets
		4.	Magnesium Stearate	1.37 kg/million tablets
		5.	Bottle 60CC Bottle 400CC	As per packing policy

			Closure 33mm CR Closure 53mm NCR	
- RA concerned may take further necessary action as per above decision of NC.				

Case No.A-37	M/S Glenmark Pharmaceuticals Ltd.
M.No.2/09	F.No.01/82/50/267/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/805/AM08
Adv. Lic. No0310450439 dated 16.11.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Cilazapril under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-38	M/S Arch Pharma Labs Ltd.
M.No.2/09	F.No.01/82/50/268/AM 08
Meeting Date 08.04.2008	RLA F. No. 03/94/40/715/AM08
Adv. Lic. No. 0310451131 dated 22.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product (1'R,2'S,5'R)-Methyl-5S-(Cytosine-1#YL)-1,3-Oxathiolane-2R-Carboxylate under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 07.04.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(1'R,2'S,5'R)-Methyl-5S-(Cytosine-1#YL)-1,3-Oxathiolane-2R-Carboxylate	1kg.	1.	Menthol	0.81 kg/kg
		2.	2,5-Dihydroxy-1,4-Diethane	0.348 kg/kg
		3.	Cytosine	0.455 kg/kg
		4.	Cyclohexane	1.535 kg/kg
		5.	Toluene	3.023 kg/kg
		6.	N-Hexane	3.728 kg/kg
		7.	Ethyl Acetate	0.920 kg/kg

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

Case No.C-6	M/S Benzo Chem Industries Pvt. Ltd.
M.No.2/09	F.No.01/83/162/901/AM 08
Meeting Date 08.04.2008	
The Committee considered the case as per agenda for modification of SION for export product 'Para Chloro Phenyl Acetic Acid A-2468. Committee observed that firm has not produced export product by this route in the past and it is premature to fix SION. It was, therefore, decided to close the case.	

Case No.C-7	M/S Amsal Chem Pvt. Ltd.
M.No.2/09	F.No.01/87/50/456/AM08
Meeting Date 08.04.2008	

The Committee considered the case as per agenda for modification of DEPB Sl.No.55.

Committee observed that firm was requested to furnish Central Excise Data and Pharmexcil was requested to furnish All Industry Data vide letter dated 22.01.2008, but no reply has been received. Committee, therefore, decided to close the case.

1	Case No.:31/21/82-ALC4/2007	Party Name:KUMAR ORGANIC PRODUCTS LIMITED,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Rejected
	HQ File :01/82/050/00057/AM06/	RLA File :07/24/040/00013/AM06/	Lic.No/Date:0710037427 21.04.2005	
	Decision :Committee considered case as per agenda for ratification of norms for export product Minoxidil under para 4.7 of HBP. Committee observed that RA/firm was requested to furnish application vide letter dated 05.03.2008, but application has not been received. Committee, therefore, decided o close the case. RA concerned may take further necessary action as per above decision of NC.			

2	Case No.:135/24/87-ALC1/2007	Party Name:SUDEEP PHARMA LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved									
	HQ File :01/87/050/00174/AM06/	RLA File :34/24/040/00021/AM06/	Lic.No/Date:3410013421 18.05.2005										
	Decision : Committee considered case as per agenda for ratification of norms for export product Di Calcium Phosphate Anhydrous USP or Di Calcium Phosphate Anhydrous (D.C.) under para 4.7 of HBP. Committee in light of written comments forwarded by Chemical Division vide their U.O. No.14010/24/2004/Ch.III signed on 08.04.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>Di Calcium Phosphate Anhydrous</td><td>1kg.</td><td>1.</td><td>Phosphoric Acid 85%</td><td>0.890 kg/kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	Di Calcium Phosphate Anhydrous	1kg.	1.	Phosphoric Acid 85%
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product									
Di Calcium Phosphate Anhydrous	1kg.	1.	Phosphoric Acid 85%	0.890 kg/kg									

3	Case No.:205/21/82-ALC4/2007	Party Name:IGOR PHARMACHEM LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved
	HQ File :01/82/050/00268/AM06/	RLA File :09/24/040/00086/AM06/	Lic.No/Date:0910023219 21.06.2005	
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-Aminomethyl-7-Chloro-2,3-Dihydro-5-(2-Fluorophenyl)-1H-1,4-Benzodiazepine Dimaleate under para 4.7 of HBP. Committee in consultation with the representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as applied by firm. RA concerned may take further necessary action as per above decision of NC.			

4	Case No.:579/21/82-ALC4/2007	Party Name:KUMAR ORGANIC PRODUCTS LIMITED,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/82/050/01174/AM07/	RLA File :07/24/040/00449/AM07/	Lic.No/Date:0710047985 19.10.2006	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Zinc Pyrithione under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of Chemical Division.			

5	Case No.:1/42/83-ALC1/2006	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved									
	HQ File :01/83/050/00936/AM07/	RLA File :09/24/040/00218/AM07/	Lic.No/Date:0910028286 21.11.2006										
	Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Benzisoxazole-3-methane Sulfonic acid sodium salt 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 08.04.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>1,2-Benzisoxazole-3-</td><td>1kg.</td><td>1.</td><td>4-Hydroxy coumarin</td><td>2.34 kg/kg</td></tr> </tbody> </table>				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	1,2-Benzisoxazole-3-	1kg.	1.	4-Hydroxy coumarin
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product									
1,2-Benzisoxazole-3-	1kg.	1.	4-Hydroxy coumarin	2.34 kg/kg									

	methane sulfonic acid Sodium Salt	2.	Hydroxylamine hcl	1.00 kg/kg
		3.	Bromine	1.73 kg/kg
		4.	Dichloro methane	0.87 kg/kg
		5.	IPA	1.00 kg/kg
		6.	Sodium sulphite	1.01 kg/kg
		7.	Pyridine	1.765 kg/kg
		8.	Methanol	3.28 kg/kg
		RA concerned may take further necessary action as per above decision of NC.		

6	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status: Case Withdrawn
	HQ File :01/82/050/01441/AM07/	RLA File :09/24/040/00390/AM07/	Lic.No/Date:0910028634 13.12.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-Lysine-Praline (Lyspro(Isolated))under para 4.7 of HBP. Committee decided to withdraw case as case has already been approved in its 1/09 meeting held on 01.04.2008.			

7	Case No.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status: Case Deferred
	HQ File :01/82/050/01804/AM07/	RLA File :03/94/040/01443/AM07/	Lic.No/Date:0310422972 13.03.2007	Defer Date: 21.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Triomune 30/Lamivudine, Stavudine and nevirapine Tablets and Triomune 40/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee decided to call for a copy of Drug Manufacturing Licence from firm. Accordingly, case was deferred for six weeks.			

8	Case No.:665/24/83-ALC1/2007	Party Name:SIBRA PHARMACEUTICALS LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00497/AM08/	RLA File :09/24/040/00370/AM07/	Lic.No/Date:0910030503 11.06.2007	Defer Date: 21.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product (1R,2S,5R)-Methyl-5(S)-Cytosin-1,YL-1,3-Oxathiolane-2R-Carboxylate under para 4.7 of HBP.			

Committee decided to defer case for six weeks for comments of PI Division.

9	Case No.:670/24/83-ALC1/2007	Party Name:ISHITA DRUGS & INDUSTRIES LTD	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00503/AM08/	RLA File :08/24/040/00049/AM08/	Lic.No/Date:0810065340 12.06.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Sulfanilamide under para 4.7 of HBP. Committee decided to forward a copy of application to Chemical Division for their comments. Accordingly, case was deferred for four weeks.			

10	Case No.:682/24/83-ALC1/2007	Party Name:SALICYLATES & CHEMICALS P.LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00526/AM08/	RLA File :09/24/040/00074/AM08/	Lic.No/Date:0910030570 15.06.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Saligerm G-2 under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of Chemical Division.			

11	Case No.:82/19/83-ALC1/2007	Party Name:PUNJAB CHEMICALS AND CROP PROTECTION LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00641/AM08/	RLA File :03/95/040/00229/AM08/	Lic.No/Date:0310433835 25.06.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 3,5-Di Methoxy-4-Hydroxy Benzamide (Syringamide) under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of Chemical Division.			

12	Case No.:730/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Withdrawn
	HQ File :01/83/050/00623/AM08/	RLA File :09/24/040/00120/AM08/	Lic.No/Date:0910030686 29.06.2007	
	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.			

Committee decided to withdraw case as case has already been approved in its 1/09 meeting held on 01.04.2008.

13	Case No.:755/24/83-ALC1/2007	Party Name:VIVIMED LABS LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00685/AM08/	RLA File :09/24/040/00111/AM08/	Lic.No/Date:0910030800 06.07.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Octyne-B/Octocrylene/2-Ethylhexyl-2-Cyano-3,3-Diphenylacrylate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of Chemical Division.			

14	Case No.:784/24/83-ALC1/2007	Party Name:KAIVAL CHEMICALS P LTD	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00733/AM08/	RLA File :34/24/040/00073/AM08/	Lic.No/Date:3410019192 13.07.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product L(-)-Di-P-Toluoyl Tartaric Acid under para 4.7 of HBP. Committee decided to forward a copy of application to Chemical Division for their comments. Accordingly, case was deferred for four weeks.			

15	Case No.:920/24/83-ALC1/2007	Party Name:METROPOLITAN OVERSEAS LIMITED,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/00933/AM08/	RLA File :03/95/040/00301/AM08/	Lic.No/Date:0310438008 01.08.2007	Defer Date: 21.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product N-[1-(S)-Ethoxy Carbonyl-3-Phenyl Propyl]-L-Alanine (ECPP-Alanina Ale) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/193/2006-PI-III dated 08.04.2008 observed that norms applied by firm are not as per the chemistry furnished by them. Committee, therefore, decided to call for technical justification along with calculations for working out the quantative requirement from firm. Accordingly, case was deferred for six weeks.			

16	Case No.:12/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status: Case Withdrawn
	HQ File :01/83/050/01086/AM08/	RLA File :03/94/040/00555/AM08/	Lic.No/Date:0310441561	:

31.08.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Saquinavir 200mg Capsules/Saquivir 200mg Capsules under para 4.7 of HBP.

Committee decided to withdraw case as case has already been approved in its 1/09 meeting held on 01.04.2008.

17	Case No.:54/27/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01128/AM08/	RLA File :03/94/040/00525/AM08/	Lic.No/Date:0310441978 06.09.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

18	Case No.:69/27/83-ALC1/2007	Party Name:CODEXIS LABORATORIES INDIA PVT.LTD,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved																											
	HQ File :01/83/050/01143/AM08/	RLA File :05/24/040/00396/AM08/	Lic.No/Date:0510208776 10.09.2007																												
	Decision : Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1,1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1-3-Dioxane-4-Acetate (ATS-8) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/20/2007-PI-III dated 24.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="7">(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)</td><td rowspan="7">1kg.</td><td>1.</td><td>Ethyl [®]-4-cyno-3-Hydroxy Butanoate</td><td>1.00 kg/kg</td></tr> <tr> <td>2.</td><td>N-Butyl Lithium (15% in Hexane)</td><td>1.90 kg/kg</td></tr> <tr> <td>3.</td><td>Tertiary Butyl Acetate</td><td>2.11 kg/kg</td></tr> <tr> <td>4.</td><td>Tetra Hydro Furan</td><td>5.63 kg/kg</td></tr> <tr> <td>5.</td><td>2,2-Dimethoxy propane</td><td>2.79 kg/kg</td></tr> <tr> <td>6.</td><td>Ketoreductase YDH/KRED</td><td>0.013 kg/kg</td></tr> <tr> <td>7.</td><td>Glucose Dehydrogenase</td><td>0.0045 kg/kg</td></tr> </tbody> </table>				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl [®] -4-cyno-3-Hydroxy Butanoate	1.00 kg/kg	2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg	3.	Tertiary Butyl Acetate	2.11 kg/kg	4.	Tetra Hydro Furan	5.63 kg/kg	5.	2,2-Dimethoxy propane	2.79 kg/kg	6.	Ketoreductase YDH/KRED	0.013 kg/kg	7.	Glucose Dehydrogenase
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product																											
(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl [®] -4-cyno-3-Hydroxy Butanoate	1.00 kg/kg																											
		2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg																											
		3.	Tertiary Butyl Acetate	2.11 kg/kg																											
		4.	Tetra Hydro Furan	5.63 kg/kg																											
		5.	2,2-Dimethoxy propane	2.79 kg/kg																											
		6.	Ketoreductase YDH/KRED	0.013 kg/kg																											
		7.	Glucose Dehydrogenase	0.0045 kg/kg																											

			Enzyme GDH	
		8.	B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)	0.90 gm/kg
RA concerned may take further necessary action as per above decision of NC.				

19	Case No.:10/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Withdrawn
	HQ File :01/82/050/00180/AM08/	RLA File :03/94/040/00615/AM08/	Lic.No/Date:0310442878 12.09.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP. Committee decided to withdraw case as case has already been approved in its 1/09 meeting held on 01.04.2008.			

20	Case No.:2/25/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved													
	HQ File :01/82/050/00196/AM08/	RLA File :03/94/040/00664/AM08/	Lic.No/Date:0310445042 03.10.2007														
	Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 12.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>Abacavir Sulphate tablets 300mg</td><td rowspan="2">1 No.</td><td>1.</td><td>Triethyl orthoformate</td><td>0.69 kg/kg of Abacavir sulphate</td></tr> <tr> <td>Abacavir sulphate 306mg/tablet</td><td>2.</td><td>Cyclopropylamine</td><td>0.19kg/kg of Abacavir sulphate</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	Abacavir Sulphate tablets 300mg	1 No.	1.	Triethyl orthoformate	0.69 kg/kg of Abacavir sulphate	Abacavir sulphate 306mg/tablet	2.	Cyclopropylamine
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product													
Abacavir Sulphate tablets 300mg	1 No.	1.	Triethyl orthoformate	0.69 kg/kg of Abacavir sulphate													
Abacavir sulphate 306mg/tablet		2.	Cyclopropylamine	0.19kg/kg of Abacavir sulphate													

21	Case No.:7/29/83-ALC1/2007	Party Name:CODEXIS LABORATORIES INDIA PVT.LTD,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved																														
	HQ File :01/83/050/01272/AM08/	RLA File :05/24/040/00518/AM08/	Lic.No/Date:0510209861 03.10.2007																															
	Decision : Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1,1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1-3-Dioxane-4-Acetate (ATS-8) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/20/2007-PI-III dated 24.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="8">(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)</td><td rowspan="8">1kg.</td><td>1.</td><td>Ethyl [®]-4-cyno-3-Hydroxy Butanoate</td><td>1.00 kg/kg</td></tr> <tr> <td>2.</td><td>N-Butyl Lithium (15% in Hexane)</td><td>1.90 kg/kg</td></tr> <tr> <td>3.</td><td>Tertiary Butyl Acetate</td><td>2.11 kg/kg</td></tr> <tr> <td>4.</td><td>Tetra Hydro Furan</td><td>5.63 kg/kg</td></tr> <tr> <td>5.</td><td>2,2-Dimethoxy propane</td><td>2.79 kg/kg</td></tr> <tr> <td>6.</td><td>Ketoreducate YDH/KRED</td><td>0.013 kg/kg</td></tr> <tr> <td>7.</td><td>Glucose Dehydrogenase Enzyme GDH</td><td>0.0045 kg/kg</td></tr> <tr> <td>8.</td><td>B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)</td><td>0.90 gm/kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl [®] -4-cyno-3-Hydroxy Butanoate	1.00 kg/kg	2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg	3.	Tertiary Butyl Acetate	2.11 kg/kg	4.	Tetra Hydro Furan	5.63 kg/kg	5.	2,2-Dimethoxy propane	2.79 kg/kg	6.	Ketoreducate YDH/KRED	0.013 kg/kg	7.	Glucose Dehydrogenase Enzyme GDH	0.0045 kg/kg	8.	B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product																														
(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl [®] -4-cyno-3-Hydroxy Butanoate	1.00 kg/kg																														
		2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg																														
		3.	Tertiary Butyl Acetate	2.11 kg/kg																														
		4.	Tetra Hydro Furan	5.63 kg/kg																														
		5.	2,2-Dimethoxy propane	2.79 kg/kg																														
		6.	Ketoreducate YDH/KRED	0.013 kg/kg																														
		7.	Glucose Dehydrogenase Enzyme GDH	0.0045 kg/kg																														
		8.	B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)	0.90 gm/kg																														

22	Case No.:30/29/83-ALC1/2007	Party Name:OMKAR SPECIALITY CHEMICALS PVT. LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01295/AM08/	RLA File :03/95/040/00611/AM08/	Lic.No/Date:0310445277 05.10.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Benzene Seleninic Anhydride 99.0% purity minimum (on dry basis) under para 4.7 of HBP.			

Committee decided to defer case for four weeks for comments of Chemical Division.

23	Case No.:24/30/83-ALC1/2007	Party Name:AUCTUS PHARMA PRIVATE LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved															
	HQ File :01/83/050/01393/AM08/	RLA File :09/24/040/00319/AM08/	Lic.No/Date:0910031843 23.10.2007																
	Decision : Committee considered case as per agenda for ratification of norms for export product Refaximin under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/123/2007-PI-III dated 24.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="3">Rifaximin</td><td rowspan="3">1kg.</td><td>1.</td><td>Rifamycin-O</td><td>1.52 kg/kg</td></tr> <tr> <td>2.</td><td>2-Amino-4-Picoline</td><td>0.43 kg/kg</td></tr> <tr> <td>3.</td><td>Methanol</td><td>2.56 kg/kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	Rifaximin	1kg.	1.	Rifamycin-O	1.52 kg/kg	2.	2-Amino-4-Picoline	0.43 kg/kg	3.	Methanol
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product															
Rifaximin	1kg.	1.	Rifamycin-O	1.52 kg/kg															
		2.	2-Amino-4-Picoline	0.43 kg/kg															
		3.	Methanol	2.56 kg/kg															

24	Case No.:19/32/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved									
	HQ File :01/83/050/01441/AM08/	RLA File :22/24/040/00046/AM08/	Lic.No/Date:2210007184 25.10.2007										
	Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin Granules 42% (Suspension Grade) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/159/2005-PI-III dated 08.04.2008 and in consultation with representative of PI Division 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:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>Clarithromycin Granules</td><td>1kg.</td><td>1.</td><td>Clarithromycin (OR)</td><td>0.4242 kg/kg</td></tr> </tbody> </table>				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	Clarithromycin Granules	1kg.	1.	Clarithromycin (OR)
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product									
Clarithromycin Granules	1kg.	1.	Clarithromycin (OR)	0.4242 kg/kg									

42% (Suspension Grade)			Its raw material as per SION A-2263 on pro-rata basis	
		2.	Carbopol	0.30 kg/kg
		3.	HPMC Phthalate	0.30 kg/kg
RA concerned may take further necessary action as per above decision of NC.				

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Case No.:20/32/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved
HQ File :01/83/050/01442/AM08/	RLA File :22/24/040/00045/AM08/	Lic.No/Date:2210007185 25.10.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin Granules 27.5% (Suspension Grade) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/159/2005-PI-III dated 08.04.2008 and in consultation with representative of PI Division 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	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Clarithromycin Granules 27.5% (Suspension Grade)	1kg.	1.	Clarithromycin (OR)	0.2777 kg/kg
			Its raw material as per SION A-2263 on pro-rata basis	
		2.	Carbopol	0.20 kg/kg
		3.	HPMC Phthalate	0.54 kg/kg

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

26	Case No.:80/32/83-ALC1/2007	Party Name:CODEXIS LABORATORIES INDIA PVT.LTD,		Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved
	HQ File :01/83/050/01502/AM08/	RLA File :05/24/040/00562/AM08/		Lic.No/Date:0510211568 05.11.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1,1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1-3-Dioxane-4-Acetate (ATS-8) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/20/2007-PI-III dated 24.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
(4-R-Cis)-1,1 dimethyl ethyl-6-cyanomethyl-2,2 dimethyl-1,3-dioxane-4-acetate (ATS 8)	1kg.	1.	Ethyl [®] -4-cyno-3-Hydroxy Butanoate	1.00 kg/kg
		2.	N-Butyl Lithium (15% in Hexane)	1.90 kg/kg
		3.	Tertiary Butyl Acetate	2.11 kg/kg
		4.	Tetra Hydro Furan	5.63 kg/kg
		5.	2,2-Dimethoxy propane	2.79 kg/kg
		6.	Ketoreductase YDH/KRED	0.013 kg/kg
		7.	Glucose Dehydrogenase Enzyme GDH	0.0045 kg/kg
		8.	B-Nicotinamide-adenine dinucleotide phosphate oxidized form, monosodium salt (Enzyme NADP)	0.90 gm/kg

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

27	Case No.:21/33/83-ALC1/2007		Party Name:SHODHANA LABORATORIES LTD.		Meet No/Date:2/82-ALC4/2008 08.04.2008		Status:Case Approved	
	HQ File :01/83/050/01550/AM08/		RLA File :09/24/040/00328/AM08/		Lic.No/Date:0910032054 12.11.2007			
	Decision : Committee considered case as per agenda for ratification of norms for export product 4-(2,3-Epoxy Propoxy) Carbazole under para 4.7 of HBP.							
	Committee in light of its earlier decision taken in its 35/08 meeting held on 01.01.2008 and in consultation with representative of PI Division 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	Export	Sl.No.	Import items	Qty. allowed per			

	Qty.			unit of export product
4-(2,3-Epoxy Propoxy) Carbazole	1kg.	1.	4-Hydroxy Carbazole	1.14 kg/kg
		2.	Epichlorophdrin	2.02kg/kg
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.				

28	Case No.:22/33/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01551/AM08/	RLA File :09/24/040/00332/AM08/	Lic.No/Date:0910032055 12.11.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-(2-Methoxy Phenoxy) Ethylamine under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

29	Case No.:26/33/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved												
	HQ File :01/83/050/01555/AM08/	RLA File :09/24/040/00359/AM08/	Lic.No/Date:0910032060 13.11.2007													
	Decision : Committee considered case as per agenda for ratification of norms for export product 4-(2,3-Epoxy Propoxy) Carbazole under para 4.7 of HBP. Committee in light of its earlier decision taken in its 35/08 meeting held on 01.01.2008 and in consultation with representative of PI Division 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:- <table> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> <tr> <td rowspan="2">4-(2,3-Epoxy Propoxy) Carbazole</td><td rowspan="2">1kg.</td><td>1.</td><td>4-Hydroxy Carbazole</td><td>1.14 kg/kg</td></tr> <tr> <td>2.</td><td>Epichlorophdrin</td><td>2.02kg/kg</td></tr> </table> RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	4-(2,3-Epoxy Propoxy) Carbazole	1kg.	1.	4-Hydroxy Carbazole	1.14 kg/kg	2.	Epichlorophdrin
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product												
4-(2,3-Epoxy Propoxy) Carbazole	1kg.	1.	4-Hydroxy Carbazole	1.14 kg/kg												
		2.	Epichlorophdrin	2.02kg/kg												

30	Case No.:27/33/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01556/AM08/	RLA File :09/24/040/00358/AM08/	Lic.No/Date:0910032061 13.11.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-(2-Methoxy Phenoxy) Ethylamine under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

31	Case No.:1/38/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01563/AM08/	RLA File :04/24/040/00281/AM08/	Lic.No/Date:0410092096 15.11.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product (6-methoxy-1-oxoisindolin-2-yl)methyl pivalate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

32	Case No.:34/39/83-ALC1/2007	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved															
	HQ File :01/83/050/01613/AM08/	RLA File :09/24/040/00385/AM08/	Lic.No/Date:0910032245 28.11.2007																
	Decision : Committee considered case as per agenda for ratification of norms for export product (s)Alpha-Ethyl-2-Oxo-1-Pyrrolidineacetic Acid (LVA-40) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/112/2007-PI-III dated 31.03.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="3">(S) Alpha-ethyl-2-oxo-1-pyrrolidineacetic acid</td><td rowspan="3">1kg.</td><td>1.</td><td>2-Pyrrolidone</td><td>1.41 kg/kg</td></tr> <tr> <td>2.</td><td>Methyl-2-bromobutyrate</td><td>3.00 kg/kg</td></tr> <tr> <td>3.</td><td>®-(+)- alphamethylbenzylamine</td><td>0.474 kg/kg</td></tr> </tbody> </table>				Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product	(S) Alpha-ethyl-2-oxo-1-pyrrolidineacetic acid	1kg.	1.	2-Pyrrolidone	1.41 kg/kg	2.	Methyl-2-bromobutyrate	3.00 kg/kg	3.	®-(+)- alphamethylbenzylamine
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product															
(S) Alpha-ethyl-2-oxo-1-pyrrolidineacetic acid	1kg.	1.	2-Pyrrolidone	1.41 kg/kg															
		2.	Methyl-2-bromobutyrate	3.00 kg/kg															
		3.	®-(+)- alphamethylbenzylamine	0.474 kg/kg															

		4.	Methyl iso butyl ketone	2.11 kg/kg
RA concerned may take further necessary action as per above decision of NC.				

33	Case No.:68/39/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01647/AM08/	RLA File :04/24/040/00289/AM08/	Lic.No/Date:0410092451 30.11.2007	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-Fluoro Adenosin Triacetate (2-FAT) under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

34	Case No.:170/39/83-ALC1/2007	Party Name:MAHAVIR DYE CHEM	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Rejected
	HQ File :01/83/050/01749/AM08/	RLA File :52/24/040/00023/AM08/	Lic.No/Date:5210022614 14.12.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-(3-Aminophenyl Sulfonamide)Naphthalene-6.8-Disulfonic Acid under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.14010/48/2004-Ch.II signed on 08.04.2008 observed that firm has started their manufacturing process from Nitro Benzene and Amino G Acid and import item Beta Napthol is not consumed in the process. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of NC.			

35	Case No.:10/42/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved
	HQ File :01/83/050/01786/AM08/	RLA File :22/24/040/00060/AM08/	Lic.No/Date:2210007348 01.01.2008	
	Decision : Committee considered case as per agenda for ratification of norms for export product Atorvastatin Calcium under para 4.7 of HBP. Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower:-			

Export product	Export Qty.	SL.No.	Import items	Qty. allowed per unit of export product
Atorvastatin Calcium	1kg.	1.	Methyl Isobutyl Acetate	1.76 kg/kg
		2.	Betaalanine	0.100 kg/kg
		3.	3-Ethyl-5-0(2-hydroxyethyl)-4-Methyl Thiozolium Bromide	0.30 kg/kg
		4.	4R-cis)-1,1-dimethyl ethyl-6-cyanomethyl-2, 2-dimethyl-1,3-dioxane-4-acetate(ATS-8)	1.08 kg/kg
		5.	Sodium Metabisulphide	0.037 kg/kg
		6.	Parafluoro benzaldehyde	0.85 Kg/Kg
		7.	IPA	8.375 kg/kg
		8.	Tertiary Butyl Methyl Ether	4.37 kg/kg

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

36	Case No.:12/42/83-ALC1/2007	Party Name:PARABOLIC DRUGS LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/83/050/01788/AM08/	RLA File :22/24/040/00053/AM08/	Lic.No/Date:2210007356 04.01.2008	Defer Date: 21.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 7-AVCA under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

37	Case No.:2/2/82-ALC4/2008	Party Name:DISHMAN PHARMACEUTICALS & CHEMICALS LTD	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Approved
	HQ File :01/82/050/00617/AM08/	RLA File :08/24/040/00277/AM07/	Lic.No/Date:0810069798 24.01.2008	
	Decision : Committee considered case as per agenda for ratification of norms for export product Benzyl Tri Butyl Ammonium Chloride under para 4.7 of HBP.			

Committee in light of written comments forwarded by Chemical Division vide their U.O. No.14010/84/2002-CH-III signed on 08.04.2008 and in consultation with representative of Chemical Division 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	Export Qty.	Sl.No.	Import items	Qty. allowed per unit of export product
Benzyl Tributyl Ammonium Chloride	1kg.	1.	Tributyl Amine	0.693 kg/kg
		2.	Methyl Isobutyl Ketone	0.230 kg/kg
		3.	Methyl Ethyl Ketone	0.380 kg/kg
		4.	Activated Carbon	0.010 kg/kg

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

38	Case No.:1/2/82-ALC4/2008	Party Name:KUDOES CHEMIE LTD.,	Meet No/Date:2/82-ALC4/2008 08.04.2008	Status:Case Deferred
	HQ File :01/82/050/00616/AM08/	RLA File :22/24/040/00080/AM08/	Lic.No/Date:2210007593 20.03.2008	Defer Date: 06.05.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Caffeine under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			