

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

Para 4.7 Decision(DRAFT)

MEETING NUMBER : 38/82-ALC4/2007 MEETING DATE : 22.01.2008

The Meeting No.38/08 for the licensing year 2007-08 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2004-09 pertaining to Pharma Products was held on 23.01.2008 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No.37/08 dated 16.01.2008 was ratified by the Committee.

Case No.B-497	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/162/285/AM08
Meeting Date:22.01.2008	RLA F.No.03/24/40/1482/AM05
Advance Licence No.0310295800 dated 07.10.04	
Committee considered case as per agenda for ratification of norms for export product Cilazapil under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-498	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/1484/AM06
Meeting Date:22.01.2008	RLA F.No.03/94/40/1374/AM06
Advance Licence No.0310372003 dated 17.03.06	
Committee considered case as per agenda for ratification of norms for export product Cilazapil under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-499	M/S Calyx Chemicals & Pharma. Pvt. Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/1369/AM04
Meeting Date:22.01.2008	RLA F.No.03/24/40/2120/AM04

Advance Licence No.0310249192 dated 22.01.04	
Committee considered case as per agenda for allowing additional import item namely Pyrazine 2,3 Dicarboxylic Acid for export of Zopiclone BP/USP under para 4.7 of HBP.	
Committee decided to defer case for two weeks for comments of PI Division.	

Case No.B-500	M/S Glenmark Pharmaceuticals Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/696/AM06		
Meeting Date:22.01.2008	RLA F.No.03/94/40/670/AM06		
Advance Licence No.0310348307 dated 21.09.05			
Committee considered case as per agenda for ratification of norms for export product Ethoxycarbonylamine under para 4.7 of HBP.			
The Committee observed that representation of firm was received on 23.11.2007 and in light of the written comments forwarded by PI Division vide their U.O.No.35011/253/2006-PI-III dated 18.4.2007 and in consultation with representative of PI Division present in meeting decided to ratify Norms on repeat basis under para para 4.7 of HBP as per details below or as applied by the firm whichever is lower:-			
Export product	Export Quantity	Import items	Quantity allowed per unit of export product
Ethoxy Carbonylalanine	1kg.	1. L-Norvaline	1.03kg/kg
		2. 10% Palladium on Carbon	0.100kg/kg
		3. Acetone	4.56kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.B-501	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/162/207/AM08
Meeting Date:22.01.2008	RLA F.No.03/24/40/789/AM04
Advance Licence No.0310217859 dated 11.08.03	

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

Committee in light of the written comments forwarded by PI Division vide their U.O.No.35011/243/2006-PI-III dated 05.12.2006 and in consultation with representative of PI Division 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	Export Quantity	Import items	Quantity allowed per unit of export product
Cilostazol	1kg.	1)5-(4-chlorobutyl)-1-cyclohexyl-1H-Tetrazole	0.88kg/kg
		2)6-Hydroxy-3,4-Dihydro-1H-Quinolin-2-one	0.59kg/kg

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

Case No.B-502	M/S Brawn Laboratories Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/154/AM08		
Meeting Date:22.01.2008	RLA F.No.05/24//40/163/AM08		
Advance Licence No.0510204890 dated 13.06.07			
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 firm has not submitted copy of DML for second export product namely Lincomycin Capsules and therefore, no norms can be ratified in the absence of DML. As regards first item namely Kanamycin Acid Sulphate Inj BP 1gm, Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/162/2006-PI-III dated 23.01.2008 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 Quantity	Import items	Quantity allowed per unit of export product

Kanamycin Acid Sulphate Injection 1gm Vial (ITC(HS) No.30042069)	1 Vial	Kanamycin Acid Sulphate	1.39gm/vial
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RA concerned may take further necessary action as per above decision of Norms Committee.

Case No.B-503	M/S Avignon Exim Pvt. Ltd.
Norms Committee Meeting No.38/08	F.No.01/87/50/1102/AM07
Meeting Date:22.01.2008	RLA F.No.03/94/40/1374/AM07
Advance Licence No.0310422847 dated 13.03.07	
Committee considered case as per agenda for ratification of norms for export product Niacinamide BP/USP under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of MSME.	

Case No.B-504	M/S KDL Biotech Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/1415/AM05		
Meeting Date:22.01.2008	RLA F.No.03/24//40/1364/AM05		
Advance Licence No.0310301988 dated 11.11.04			
Committee considered case as per agenda for ratification of norms for export product Immobilized Pencillin G Amidase Enzyme 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/05/176/2004/PID dated 04.01.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-			
Export product	Export Quantity	Import items	Quantity allowed per unit of export product
Immobilized Penicillin-G-Amidase enzyme	1kg.	1)Yeast Extract	2.456kg/kg
		2)Malic acid	4.001kg/kg
		3)Sodium Hydroxide	0.600kg/kg
		4)Dipotassium	4.500kg/kg

		dihydroden Phosphate (k ₂ HPO ₄)	
		5)Potassium dihydrogen Phosphate ((KH ₂ PO ₄)	1.001kg/kg
		6)Acetic acid	0.015kg/kg
		7)P3 Ultracil	0.500kg/kg
		8)Iso Propyl Alcohol	0.422kg/kg
		9)Glycedyl Methacrylate	0.643kg/kg
		10)Acrylonitrile	0.153kg/kg
		11)Divinyl Benzene	0.429kg/kg
		12)Cyclohexanol	1.521kg/kg
		13)Methanol denine Hemi Sulphate Dihydrate	12.857kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.B-505	M/S Neuland Laboratories Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/246/AM08
Meeting Date:22.01.2008	RLA F.No.09/24//40/307/AM08
Advance Licence No.0910032016 dated 07.11.07	
Committee considered case as per agenda for amendment in the description of import item No.1 under para 4.7 of HBP. Committee in consultation with representative of PI Division present in meeting decided to allow amendment in description of import item No.1 to read as “Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride [(S,S)-2-azabicyclo (3.3.0)octane-3-carboxylic acid benzylester Hydrochloride’]. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-506	M/S Hetero Drugs Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/50/1505/AM08
Meeting Date:22.01.2008	RLA F.No.09/24//40/344/AM08
Advance Licence No.0910031992 dated	

05.11.07	
Committee considered case as per agenda for allowing additional input namely N,N-Carbonyldimidazole under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/87/2007-PI-III dated 23.01.2008 decided to allow additional input as per details below or as applied by firm whichever is lower:- N,N Carbonyl dimidazole-----0.42kg/kg RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-507	M/S Ranbaxy Laboratories Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/608/AM08		
Meeting Date:22.01.2008	RLA F.No.05/24/40/248/AM08		
Advance Licence No.0510205474 dated 27.06.07			
Committee considered case as per agenda for revision of norms for export product Pravastatin Sodium 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 21.01.2008 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 Quantity	Import items	Quantity allowed per unit of export product
Pravastatin Sodium (ITC(HS)No.294200 90)	1kg.	1.Compactin	4.00kg/kg
		2.Anti Form SAG-71	0.050kg/kg
		3.Acetonitrile	19.51kg/kg
		4.Acetone	10.67kg/kg
		5.Activated Carbon	0.100kg/kg
		6.Methanol	2.88kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.B-508	M/S Ranbaxy Laboratories Ltd.
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Norms Committee Meeting No.38/08	F.No.01/83/50/167/AM08		
Meeting Date:22.01.2008	RLA F.No.05/24/40/49/AM08		
Advance Licence No.0510202775 dated 20.04.07			
Committee considered case as per agenda for revision of norms for export product Pravastatin Sodium 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 21.01.2008 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 Quantity	Import items	Quantity allowed per unit of export product
Pravastatin Sodium (ITC(HS)No.294200 90)	1kg.	1.Compactin	4.00kg/kg
		2.Aanti Form SAG-71	0.050kg/kg
		3.Acetonitrile	19.51kg/kg
		4.Acetone	10.67kg/kg
		5.Activated Carbon	0.100kg/kg
		6.Methanol	2.88kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.B-509	M/S Ranbaxy Laboratories Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/617/AM08		
Meeting Date:22.01.2008	RLA F.No.05/24/40/400/AM07		
Advance Licence No.0510189882 dated 31.08.06			
Committee considered case as per agenda for revision of norms for export product Pravastatin Sodium 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 21.01.2008 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 Quantity	Import items	Quantity allowed per unit of

			export product
Pravastatin Sodium (ITC(HS)No.29420090)	1kg.	1.Compactin	4.00kg/kg
		2.Aanti Form SAG-71	0.050kg/kg
		3.Acetonitrile	19.51kg/kg
		4.Acetone	10.67kg/kg
		5.Activated Carbon	0.100kg/kg
		6.Methanol	2.88kg/kg

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

Case No.B-510	M/S Shilpa Medicare Ltd.
Norms Committee Meeting No.38/08	F.No.01/87/50/1517/AM06
Meeting Date:22.01.2008	RLA F.No.07/24/40/1025/AM06
Advance Licence No.0710043911 dated 23.03.06	

Committee considered case as per agenda for ratification of norms for export product N+ β -D-Ribofuranosyl]-5-Hydroxyimidazole-4-Carboxamide Technical Grade under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/135/2006-PI-III dated 21.01.2008 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 Quantity	Import items	Quantity allowed per unit of export product
N+ β -D-Ribofuranosyl]-5-hydroxyimidazole-2-carboxamide Technical Grade (ITC(HS)No.29420090)	1kg.	1)N-(2,3,5-Tri-O-Benzoyl)-B-D-Ribofuranosyl)-5-Hydroxy Imidazole-4-carboxamide	7.50kg/kg
		2)Amberlite IRC 748 Resin	0.95kg/kg
		3)Amberlite IRA 900 ClResin	1.70kg/kg
		4)Tetrahydrofuran	18.66kg/kg

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

Case No.B-511	M/S SMS Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/162/424/AM07
Meeting Date:22.01.2008	RLA F.No.09/24/40/02/AM06
Advance Licence No.0910023407 dated 05.07.05	
Committee considered case as per agenda for revision of norms for export product D-erythro,d-threo-2-Deoxy-2,2-difluoro penta furanos-1 ulose-3,5-dibenzoate under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-512	M/S SMS Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/162/425/AM07
Meeting Date:22.01.2008	RLA F.No.09/24/40/377/AM06
Advance Licence No.0910025027 dated 28.11.05	
Committee considered case as per agenda for revision of norms for export product D-erythro,d-threo-2-Deoxy-2,2-difluoro penta furanos-1 ulose-3,5-dibenzoate under para 4.7 of HBP.	
Committee decided to defer case for comments of PI Division.	

Case No.B-513	M/S Vasudha Pharma Chem Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/50/1097/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/209/AM08
Advance Licence No.0910031382 dated 03.09.07	
Committee considered case as per agenda for revision of norms for export product Amitriptyline Crude under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.B-514	M/S Vasudha Pharma Chem Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/50/1098/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/226/AM08
Advance Licence No.0910031383 dated 03.09.07	
Committee considered case as per agenda for revision of norms for export	

product Dibenzosuberone under para 4.7 of HBP.

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

Case No.A-975	M/S Amoli Organics Pvt. Ltd.
Norms Committee Meeting No.38/08	F.No.01/87/50/606/AM07
Meeting Date:22.01.2008	RLA F.No.03/94/40/411/AM07
Advance Licence No.0310380982 dated 24.07.06	
Committee considered case as per agenda for ratification of norms for export product Noscapine Resin Complex under para 4.7 of HBP. Committee observed that firm was requested to furnish technical details vide letter dated 12.12.2007, but same has not been received. Committee, therefore, decided to close the case as norms can not be ratified in the absence of technical details. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.A-976	M/S Bal Pharma Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/297/AM08
Meeting Date:22.01.2008	RLA F.No.07/24/40/671/AM08
Advance Licence No.0710055101 dated 26.12.07	
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 six weeks for comments of PI Division.	

Case No.A-977	M/S Aurobindo Pharma Ltde.
Norms Committee Meeting No.38/08	F.No.01/82/50/296/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/428/AM08
Advance Licence No.0910032472 dated 26.12.07	
Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 4.7 of HBP.	

Committee decided to defer case for two weeks for comments of PI Division.
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Case No.A-978	M/S Aurobindo Pharma Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/294/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/413/AM08
Advance Licence No.0910032473 dated 26.12.07	
Committee considered case as per agenda for ratification of norms for export product Florfenicol under para 4.7 of HBP.	
Committee decided to defer case for two weeks for comments of PI Division.	

Case No.A-979	M/S Aurobindo Pharma Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/253/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/205/AM08
Advance Licence No.0910031156 dated 16.08.07	
Committee considered case as per agenda for ratification of norms for export product Ceftiofur Sodium Sterile under para 4.7 of HBP.	
Committee decided to defer case for two weeks for comments of PI Division.	

Case No.A-980	M/S Coral Drugs Pvt. Ltd
Norms Committee Meeting No.38/08	F.No.01/82/50/298/AM08
Meeting Date:22.01.2008	RLA F.No.05/24/40/699/AM08
Advance Licence No.0510213410 dated 12.12.07	
Committee considered case as per agenda for ratification of norms for export product Finasteride under para 4.7 of HBP.	
Committee observed that firm has not submitted technical details as per Appendix 33 alongwith their application for Advance licence. Committee, therefore, decided to ask RA as to how Advance licence has been issued to firm without technical details. Committee also decided to call for technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.	

Case No.A-981	M/S Coral Drugs Pvt. Ltd
Norms Committee Meeting No.38/08	F.No.01/82/50/299/AM08
Meeting Date:22.01.2008	RLA F.No.05/24/40/601/AM08
Advance Licence No.0510212483 dated 26.11.07	
Committee considered case as per agenda for ratification of norms for export product Flutamide 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 licence. Committee, therefore, decided to ask RA as to how Advance licence has been issued to firm without technical details. Committee also decided to call for technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.	

Case No.A-982	M/S Gland Pharma Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/254/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/314/AM08
Advance Licence No.0710055101 dated 26.12.07	
Committee considered case as per agenda for ratification of norms for export product Adenosine Injection USP under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-983	M/S Global Calcium Pvt. Ltd.
Norms Committee Meeting No.38/08	F.No.01/83/162/1033/AM08
Meeting Date:22.01.2008	RLA F.No.07/24/40/53/AM08
Advance Licence No.0710051439 dated 26.04.07	
Committee considered case as per agenda for ratification of norms for export product (1) Calcium Gluconate Injectable Grade (2) Calcium Lactate Gluconate, (3) Calcium Glubionate and (4) Calcium Borogluconate under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-984	M/S Nicholas Piramal India Ltd.
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Norms Committee Meeting No.38/08	F.No.01/82/50/302/AM08
Meeting Date:22.01.2008	RLA F.No.09/24/40/868/AM08
Advance Licence No.0310454138 dated 14.12.07	
Committee considered case as per agenda for ratification of norms for export product Ultrazyme Tablets (7458X) [contact lens cleaning tablets) under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of DBT.	

Case No.A-985	M/S Neuland Laboratories Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/304/AM08		
Meeting Date:22.01.2008	RLA F.No.09/24/40/363/AM08		
Advance Licence No.0910032148 dated 26.11.07			
Committee considered case as per agenda for ratification of norms for export product Ramipril under para 4.7 of HBP.			
Committee in light of its earlier decision taken in its 22/82 meeting held on 04.10.2007 vide Case No.1/22/82 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 Quantity	Import items	Quantity allowed per unit of export product
Ramipril (ITC(HS) No.300490 71)	1kg.	1.Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride [(S,S)-2-azabicyclo (3.3.0)octane-3-carboxylic acid benzylester Hydrochloride’].	2.70kg/kg
		2. S(+)-Mandelic acid	0.81kg/kg
		3. Methylene chloride	2.50kg/kg
		4.Cyclohexane	2.50kg/kg
		5. Isopropyl Alcohol	2.50kg/kg
		6. ECPP Alanine	1.23kg/kg
		7. 1-Hydroxy Benzotriazole	0.72kg/kg
		8. Dicyclohexyl Carbodimide	1.00kg/kg
		9. Di-isopropyl ether	2.50kg/kg

		10. 5% Palladium on carbon	0.20kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.A-986	M/S Intas Pharmaceuticals Ltd.
Norms Committee Meeting No.38/08	F.No.01/82/50/301/AM08
Meeting Date:22.01.2008	RLA F.No.08/24/40/226/AM08
Advance Licence No.0810069241 dated 28.12.07	
Committee considered case as per agenda for ratification of norms for export product Doxycyclone Hyclate Tablets USP under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-987	M/S Medreich Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/303/AM08		
Meeting Date:22.01.2008	RLA F.No.07/24/40/620/AM08		
Advance Licence No.0710054772 dated 03.12.07			
Committee considered case as per agenda for ratification of norms for export product Glucosamine 1500mg systaubed rekease tavkets (ii) Glucosamine 1000mg Sustained release tablets and (iii) Glucosamine 750mg Sustained release tablets under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/270/2006-PI-III dated 23.01.2008 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 Qty.	Import items	Qty. allowed per unit of export product
Glucosamine 1500mg Sustained Release Tablet (ITC(HS)No.30049	1 tablet	Glucosamine sulphate Sodium Sulphate	1836mg/1500mg tablet

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Glucosamine 1000mg Sustained Release Tablet (ITC(HS)No.30049 069)	1 tablet	Glucosamine sulphate Sodium Sulphate	1358.64mg/1000m g tablet
Glucosamine 750mg Sustained Release Tablet (ITC(HS)No.30049 069)	1 tablet	Glucosamine sulphate Sodium Sulphate	1018.98mg/750mg tablet

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

Case No.A-988	M/S Medreich Ltd.		
Norms Committee Meeting No.38/08	F.No.01/82/50/48/AM08		
Meeting Date:22.01.2008	RLA F.No.07/24/40/810/AM07		
Advance Licence No.0710050467 dated 06.03.07			
Committee considered case as per agenda for ratification of norms for export product Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 45mg +Codeine Phosphate 10mg Tablets 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 23.01.2007 and in consultation with representative of PI Division 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	Export Qty.	Import items	Qty allowed per unit of export product
Paracetamol 450mg + Caffiene Anhydrous 45mg + Doxylamine Succinate 5mg + Codeine	1 tablet	1.Paracetamol	459mg/tab.
		2.Doxylamine Succinate	5.1mg/tab.
		3.Spectracolquin oline yellow 800744 B-20	Neither the description nor CI No. matches with the description given in the MBF. Hence not allowed.

3	Case No.:35/31/82-ALC1/2006	Party Name:CLARIANT CHEMICALS [INDIA] LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Withdrawn
	HQ File : 01/82/050/01132/AM07/	RLA File : 03/94/040/00773/AM07/	Lic.No/Date:0310403496 11.10.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 5 Fluoro Cyto Sine under para 4.7 of HBP. Committee decided to withdraw case as same has already been approved in 37/08 meeting held on 15.01.2008.			

4	Case No.:1/42/83-ALC1/2006	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/00936/AM07/	RLA File : 09/24/040/00218/AM07/	Lic.No/Date:0910028286 21.11.2006	Defer Date: 04.03.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Benzisoxazole-3-Methane Sulphonic acid sodium salt under para 4.7 of HBP. Committee decided to call for sequence of events in chronological order from RA. Accordingly, case was deferred for six weeks.			

5	Case No.:16/49/82-ALC1/2006	Party Name:LUPIN LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/01721/AM07/	RLA File : 03/95/040/01297/AM07/	Lic.No/Date:0310416716 22.01.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Strile Ceftriaxone Sodium-Non Infringing under para 4.7 of HBP. Committee decided to examine case on file as non-infringing process is involved in manufacturing export product.			

6	Case No.:4/9/82-ALC4/2007	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File :	RLA File :	Lic.No/Date:0310419	

01/82/050/01644/AM07/	03/94/040/01206/AM07/	586 14.02.2007	
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Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium USP under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No. 35011/204/2006-PI-III dated 21.01.2008 and in consultation with representative of PI Division 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	Export Qty.	Import items	Qty. allowed per unit of export product
Losartan Potassium	1kg.	1. 2-Cyano-4-Methyl Phiphenyl	0.79kg/kg
		2. N-Bromo Succinimide	0.38kg/kg
		3. 2-Butyl-4-chloro-5-formyl Imidazole	0.62kg/kg
		4. Sodium Borohydride	0.048kg/kg
		5. Sodium Azide	0.50kg/kg
		6. Triethyl Amine Hcl	2.20kg/kg

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

7	Case No.:8/2/83-ALC1/2007	Party Name:PAB ORGANICS PVT.LTD,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01256/AM07/	RLA File : 34/24/040/00259/AM07/	Lic.No/Date:3410018 108 19.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product 5-Bromo Phthalide 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 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.	Import items	Qty. allowed per unit of export product

5-Bromo Phthalide (ITC(HS)No.29420 090)	1kg.	1. Hydrobromic Acid 48%	0.87kg/kg
		2. 5-Amino Phthalide	3.35kg/kg

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

8	Case No.:3/19/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/82/050/01663/AM07/	RLA File : 05/24/040/00951/AM07/	Lic.No/Date:0510199 828 21.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Nalidixic Acid under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/111/2007-PI-III dated 21.01.2008 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.	Import items	Qty. allowed per unit of export product
	Nalidixic Acid (ITC(HS)No.29183 030)	1kg.	1. Sodium Metal	0.4077kg/kg
			2. Alumina-Silica Catalyst	0.0540kg/kg
			3. Denatured Ethyl Alcohol	4.59kg/kg
			4. Triethyl ortho formate	1.233kg/kg
			5. Para Toluene Sulfonic acid Monohydrate	0.003kg/kg
			6. Diethyl Malonate	1.333kg/kg
			7. Ethyl Alcohol	0.200kg/kg
			8. Diphenyl DT	Not a raw material. Hence not allowed
			9. Ethyl bromide	0.58kg/kg
			10. Dimethyl Formamide	0.833kg/kg

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

9	Case No.:879/21/82-ALC4/2007	Party Name:LAKE CHEMICALS PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/01714/AM07/	RLA File : 07/24/040/00780/AM07/	Lic.No/Date:0710050314 27.02.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Dorzolamide Hcl under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.				

10	Case No.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	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: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product (1) Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets and (2) Triomune 40/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

11	Case No.:474/24/83-ALC1/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Rejected
	HQ File : 01/83/050/01382/AM07/	RLA File : 07/24/040/00879/AM07/	Lic.No/Date:0710050972 29.03.2007	:
Decision : Committee considered case as per agenda for ratification of norms for export product N-[B-D-Ribofuranosyl]-5-Hydroxyimidazole-4-Carboxamide Technical Grade under para 4.7 of HBP. Committee observed that firm was requested to furnish technical information vide letter dated 27.08.2007, but they have furnished incomplete information. Accordingly, Committee decided to close the case				

as norms can not be ratified in absence of complete information.

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

12	Case No.:25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/00016/AM08/	RLA File : 04/24/040/00501/AM07/	Lic.No/Date:0410088727 02.04.2007	Defer Date: 04.03.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Allylestrenol under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.				

13	Case No.:9/21/82-ALC4/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/82/050/00009/AM08/	RLA File : 09/24/040/00543/AM07/	Lic.No/Date:0910029931 10.04.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product 7-Amino-3[(Z/E)-1-Propen-1-YL]-3-Cephem-4-Carbocyclic Acid (APRA) under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.				

14	Case No.:26/9/82-ALC4/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Withdrawn
	HQ File : 01/82/050/00010/AM08/	RLA File : 09/24/040/00555/AM07/	Lic.No/Date:0910029933 10.04.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product 2-Chloro methyl-3-methyl-4-(2,2,2-trifluoroethoxy)pyridine Hcl (Lansoprazole Chloro intermediate) under para 4.7 of HBP. Committee decide to withdraw case as same has already been rejected				

in its 33/08 meeting held on 18.12.2007.

Case No.:566/24/83-ALC1/2007	Party Name:MOREPEN LABORATORIES LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Approved
HQ File : 01/83/050/00239/AM08/	RLA File : 05/24/040/00080/AM08/	Lic.No/Date:0510203 207 03.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium Min Assay 97% 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 21.01.2008 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.	Import items	Qty. allowed per unit of export product
15 Montelukast Sodium (ITC(HS)No.29420 000)	1kg.	1. 7-chloro quinaldine	8.07kg/kg
		2. Isophthal Dehyde	10.406kg/kg
		3. Tetrahydrofuran	38.47kg/kg
		4. Isopropyl Alcohol	3.33kg/kg
		5. Methylene Chloride	64.64kg/kg
		6. Triethylamine	11.67kg/kg
		7. Methyl-2-iodo benzoate	8.67kg/kg
		8. Dimethyl formamide	4.63kg/kg
		9. (-)Di-Isopinoicamphey L Chloro Borane)-DPC IN Heptane)	13.80kg/kg
		10. Ceric chloride	2.466kg/kg
		11. Acetonitrile	10.13kg/kg
		12. N-Butyl Lithium (15% in Hexane)	3.53kg/kg
		13. 1,1 Cyclopropane Di Methanol	2.88kg/kg
		14. Di-isopropyl Ethylamine	1.24kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.:11/22/83-ALC1/2007	Party Name:ORGANON (INDIA) LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved																
HQ File : 01/83/050/00260/AM08/	RLA File : 02/24/040/00024/AM08/	Lic.No/Date:0210100541 04.05.2007																	
Decision : Committee considered case as per agenda for ratification of norms for export product Norandrostenedione (Nordion) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/9/2006-PI-III dated 23.01.2008 and in consultation with representative of PI Division 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:- <table border="1" data-bbox="228 821 1430 1129"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="5">Norandrostenedione (not less than 90% purity (ITC(HS)No.42515 005)</td><td rowspan="5">1kg.</td><td>1. Sitolactone</td><td>1.26kg/kg</td></tr> <tr> <td>2. Chloroket</td><td>1.17kg/kg</td></tr> <tr> <td>3. Pyridine</td><td>0.56kg/kg</td></tr> <tr> <td>4. Methanol</td><td>2.88kg/kg</td></tr> <tr> <td>5. Toluene</td><td>5.71kg/kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of Norms Committee.				Export product	Export Qty.	Import items	Qty. allowed per unit of export product	Norandrostenedione (not less than 90% purity (ITC(HS)No.42515 005)	1kg.	1. Sitolactone	1.26kg/kg	2. Chloroket	1.17kg/kg	3. Pyridine	0.56kg/kg	4. Methanol	2.88kg/kg	5. Toluene	5.71kg/kg
Export product	Export Qty.	Import items	Qty. allowed per unit of export product																
Norandrostenedione (not less than 90% purity (ITC(HS)No.42515 005)	1kg.	1. Sitolactone	1.26kg/kg																
		2. Chloroket	1.17kg/kg																
		3. Pyridine	0.56kg/kg																
		4. Methanol	2.88kg/kg																
		5. Toluene	5.71kg/kg																

17	Case No.:12/17/83-ALC1/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/00263/AM08/	RLA File : 05/24/040/00106/AM08/	Lic.No/Date:0510203343 07.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product 1,4-Dihydro-1-ethyl-7-methyl-1-4-oxo-1,8-naphthyridine-3-carboxylic acid-Crude under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/111/2007-PI-III dated 21.01.2008 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.	Import items	Qty. allowed per unit of export product
1,4 Dihydro-1-Ethyl-7-Methyl-4-Oxo-1,8 Naphthridine-3-Carboxylic Acid-Crude (ITC(HS)No.29183 030)	1kg.	1. Sodium Metal	0.36kg/kg
		2. Alumina-Silica Satalyst	0.048kg/kg
		3. Denatured Ethyl Alcohol	4.13kg/kg
		4. Triethyl ortho formate	1.10kg/kg
		5. Para Toluene Sulfonic acid Monohydrate	0.0027kg/kg
		6. Diethyl Malonate	1.20kg/kg
		7. Ethyl Alcohol	0.180kg/kg
		8. Diphenyl DT	Not a raw material. Hence not allowed
		9. Ethyl bromide	0.520kg/kg
		10. Dimethyl Formamide	0.750kg/kg

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

18	Case No.:614/24/83-ALC1/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/00369/AM08/	RLA File : 03/95/040/01471/AM07/	Lic.No/Date:0310430 058 21.05.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Ultrazyme Tablets (7458X) [Contact Lens Cleaning Agent] under para 4.7 of HBP.				
Committee decided to defer case for four weeks for comments of DBT.				

19	Case No.:33/9/82-ALC4/2007	Party Name:DR. WILLMAR SCHWABE INDIA PVT LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:C ase Deferred
	HQ File : 01/82/050/00044/AM08/	RLA File : 05/24/040/00826/AM07/	Lic.No/Date:0510203 948 22.05.2007	Defer Date: 04.03.2008

Decision : Committee considered case as per agenda for ratification of norms for export product White Sugar Globuli (Unarzneiliche Globuli) under para 4.7 of HBP.

Committee was informed that technical comments for above export product has been received from Ministry of Food Processing Industry/Directorate of Sugar in DES-VI Section. Committee, therefore, decided to call for concerned file from DES-VI Section. It was also decided to refer case to Ministry of Food Processing Industry/Directorate of Sugar for their comments. Accordingly, case was deferred for six weeks.

Case No.:635/24/83-ALC1/2007	Party Name:JUPITER BIOSCIENCE LIMITED,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/00411/AM08/	RLA File : 09/24/040/00045/AM08/	Lic.No/Date:0910030 362 28.05.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product N-T-Boc-L-Phenylalanine 99% pure 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 21.01.2008 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 Qty.	Import items	Qty. allowed per unit of export product
N-T-BOC-L-Phenyl Alanine (ITC(HS)No.29374 000)	1kg.	1. L-Phenyl Alanine	0.622kg/kg
		2. Di-Tertiary-Butyl Dicarboxylate Anhydride	0.821kg/kg
		3. Isopropyl Alcohol	0.394kg/kg
		4. N-Hexane	0.986kg/kg
		5.Ethyl Acetate	1.134kg/kg
		6.Sodium Hydroxide	0.150kg/kg

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

21	Case No.:645/24/83-ALC1/2007	Party Name:AYURSIDDHA INC.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
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	HQ File : 01/83/050/00438/AM08/	RLA File : 05/24/040/00105/AM08/	Lic.No/Date:0510204 254 30.05.2007	Defer Date: 19.02.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Blockbuster All Clear Capsules Made of Citrolive (olive Leaf Citrus) under para 4.7 of HBP. Committee decided to forward a copy of application to Deptt. Of MSME for their comments. Accordingly, case was deferred for four weeks.			

	Case No.:680/24/83- ALC1/2007	Party Name:DCM SHRIRAM INDUSTRIES LTD,	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
	HQ File : 01/83/050/00524/AM08/	RLA File : 05/24/040/00166/AM08/	Lic.No/Date:0510204 918 14.06.2007	Defer Date: 19.02.20 08
22	Decision : Committee considered case as per agenda for ratification of norms for export product D(-)Para Hydroxy Phenyl Glycine Sane Salt under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.			

	Case No.:83/19/83- ALC1/2007	Party Name:SUMITOMO CHEMICAL INDIA PRIVATE LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
	HQ File : 01/83/050/00643/AM08/	RLA File : 03/95/040/01529/AM07/	Lic.No/Date:0310433 838 25.06.2007	Defer Date: 12.02.20 08
23	Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Methylenedioxybenzyne under para 4.7 of HBP. Committee observed that firm was requested to furnish end use of export product and technical literature in support of above, but information has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for three weeks.			

24	Case No.:730/24/83- ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status: Case Deferred
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HQ File : 01/83/050/00623/AM08/	RLA File : 09/24/040/00120/AM08/	Lic.No/Date:0910030 686 29.06.2007	Defer Date: 19.02.20 08
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 defer case for four weeks for comments of PI Division.			

Case No.:19/23/83- ALC1/2007	Party Name:SEQUENT SCIENTIFIC LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status: Case Deferred
HQ File : 01/83/050/00655/AM08/	RLA File : 07/24/040/00234/AM08/	Lic.No/Date:0710052 301 04.07.2007	Defer Date: 12.02.20 08
25	Decision : Committee considered case as per agenda for ratification of norms for export product L-(+)-Selenomethionine under para 4.7 of HBP. Committee observed that firm was requested to furnish end use of export product and technical literature in support of above, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for three weeks.		

26	Case No.:103/19/83- ALC1/2007	Party Name:AVIK PHARMACEUTICAL LTD.,	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Approved
	HQ File : 01/83/050/00712/AM08/	RLA File : 03/94/040/00198/AM08/	Lic.No/Date:0310435 816 11.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Clobetasol 17-Propionate BP/USP under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/134/2005-PI-III dated 23.01.2008 in the case of M/S Anuh Pharma Ltd. 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.	Import items	Qty. allowed per unit of export

			product
Clobetasol Propionate (ITC(HS)No.29379 300)	1kg.	1. Betamethasone base BP	1.19kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

27	Case No.:797/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/00755/AM08/	RLA File : 05/24/040/00286/AM08/	Lic.No/Date:0510206321 16.07.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Citalopram Hydrobromide under para 4.7 of HBP. Committee decided to examine case on file as the application of firm is based on non infringing process.			

28	Case No.:95/21/82-ALC4/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00144/AM08/	RLA File : 03/95/040/00389/AM08/	Lic.No/Date:0310437508 26.07.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocare Tablets (Contact Lens Cleaning Agent) under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of DBT.			

29	Case No.:3/18/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00142/AM08/	RLA File : 03/94/040/00455/AM08/	Lic.No/Date:0310438406 06.08.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir/Arved Tablets under para 4.7 of HBP.			

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

Case No.:897/24/83-ALC1/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/00905/AM08/	RLA File : 05/24/040/00287/AM08/	Lic.No/Date:0510207300 07.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP. Committee in light of written comments forwarded by Deptt. Of MSME vide their U.O. No.5(9)/2005-Chem dated 21.01.2008 and in consultation with representative of D/O MSME 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.	Import items	Qty. allowed per unit of export product
Camptothecin purity Minimum 99% (ITC(HS)No.13021919)	1kg.	1. Mappia foetida (containing Camptothecin 0.14%± 0.02%)	952kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.:962/24/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
HQ File : 01/83/050/00978/AM08/	RLA File : 03/94/040/00493/AM08/	Lic.No/Date:0310439377 14.08.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Phenyl Thio Proline under para 4.7 of HBP. Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for four weeks.			

32

Case No.:5/20/82-ALC4/2007	Party Name:RICHY GOLD INTERNATIONAL	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/82/050/00162/AM08/	RLA File : 03/95/040/00461/AM08/	Lic.No/Date:0310439 444 14.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Oral Rehydration Salt BP under para 4.7 of HBP.			
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/104/2007-PI-III dated 21.01.2008 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.	Import items	Qty. allowed per unit of export product
Oral Rehydration Salt BP 30gm. Sachet (ITC(HS)No.30049 086)	1kg.	Dextrose Anhydrous	0.666kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

33	Case No.:16/25/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01041/AM08/	RLA File : 03/94/040/00516/AM08/	Lic.No/Date:0310439 736 16.08.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

34	Case No.:14/25/83-ALC1/2007	Party Name:SANJAY SALES CORPORATION	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Transferred
	HQ File : 01/83/050/01039/AM08/	RLA File : 03/95/040/00475/AM08/	Lic.No/Date:0310439 724	

		16.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Sodium Salicylate under para 4.7 of HBP. Committee decided to transfer case to DES-IV as export product pertains to chemical sector.			

35	Case No.:7/25/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/01032/AM08/	RLA File : 09/24/040/00231/AM08/	Lic.No/Date:0910031314 29.08.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Didanosine under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

36	Case No.:32/25/83-ALC1/2007	Party Name:METROPOLITAN OVERSEAS LIMITED,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Rejected
	HQ File : 01/83/050/01057/AM08/	RLA File : 03/95/040/00511/AM08/	Lic.No/Date:0310441319 30.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product N-[1-(S)-Ethoxy Carbonyl-3-phenyl propyl]-L-Alanine 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 22.01.2008 observed that norms applied by firm are not as per chemistry furnished by them. Accordingly, Committee decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.				

37	Case No.:42/25/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/01067/AM08/	RLA File : 03/94/040/00299/AM08/	Lic.No/Date:0310441432 30.08.2007	Defer Date: 05.02.2008

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

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

38	Case No.:6/27/83-ALC1/2007	Party Name:VANI CHEMICALS & INTERMEDIATES LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01080/AM08/	RLA File : 09/24/040/00009/AM08/	Lic.No/Date:0910031330 31.08.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product 4-(3,4-Dichlorophenyl)1-Tetralone under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.				

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Case No.:8/27/83-ALC1/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Approved
HQ File : 01/83/050/01082/AM08/	RLA File : 05/24/040/00439/AM08/	Lic.No/Date:0510208408 31.08.2007	

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

Committee in light of written comments forwarded by Deptt. Of MSME vide their U.O. No.5(9)/2005-Chem dated 21.01.2008 and in consultation with representative of D/O MSME 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.	Import items	Qty. allowed per unit of export product
Camptothecin purity Minimum 99% (ITC(HS)No.13021919)	1kg.	1. Mappia foetida (containing Camptothecin 0.14%± 0.02%)	952kg/kg

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

40	Case No.:4/22/82-ALC4/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/82/050/00174/AM08/	RLA File : 09/24/040/00207/AM07/	Lic.No/Date:0910031328 31.08.2007	Defer Date: 05.02.2008
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. Committee decided to defer case for two weeks for comments of PI Division.				

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Case No.:19/27/83-ALC1/2007	Party Name:TITAN LABORATORIES PVT. LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/01093/AM08/	RLA File : 03/95/040/00427/AM08/	Lic.No/Date:0310441528 31.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Orlistat Pellets 50% under para 4.7 of HBP.			
The Committee in light of the oral comments of the representative of PI Division in the 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.	Import items	Qty. allowed per unit of export product
Orlistate Pellets 50% (ITC(HS)No.29322990)	1kg.	Orlistat	0.505kg/kg as per SION
RA concerned may take further necessary action as per above decision of Norms Committee.			

42	Case No.:9/27/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
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	HQ File : 01/83/050/01083/AM08/	RLA File : 03/95/040/00534/AM08/	Lic.No/Date:0310441 537 31.08.2007	Defer Date: 29.01.20 08
	Decision : 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 the case as firm has already been called for personal hearing in its meeting to be held on 29.01.2008.			

	Case No.:5/22/82- ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
43	HQ File : 01/82/050/00175/AM08/	RLA File : 03/94/040/00571/AM08/	Lic.No/Date:0310441 556 31.08.2007	Defer Date: 19.02.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir/Arved Tablets under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

	Case No.:33/27/83- ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
44	HQ File : 01/83/050/01107/AM08/	RLA File : 09/24/040/00192/AM07/	Lic.No/Date:0910031 403 05.09.2007	Defer Date: 05.02.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product GCLE-Stage-1 under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.			

45	Case No.:32/27/83- ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	StatusCa se Deferred:
	HQ File : 01/83/050/01106/AM08/	RLA File : 09/24/040/00388/AM07/	Lic.No/Date:0910031 402 05.09.2007	Defer Date: 05.02.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.			

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

46	Case No.:31/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	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: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Pivmecillinam Hydrochloride under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.				

47	Case No.:35/27/83-ALC1/2007	Party Name:SHREE GANESH CHEMICALS	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/01109/AM08/	RLA File : 34/24/040/00089/AM08/	Lic.No/Date:3410019570 05.09.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Di Ethyl Amino Ethyl Chloride Hydrochloride under para 4.7 of HBP. Committee decided to examine the case on file as to whether the export product falls under SCOMET list. Accordingly, case was deferred for four weeks.				

48	Case No.:43/27/83-ALC1/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status: Case Deferred
	HQ File : 01/83/050/01117/AM08/	RLA File : 34/24/040/00110/AM08/	Lic.No/Date:3410019573 06.09.2007	Defer Date: 04.03.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Venlafaxine Hydrochloride Extended Release Pellets Stage 1 under para 4.7 of HBP. Committee decided to call for complete description of export product				

alongwith copy of DML from firm. Accordingly, case was deferred for six weeks.

49	Case No.:68/27/83-ALC1/2007	Party Name:AVIK PHARMACEUTICAL LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01142/AM08/	RLA File : 03/94/040/00531/AM08/	Lic.No/Date:0310442 331 10.09.2007	Defer Date: 04.03.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Ethisterone under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

50	Case No.:64/27/83-ALC1/2007	Party Name:KARNATAKA CHEMSYN LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Transferred
	HQ File : 01/83/050/01138/AM08/	RLA File : 07/24/040/00408/AM08/	Lic.No/Date:0710053 251 10.09.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 5-Hydroxy Methyl 4-Methyl Imidazole 99.5% purity under para 4.7 of HBP. Committee observed that firm has given end use of export product stating that this product is an intermediate and is used in the manufacture of some high quality pigments. Accordingly, Committee decided to transfer case to DES-IV.			

51	Case No.:72/27/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01146/AM08/	RLA File : 03/95/040/00570/AM08/	Lic.No/Date:0310442 436 11.09.2007	Defer Date: 19.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium-Non Infringing under para 4.7 of HBP. Committee decided to examine the case on file as the application is based on non infringing process.			

52	Case No.:10/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00180/AM08/	RLA File : 03/94/040/00615/AM08/	Lic.No/Date:0310442878 12.09.2007	Defer Date: 19.02.2008
	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 defer case for four weeks for comments of PI Division.			

53	Case No.:84/27/83-ALC1/2007	Party Name:CODEXIS LABORATORIES INDIA PVT.LTD,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01158/AM08/	RLA File : 05/24/040/00426/AM08/	Lic.No/Date:0510208879 12.09.2007	Defer Date: 19.02.2008
	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) NLT 99% under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

54	Case No.:98/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01172/AM08/	RLA File : 09/24/040/00258/AM08/	Lic.No/Date:0910031511 14.09.2007	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumerate under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.			

55	Case No.:101/27/83-ALC1/2007	Party Name:DOCTORSORGANIC CHEMICALS LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
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	HQ File : 01/83/050/01175/AM08/	RLA File : 26/24/040/00002/AM08/	Lic.No/Date:2610006 381 14.09.2007	Defer Date: 04.03.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Sertraline Hydrochloride Solid under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

	Case No.:134/27/83- ALC1/2007	Party Name:AARTI INDUSTRIES LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
56	HQ File : 01/83/050/01208/AM08/	RLA File : 03/94/040/00607/AM08/	Lic.No/Date:0310443 695 19.09.2007	Defer Date: 04.03.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Fluticasone Propionate under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

	Case No.:163/27/83- ALC1/2007	Party Name:SRI KRISHNA DRUGS LIMITED.,	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
57	HQ File : 01/83/050/01237/AM08/	RLA File : 09/24/040/00145/AM08/	Lic.No/Date:0910031 618 26.09.2007	Defer Date: 04.03.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Folic Acid under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

	Case No.:173/27/83- ALC1/2007	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Approved
58	HQ File : 01/83/050/01247/AM08/	RLA File : 05/24/040/00486/AM08/	Lic.No/Date:0510209 640 27.09.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Hyoscine-n-Butyl Bromide or Hyoscine Hydro			

Bromide under para 4.7 of HBP.

Committee in consultation with representative of Department of MSME 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.	Import items	Qty. allowed per unit of export product
Hyoscine-N-Butyl Bromide or Hyoscine Hydro Bromide (ITC(HS)No.29392 900)	1kg.	1.Dubosia Leaves	85.00kg/kg
		2.Methylene Chloride	68.55kg/kg
		3.Methanol	26.34kg/kg

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

59	Case No.:8/29/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01273/AM08/	RLA File : 09/24/040/00251/AM08/	Lic.No/Date:0910031700 03.10.2007	Defer Date:

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/254/2006-PI-III dated 23.01.2008 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.	Import items	Qty. allowed per unit of export product
Doxofylline (ITC(HS)No.29420 090)	1kg.	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

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

Norms Committee.

60	Case No.:39/29/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01304/AM08/	RLA File : 03/94/040/00643/AM08/	Lic.No/Date:0310445 399 08.10.2007	Defer Date: 19.02.20 08
	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.			
61	Case No.:84/29/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01349/AM08/	RLA File : 03/94/040/00712/AM08/	Lic.No/Date:0310446 240 12.10.2007	Defer Date: 19.02.20 08
	Decision : Committee considered case as per agenda for ratification of norms for export product Gentadox Powder under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			
62	Case No.:14/30/83-ALC1/2007	Party Name:KAIVAL CHEMICALS P LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01383/AM08/	RLA File : 34/24/040/00157/AM08/	Lic.No/Date:3410019 869 18.10.2007	Defer Date 04.03.20 08:
	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 defer case for six weeks for comments of PI Division.			
63	Case No.:28/30/83-ALC1/2007	Party Name:AUCTUS PHARMA PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred

	HQ File : 01/83/050/01397/AM08/	RLA File : 09/24/040/00291/AM08/	Lic.No/Date:0910031 844 23.10.2007	Defer Date: 05.02.20 08
	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. Committee decided to defer case for two weeks for comments of PI Division.			

	Case No.:7/28/82- ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status: Case Withdraw n
64	HQ File : 01/82/050/00241/AM08/	RLA File : 03/94/040/00783/AM08/	Lic.No/Date:0310448 115 26.10.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Toltrazuril Oral Solution2.5%/Cipcox 2.5% Solution under para 4.7 of HBP. Committee decided to withdraw case as same has already been approved in its 35/08 meeting held on 08.01.2008.			

	Case No.:4/28/82- ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status: Case Deferred
65	HQ File : 01/82/050/00238/AM08/	RLA File : 03/94/040/00792/AM08/	Lic.No/Date:0310448 519 31.10.2007	Defer Date 19.02.20 08:
	Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir/ARVED TABLETS under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

66	Case No.:9/28/82- ALC4/2007	Party Name:VIVEK PHARMACHEM (INDIA) LTD.,	Meet No/Date:38/82- ALC4/2007 22.01.2008	Status:C ase Deferred
	HQ File : 01/82/050/00243/AM08/	RLA File : 13/24/040/00022/AM08/	Lic.No/Date:1310025 278 31.10.2007	Defer Date: 04.03.20 08

Decision : Committee considered case as per agenda for ratification of norms for export product MEROPENEM INJECTION USP 1GM. POTENCY 100% (+/-5%) under para 4.7 of HBP.

Committee decided to call for (1) Actual Potency of import item, (2) Copy of Bill of Entry, (3) Test report from foreign supplier and (4) copy of relevant DML from firm. Accordingly, case was deferred for six weeks.

67	Case No.:10/28/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00244/AM08/	RLA File : 13/24/040/00020/AM08/	Lic.No/Date:1310025 280 01.11.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Ascorbyl Palmitate Granules 95% under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.				

68	Case No.:71/32/83-ALC1/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01493/AM08/	RLA File : 22/24/040/00049/AM08/	Lic.No/Date:2210007 216 02.11.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Through Enzymatic Route Pen G 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 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.	Import items	Qty. allowed per unit of export product
	Amoxycillin Trihydrate enzymatic route	1kg.	1.Penicillin G Pot. 1 st crystal	1.664 BOU/Kg
			2.D(-) Para hydroxy phenyl glycine methyl ester	0.608kg/kg

(ITC(HS)No.29411030)	3.Oxilasa enzyme	5.0gm/kg
	4.Penicillin G Amidase enzyme	0.852kg/kg
	5.Methanol	0.0215kg/kg
	6.Butyl Acetate	0.122kg/kg
	7.Boric acid	0.032kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.		

Case No.:74/32/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved	
HQ File : 01/83/050/01496/AM08/	RLA File : 09/24/040/00242/AM08/	Lic.No/Date:0910031941 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 (Lamivudine 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 23.01.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
69	Export product	Export Qty.	Import items	Qty. allowed per unit of export product
	Menthyl-5 S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamivudine intermediate State 3) (ITC(HS)No.29420090)	1kg.	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
RA concerned may take further necessary action as per above decision of Norms Committee.				

70	Case No.:75/32/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01497/AM08/	RLA File : 09/24/040/00253/AM08/	Lic.No/Date:0910031942 02.11.2007	Defer Date: 19.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product (S)-5-Chloro-1-(Cyclopropylethynyl)-2-Amino-1-(Trifluoromethyl) Benzenemethanol (Amino Carbinol) (Efavirenz Inter) under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

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Case No.:84/32/83-ALC1/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/01506/AM08/	RLA File : 09/24/040/00340/AM08/	Lic.No/Date:0910031993 05.11.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Cefdinir 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 23.01.2008 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	Export Qty.	Import items	Qty. allowed per unit of export product
Cefdinir (ITC(HS)No.29419 090)	1kg.	1)7-Phenylacetamideo-3-Chloromethyl Cephalosporanic Acid Para Methoxybenzyl Ester (GCLE)	2.44kg/kg
		2)Ethyl-(Z)-2-Hydroxyimino-2-(2-Aminothiazole-4-YL) Acetone (EHATA)	1.896kg/kg
		3)Methylene chloride	16.88kg/kg
		4)Tetrahydrofuran	2.34kg/kg
		5)Methanol	4.68kg/kg
		6)Activated Carbon	0.100kg/kg

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

72	Case No.:100/32/83-ALC1/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01522/AM08/	RLA File : 05/24/040/00476/AM08/	Lic.No/Date:0510211700 06.11.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Pyrazolinone (Galaxy-1) under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.				

73	Case No.:89/32/83-ALC1/2007	Party Name:VITAL LABORATORIES PVT. LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01511/AM08/	RLA File : 03/95/040/00691/AM08/	Lic.No/Date:0310449448 06.11.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Digoxin BP/EP/USP under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

74	Case No.:24/33/83-ALC1/2007	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01553/AM08/	RLA File : 09/24/040/00354/AM08/	Lic.No/Date:0910032057 12.11.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Mebeverine HCl under para 4.7 of HBP. The Committee in light of its earlier decision taken in its 14/08 meeting held on 07.08.2007 and in consultation with representative of PI Division present in meeting decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower:-				

Export product	Export Qty.	Import items	Qty. allowed per unit of export product
Mebeverine Hcl (ITC(HS)No.29420 090)	1kg.	1. 2-Chloromethyl Propionate	0.66kg/kg
		2. Veratricf acid	0.56kg/kg
		3. Methyl Isobutyl ketone	0.51lit/kg
		4. 1,4-dibromo Butane	0.84kg/kg

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

75	Case No.:29/33/83-ALC1/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01558/AM08/	RLA File : 09/24/040/00341/AM08/	Lic.No/Date:0910032 076 14.11.2007	

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

Committee in light of its earlier decision taken in its 7/82 meeting held on 17.05.2006 vide case No.20/47/82 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.	Import items	Qty. allowed per unit of export product
Cefpodoxim Proxetil (ITC(HS)No.29419 090)	1kg.	1. 7 Amino Cephalosporanic Acid (7-ACA)	1.25kg/kg
		2. Mercaptobenzothiazol-2-Aminothiazol-4YL-Methoxoyimino Acetate	1.25kg/kg
		3. Alpha-chloro Ethyl Isoporopyl Carbonate (CEIPC)	0.558kg/kg
		4. 1, 8-Duatabuctui (5.4.0)-7-Undecene (DBU)	0.36kg/kg
		5. Methanol	1.51kg/kg
		6. Methylene chloride	2.32kg/kg

		7. Acetone	2.50kg/kg
		8. Tetrahydrofuran	1.56kg/kg
		9. Sodium Iodide	0.39kg/kg
		10. Activated Carbon	0.100kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.:25/39/83-ALC1/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved	
HQ File : 01/83/050/01604/AM08/	RLA File : 09/24/040/00346/AM08/	Lic.No/Date:0910032 139 23.11.2007		
Decision : Committee considered case as per agenda for ratification of norms for export product 7-Amino 3-Vinyl Cephalosporonic Acid (7 AVNA) under para 4.7 of HBP.				
Committee in light of its earlier decision taken in its 28/82 meeting held on 13.11.2007 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 firm whichever is lower:-				
76	Export product	Export Qty.	Import items	Qty. allowed per unit of export product
	7-Amino 3-Vinyl Cepholosparanic Acid (7 AVNA) (ITC(HS)No.29419 090)	1kg.	1. 7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid para Methoxy Benzyl Ester (GCLE)	2.672kg/kg
			2. Acetone-	10.11kg/kg
			3. Methylene Chloride	7.59kg/kg
			4. Methanol	7.78kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.				

77	Case No.:24/39/83-ALC1/2007	Party Name:INVENTIS DRUG DELIVERY SYSTEMS PVT LTD.	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File :	RLA File :	Lic.No/Date:0910032	

01/83/050/01603/AM08/	09/24/040/00379/AM08/	136 23.11.2007											
Decision : Committee considered case as per agenda for ratification of norms for export product Diltiazem HCL Pellets 50% under para 4.7 of HBP. Committee 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>Import items</th><th>Qty. allowed per unit of export product</th></tr> <tr> <td rowspan="2">Diltiazem Hcl Pellets 50% (ITC(HS)No.29420 090)</td><td rowspan="2">1kg.</td><td>1. Diltiazem Hcl</td><td>0.505kg/kg</td></tr> <tr> <td>2.Hydroxy Propyl Methyl Cellulose</td><td>0.094kg/kg</td></tr> </table> RA concerned may take further necessary action as per above decision of Norms Committee.				Export product	Export Qty.	Import items	Qty. allowed per unit of export product	Diltiazem Hcl Pellets 50% (ITC(HS)No.29420 090)	1kg.	1. Diltiazem Hcl	0.505kg/kg	2.Hydroxy Propyl Methyl Cellulose	0.094kg/kg
Export product	Export Qty.	Import items	Qty. allowed per unit of export product										
Diltiazem Hcl Pellets 50% (ITC(HS)No.29420 090)	1kg.	1. Diltiazem Hcl	0.505kg/kg										
		2.Hydroxy Propyl Methyl Cellulose	0.094kg/kg										

78	Case No.:35/39/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01614/AM08/	RLA File : 09/24/040/00164/AM07/	Lic.No/Date:0910032 258 28.11.2007	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Cephapirin Benzathine under para 4.7 of HBP. Committee decided to defer case for two weeks for comments of PI Division.			

79	Case No.:57/39/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01636/AM08/	RLA File : 09/24/040/00389/AM08/	Lic.No/Date:0910032 305 30.11.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Stavudine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/36/2007-PI-III dated 23.01.2008 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.	Import items	Qty. allowed per unit of export product
Stavudine (ITC(HS)No.29420 000)	1kg.	1. Beta thymidine	2.36kg/kg
		2. Pyridine	5.80kg/kg
		3.Methane Sulfonyl chloride	2.40kg/kg
		4.Methanol	6.18kg/kg
		5.N-Hexane	1.55kg/kg
		6.Potassium Tert. Butoxide	1.08kg/kg
		7.Tert. Butanol	0.82kg/kg
		8.Acetone	5.59kg/kg
		9.Iso Propyl Alcohol	4.20kg/kg

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

80	Case No.:96/39/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
	HQ File : 01/83/050/01675/AM08/	RLA File : 22/24/040/00055/AM08/	Lic.No/Date:2210007283 04.12.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Nitazoxanide under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/206/2006-PI-III dated 23.01.2008 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.	Import items	Qty. allowed per unit of export product
	Nitazoxanide (ITC(HS)No.29415 000)	1kg.	1. 2-Acetyloxy benzoic acid (Asprin)	0.916kg/kg
			2. 2-amino-5-nitro thiazole	0.59kg/kg
			3. Triethylamine	0.1288kg/kg
			4. Methylene chloride	3.17kg/kg
			5. N,N Dimethyl formamide	0.069kg/kg

		6. Acetone	2.00kg/kg
		7. Thionyl chloride	0.92kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

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Case No.:115/39/83-ALC1/2007	Party Name:DIVIS LABORATORIES LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/01694/AM08/	RLA File : 09/24/040/00400/AM08/	Lic.No/Date:0910032 363 07.12.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Cyclocytidine HCL under para 4.7 of HBP.			
Committee in light of its earlier decision taken in its 25/08 meeting held on 23.10.2007 vide Case No.B-349 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details given below or as applied by firm whichever is lower:-			
Export product	Export Qty.	Import items	Qty. allowed per unit of export product
Cyclocytidine Hcl (O,2-cyclocytidine Hcl) (ITC(HS)No.29420 029)	1kg.	1. Cytidine	2.93kg/kg
		2. Methanol	4.36kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.			

82	Case No.:138/39/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01717/AM08/	RLA File : 03/95/040/00892/AM08/	Lic.No/Date:0310453 332 10.12.2007	Defer Date: 19.04.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium – Non Infringing under para 4.7 of HBP.				

Committee decided to examine case on file as application is based on non-infringing process.

83	Case No.:173/39/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01752/AM08/	RLA File : 03/94/040/00853/AM08/	Lic.No/Date:0310453734 12.12.2007	Defer Date: 04.03.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Donepezil Hydrochloride under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

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Case No.:163/39/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:38/82-ALC4/2007 22.01.2008	Status:Case Approved
HQ File : 01/83/050/01742/AM08/	RLA File : 03/94/040/00936/AM08/	Lic.No/Date:0310454006 14.12.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Amiodarone HCL under para 4.7 of HBP.			
Committee in the light of written comments forwarded by PI Division vide theirU.O.35011/102/ 2006-PI-III dated 18.04.2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-			
Export product	Export Qty.	Import items	Qty. allowed per unit of export product
Amiodarone Hcl (ITC(HS)No.29420 090)	1kg.	1. 2-Butyl-3-(3,5-Diiodo-4-Hydroxybenzoyl) Benzofuran	1.04kg/kg
		2. Iso Propyl Alcohol	0.75kg/kg
		3. Toluene	1.95kg/kg

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

