

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

Para 4.7 Decision

MEETING NUMBER : 43/82-ALC4/2007 MEETING DATE : 04.03.2008

The Meeting No.43/08 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 due for 26.02.08 was actually held on **04.03.2008** under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No16/08 dated 21.08.2007, 17/08 dated 28.08.2007, 18/08 dated 06.09.2007, 19/08 dated 11.09.2007 and 20/08 dated 18.09.2007 were ratified by the Committee.

Case No.B-560	M/S Artemis Biotech
Norms Committee Meeting No.43/08	F.No.01/87/50/01324/AM05
Meeting Date:26.02.2008	RLA F.No.03/24/41/175/AM05
Adv.Lic.No.03102310813 dated 05.01.2005	
Committee considered case as per agenda for ratification of norms for export product Losarton Potassium under para 4.7 of HBP.	
Committee observed that Advance Authorisation was issued on 05.01.2005 while firm has furnished required information called for vide letter dated 7.9.05 only on 10.01.2008. The information is received after a gap of more than two and half years. Committee, therefore, decided to maintain status quo.	

Case No.B-561	M/S Alembic Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/5/AM08
Meeting Date:26.02.2008	RLA F.No.34/24/40/301/AM07
Adv.Lic.No.3410018454 dated 30.03.2007	
Committee considered case as per agenda for revision of norms for export product Azithromycin Step IV under para 4.7 of HBP.	
Committee observed that firm had applied and obtained Advance Authorisation for export of Azithromycin Crude and not for Azithromycin Step-4 and Azithromycin Crude can not be treated as 100% pure. Committee, therefore, decided to maintain status quo.	

Case No.B-562	M/S Alembic Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/149/AM08
Meeting Date:26.02.2008	RLA F.No.34/24/40/84/AM08
Adv.Lic.No.3410019403 dated 13.08.2007	
Committee considered case as per agenda for revision of norms for export product Azithromycin Step 3 under para 4.7 of HBP. Committee observed that firm had obtained Advance Authorisation for export of Azithromycin Step-3 (KGA) while in the decision of NC, same was mentioned "Azithromycin Step 3 (Aza Azithromycin". Committee, therefore, in consultation with representative of PI Division present in meeting decided to allow amendment in the description of export product to read as "Azithromycin Step-3 (KGA)". RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-563	M/S Alembic Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/150/AM08
Meeting Date:26.02.2008	RLA F.No.34/24/40/85/AM08
Adv.Lic.No.3410019404 dated 13.08.2007	
Committee considered case as per agenda for revision of norms for export product Azithromycin Step IV under para 4.7 of HBP. Committee observed that firm had obtained Advance Authorisation for export of Azithromycin Step-4 (KGA) while in the decision of NC, same was mentioned "Azithromycin Step-IV (Azithromycin Crude Purity NLT 94.5%)". Committee, therefore, in consultation with representative of PI Division present in meeting decided to allow amendment in the description of export product to read as "Azithromycin Step-IV (KGA)". RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-564	M/S Alembic Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/37/AM08
Meeting Date:26.02.2008	RLA F.No.34/24/40/290/AM07
Adv.Lic.No.3410018404 dated 23.03.2007	
Committee considered case as per agenda for revision of norms for export product Azithromycin Step IV under para 4.7 of HBP.	

Committee observed that firm had applied and obtained Advance Authorisation for export of Azithromycin Crude and not for Azithromycin Step-4 and Azithromycin Crude can not be treated as 100% pure. Committee, therefore, decided to maintain status quo.

Case No.B-565	M/S Advy Chemicals
Norms Committee Meeting No.43/08	F.No.01/87/50/313/AM07
Meeting Date:26.02.2008	RLA F.No.03/94/40/310/AM07
Adv.Lic.No.0310387468 dated 29.06.2006	
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 decided to defer case for three weeks for comments of DBT.	

Case No.B-566	M/S Wockhardt Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/162/548/AM07
Meeting Date:26.02.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product D-Oxyphene Base (Powder) (SION A-166). The representative of DOR did not attend the meeting and case could not be discussed in his absence. It was decided to defer case for two weeks.	

Case No.B-567	M/S Wockhardt Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/162/215/AM08
Meeting Date:26.02.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product Dextropropoxyphene Napsylate USP (SION A-175). The representative of DOR did not attend the meeting and case could not be discussed in his absence. It was decided to defer case for two weeks.	

Case No.B-568	M/S Wockhardt Ltd.
Norms Committee Meeting No.43/08	F.No.01/83/162/428/AM07
Meeting Date:26.02.2008	
Committee considered case as per agenda for fixation of value addition for revision of DEPB rate in respect of export product Dextromethorphan hydrobromide (SION A-173). The representative of DOR did not attend the meeting and case could not be discussed in his absence. It was decided to defer case for two weeks.	

Case No.B-569	M/S Lupin Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/162/285/AM06
Meeting Date:26.02.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 3C7ACCA (SION A-2119). The representative of DOR did not attend the meeting and case could not be discussed in his absence. It was decided to defer case for two weeks.	

Case No.B-570	M/S Penam laboratories Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/162/450/AM08
Meeting Date:26.02.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 6-APA (SION A-33). The representative of DOR did not attend the meeting and case could not be discussed in his absence. It was decided to defer case for two weeks.	

Case No.A-1084	M/S Glenmark Pharmaceuticals Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/267/AM08
Meeting Date:26.02.2008	RLA F.No.
Adv.Lic.No.0310450439 dated 16.11.2007	
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.A-1085	M/S Cadila Healthcare Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/278/AM08
Meeting Date:26.02.2008	RLA F.No. 08/24/40/203/AM08
Adv.Lic.No.0810068702 dated 28.11.2007	
Committee considered case as per agenda for ratification of norms for export product Warfarin Tablets under para 4.7 of HBP.	
Committee decided to defer case for two weeks for comments of PI Division.	

Case No.A-1086	M/S Cipla Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/215/AM08
Meeting Date:26.02.2008	RLA F.No. 03/94/40/621/AM08
Adv.Lic.No.0310443538 dated 18.09.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir Tablets under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1087	M/S Cipla Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/213/AM08
Meeting Date:26.02.2008	RLA F.No. 03/94/40/534/AM08
Adv.Lic.No.0310440647 dated 23.08.2007	
Committee considered case as per agenda for ratification of norms for export product Efavir Capsules 200mg and Efavir 600 mg Tablets under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1088	M/s Cipla Ltd.
M.No.43/08	F.No.01/82/50/251/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/747/AM08
Adv. Lic. No.0310447486 dt.23.10.2007	
The Committee considered the case as per agenda for ratification of norms for the export product (1) Nevimune 200 MG Tablets/Nevirapine 200MG Tablets (2) Nevirapine Oral Suspension 50 MG/5 ML/Nevimune under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1089	M/s Cipla Ltd.
M.No.43/08	F.No.01/82/50/153/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/485/AM08
Adv. Lic. No.0310439033 dt.09.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Gemcitabine Okasa Pharma under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1090	M/s Cipla Ltd.
M.No.43/08	F.No.01/82/50/160/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/524/AM08
Adv. Lic. No.0310440273 dt.21.08.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Irinotecan Hydrochloride Injection 40MG/2ML(each Vial 2ML)/Irinotecan Hydrochloride Injection 100MG/5ML(each Vial 5ML) under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1091	M/s Cipla Ltd.
M.No.43/08	F.No.01/82/50/152/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/437/AM08
Adv. Lic. No.0310437618 dt.27.07.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Triomune 30/Lamivudine Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1092	M/S Cipla Ltd.
Norms Committee Meeting No.43/08	F.No.01/82/50/255/AM08
Meeting Date 26.02.2008	RLA F.No.03/94/40/798/AM08
Adv.Lic.No.0310448930 dated	

02.11.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablet/Lamivudine Tablet 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 Bany Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 100mg/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamidudine, Zidovudine and nevirapine Tablets/Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1093	M/s Cipla Ltd.
M.No.43/08	F.No.01/82/50/250/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/749/AM08
Adv. Lic. No.0310447493 dt.23.10.2007	
The Committee considered the case as per agenda for ratification of norms for the export product Lamivir under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1094	M/s Arch Pharma Labs Ltd.
M.No.43/08	F.No.01/82/50/268/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/715/AM08
Adv. Lic. No.0310451131 dt.22.11.2007	
The Committee considered the case as per agenda for ratification of norms for the export product (1 R₂,S₅ R)-Methyl-5S-(Cytosine-I-YL) 1-3-Oxathiolane -2R-Carboxylate/CME Compound under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-1095	M/s Arch Pharma Labs Ltd.
M.No.43/08	F.No.01/82/50/269/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/94/40/713/AM08
Adv. Lic. No.0310451128 dt.22.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product (1 R2,S,5 R)-Methyl-5S-(Cytosine-I-YL) 1-3-Oxathiolane -2R-Carboxylate/CME Compound under para 4.7 of HBP.

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

Case No.A-1096	M/s Aurobindo Pharma Ltd.
M.No.43/08	F.No.01/82/50/266/AM 08
Meeting Date 26.02.2008	RLA F. No. 09/24/40/380/AM08
Adv. Lic. No.0910032134 dt.22.11.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 04.03.2008 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 Quantity	Sl.No.	Import items	Qty. allowed per unit of export product
Didanosine	1kg.	1.	2',3-Didehydro-2',3'-Dideoxyinosine Sodium Salt	2.212kg/kg
		2.	Acetic Acid	0.534kg/kg
		3.	5% Palladium on carbon	0.050kg/kg
		4.	Activated Carbon	0.100kg/kg
		5.	Methanol	6.21kg/kg

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

Case No.A-1097	M/s Glenmark Pharmaceuticals Ltd.
M.No.43/08	F.No.01/82/50/339/AM 08
Meeting Date 26.02.2008	RLA F. No. 03/24/40/405/AM04
Adv. Lic. No.0310209606 dated 23.06.2003	

The Committee considered the case as per agenda for ratification of norms for the export product Glimepride under para 4.7 of HBP on the request of RA that no norms has been fixed earlier in this case and no decision of Committee is available with them.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/127/2006-PI-III dated 14.08.2006 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	Sl.No.	Import items	Qty allowed per unit of export product
Glimepride	1kg.	1.	4-(2-3-Ethyl-4-Methyl-2-Oxo-3-Pyrroline-1-Carboxamido Ethyl Phenyl Sulfonamide)	0.96kg/kg
		2.	Trans-4-Methyl Cyclohexyl Isocyanate	0.39kg/kg

RA concerned may take further necessary action as per above decision of Norms committee. In case any different decision has been taken contrary to above decision, the onus lies on the RA & firm.

1	Case No.:61/24/87-ALC1/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/87/050/00084/AM06/	RLA File : 34/24/040/00007/AM06/	Lic.No/Date:34100132 61 27.04.2005	Defer Date: 22.04.2008
	Decision :Committee considered case as per agenda for ratification of norms for export product Modafinil under para 4.7 of HBP. Committee observed that case was received from DES-VII on 02.01.2008. Committee decided to defer case for six weeks for comments of PI Division.			

2	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/82/050/01441/AM07/	RLA File : 09/24/040/00390/AM07/	Lic.No/Date:09100286 34 13.12.2006	Defer Date: 08.04.2008

Decision : Committee considered case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-Lysine-Prasine (Lyspro (Isolated) under para 4.7 of HBP.

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

Case No.:16/49/82-ALC1/2006	Party Name:LUPIN LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
HQ File : 01/82/050/01721/AM07/	RLA File : 03/95/040/01297/AM07/	Lic.No/Date:03104167 16 22.01.2007	Defer Date: 22.04.2008

Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium-Non Intringing under para 4.7 of HBP.

Committee decided to examine the case on file.

Case No.:879/21/82-ALC4/2007	Party Name:LAKE CHEMICALS PRIVATE LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Approved
HQ File : 01/82/050/01714/AM07/	RLA File : 07/24/040/00780/AM07/	Lic.No/Date:07100503 14 27.02.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/30/2007-PI-III dated 04.03.2008 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 Quantity	Sl.No.	Import items	Qty. allowed per unit of export product
Dorzolamide	1kg.	1.	Methyl-R-hydroxy Butyrate	4.78kg/kg
		2.	Thiophene	2.70kg/kg
		3.	Boron trifluoride itehrate	2.78kg/kg
		4.	Tetrahydrofuran	18.00kg/kg
		5.	Sodium Borohydride	0.60kg/kg

		6.	Synhydride	7.96kg/kg
RA concerned may take further necessary action as per above decision of Norms Committee.				

5	Case No.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/82/050/01804/AM07/	RLA File : 03/94/040/01443/AM07/	Lic.No/Date:03104229 72 13.03.2007	Defer Date: 08.04.2008
	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 defer case for four weeks for comments of PI Division.			

6	Case No.:951/21/82-ALC4/2007	Party Name:MAHAVIR DYE CHEM	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/82/050/01813/AM07/	RLA File : 52/24/040/00006/AM07/	Lic.No/Date:52100212 88 15.03.2007	Defer Date: 22.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 2(3-Amino Phenyl Sulfonamide)Naptalene 6.8 Di Sulfonic Acid under para 4.7 of HBP. Committee decided to forward a copy of application to Chemical Division of C&PC for their comments. Accordingly, case was deferred for six weeks.			

7	Case No.:17/9/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Rejected
	HQ File : 01/82/050/01837/AM07/	RLA File : 03/94/040/01468/AM07/	Lic.No/Date:03104237 77 21.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Exemestane under para 4.7 of HBP. Committee decided to withdraw case as case has already been rejected in its 40/08 meeting held on 03.03.2008.			

8	Case No.:25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/00016/AM08/	RLA File : 04/24/040/00501/AM07/	Lic.No/Date:04100887 27 02.04.2007	Defer Date: 22.04.2008
	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.			

9	Case No.:19/19/83-ALC1/2007	Party Name:GRANULES INDIA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/00029/AM08/	RLA File : 09/24/040/00534/AM07/	Lic.No/Date:09100298 86 04.04.2007	Defer Date: 22.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Naproxen Granules DC Grade 80% (Compresso NAP 80) under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

10	Case No.:14/14/83-ALC1/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/00127/AM08/	RLA File : 05/24/040/00041/AM08/	Lic.No/Date:05102026 22 17.04.2007	Defer Date: 22.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 3,4-Dihydro-4-oxo-6-acetyloxy-7-methoxyquinazoline under para 4.7 of HBP. Committee decided to forward a copy of application to Chemical Div. of C&PC for their comments. Accordingly, case was deferred for six weeks.			

11	Case No.:730/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/00623/AM08/	RLA File : 09/24/040/00120/AM08/	Lic.No/Date:09100306 86 29.06.2007	Defer Date: 08.04.2008

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.:80/19/83-ALC1/2007	Party Name:MDB CHEMICALS (INDIA) PVT.LTD.	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
HQ File : 01/83/050/00636/AM08/	RLA File : 31/21/040/00084/AM08/	Lic.No/Date:31100297 17 02.07.2007	Defer Date: 22.04.2008

12 Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Methylenedioxybenzene under para 4.7 of HBP.

Committee decided to forward a copy of application to Chemical Div. of C&PC for their comments. Accordingly, case was deferred for six weeks.

Case No.:113/21/82-ALC4/2007	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case
HQ File : 01/82/050/00157/AM08/	RLA File : 22/24/040/00030/AM08/	Lic.No/Date:22100069 84 20.08.2007	

13 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 withdraw case as case has been considered in its 41/82 meeting held on 03.03.2008.

Case No.:7/25/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
HQ File : 01/83/050/01032/AM08/	RLA File : 09/24/040/00231/AM08/	Lic.No/Date:09100313 14 29.08.2007	Defer Date: 22.04.2008

14 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 six weeks for comments of PI Division.

15	Case No.:12/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01086/AM08/	RLA File : 03/94/040/00555/AM08/	Lic.No/Date:03104415 61 31.08.2007	Defer Date: 08.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Saquinavir 200mg Capsules Saqvir 200mg Capsules under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

16	Case No.:54/27/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01128/AM08/	RLA File : 03/94/040/00525/AM08/	Lic.No/Date:03104419 78 06.09.2007	Defer Date: 08.04.2008
	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.			

17	Case No.:69/27/83-ALC1/2007	Party Name:CODEXIS LABORATORIES INDIA PVT.LTD,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01143/AM08/	RLA File : 05/24/040/00396/AM08/	Lic.No/Date:05102087 76 10.09.2007	Defer Date: 08.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product (4R-Cis)-1,1-Dimethylethyl-6-Cyuanomethyl-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.			

18	Case No.:10/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/82/050/00180/AM08/	RLA File : 03/94/040/00615/AM08/	Lic.No/Date:03104428 78 12.09.2007	Defer Date: 08.04.2008
	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.

Case No.:2/25/82-
ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:43/82-
ALC4/2007
26.02.2008

Status:Case
Deferred

HQ File :
01/82/050/00196/AM08/

RLA File :
03/94/040/00664/AM08/

Lic.No/Date:03104450
42
03.10.2007

Defer
Date:
08.04.2008

19 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.

Case No.:7/29/83-
ALC1/2007

Party Name:CODEXIS
LABORATORIES INDIA
PVT.LTD,

Meet No/Date:43/82-
ALC4/2007
26.02.2008

Status:Case
Deferred

HQ File :
01/83/050/01272/AM08/

RLA File :
05/24/040/00518/AM08/

Lic.No/Date:05102098
61
03.10.2007

Defer
Date:
08.04.2008

20 Decision : Committee considered case as per agenda for ratification of norms for export product (4R-Cis)-1,1-Dimethylethyl-6-Cyuanomethyl-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.

Case No.:24/30/83-
ALC1/2007

Party Name:AUCTUS
PHARMA PRIVATE LIMITED

Meet No/Date:43/82-
ALC4/2007
26.02.2008

Status:Case
Deferred

HQ File :
01/83/050/01393/AM08/

RLA File :
09/24/040/00319/AM08/

Lic.No/Date:09100318
43
23.10.2007

Defer
Date:
08.04.2008

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

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

22	Case No.:53/30/83-ALC1/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01422/AM08/	RLA File : 09/24/040/00560/AM07/	Lic.No/Date:09100318 81 24.10.2007	Defer Date: 22.04.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Cyclopropyl Diol Cyclic Sulfite under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.				

23	Case No.:51/30/83-ALC1/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Withdrawn
	HQ File : 01/83/050/01420/AM08/	RLA File : 09/24/040/00276/AM08/	Lic.No/Date:09100318 79 24.10.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Indinavir Sulphate under para 4.7 of HBP. Committee decided to withdraw case as case has been considered in its 40/82 meeting held on 03.03.2008.				

24	Case No.:82/32/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Withdrawn
	HQ File : 01/83/050/01504/AM08/	RLA File : 09/24/040/00051/AM08/	Lic.No/Date:09100319 91 05.11.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Cefepime Hcl for Injection under para 4.7 of HBP. Committee decided to withdraw case as case has been approved in its 40/82 meeting held on 03.03.2008.				

25	Case No.:92/32/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01514/AM08/	RLA File : 03/94/040/00814/AM08/	Lic.No/Date:03104494 95 06.11.2007	Defer Date: 22.04.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Pantoprazole Sodium Sesquihydrate under para				

4.7 of HBP.

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

26	Case No.:32/33/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01561/AM08/	RLA File : 09/24/040/00256/AM08/	Lic.No/Date:09100320 90 14.11.2007	Defer Date: 22.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Cyclohexyl Ester under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

27	Case No.:60/39/83-ALC1/2007	Party Name:SANJAY SALES CORPORATION	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01639/AM08/	RLA File : 03/95/040/00792/AM08/	Lic.No/Date:03104516 62 27.11.2007	Defer Date: 22.04.2008
	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 forward a copy of application to Chemical div. of C&PC for their comments. Accordingly, case was deferred for six weeks.			

28	Case No.:34/39/83-ALC1/2007	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01613/AM08/	RLA File : 09/24/040/00385/AM08/	Lic.No/Date:09100322 45 28.11.2007	Defer Date: 08.04.2008
	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 decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for four weeks.			

29	Case No.:95/39/83-ALC1/2007	Party Name:SYMBIOTEC PHARMALAB LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Approved
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HQ File : 01/83/050/01674/AM08/	RLA File : 11/24/040/00048/AM08/	Lic.No/Date:11100164 77 03.12.2007	
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Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocortisone Sodium Succinate Buffered 5% Sterile under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/209/2006-PI-III dated 04.03.2008 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 Quantity	Sl.No.	Import item	Quantity allowed per unit of export product
Hydrocortisone sodium succinate buffered 5% sterile	1kg.	1.	Hydrocortisone BP/USP	1.10kg/kg

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

Case No.:161/39/83-ALC1/2007	Party Name:SYMBIOTEC PHARMALAB LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Withdrawn
HQ File : 01/83/050/01740/AM08/	RLA File : 11/24/040/00050/AM08/	Lic.No/Date:11100165 15 11.12.2007	
30	Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocortisone Acetate BP (Micronised) under para 4.7 of HBP. Committee decided to withdraw case as case has been approved in its 40/08 meeting held on 03.03.2008.		

Case No.:160/39/83-ALC1/2007	Party Name:SYMBIOTEC PHARMALAB LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Approved
31	HQ File : 01/83/050/01739/AM08/	RLA File : 11/24/040/00046/AM08/	Lic.No/Date:11100165 26 12.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocortisone Sodium Succinate for Injection		

USP under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/209/2006-PI-III dated 04.03.2008 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 Quantity	Sl.No.	Import item	Quantity allowed per unit of export product
Hydrocortisone sodium succinate buffered 5% sterile	1kg.	1.	Hydrocortisone BP/USP	1.10kg/kg

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

32	Case No.:9/40/83-ALC1/2007	Party Name:KUDUES CHEMIE LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/83/050/01774/AM08/	RLA File : 22/24/040/00059/AM08/	Lic.No/Date:22100073 29 27.12.2007	Defer Date: 22.04.2008
	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 six weeks for comments of PI Division.			

33	Case No.:1/43/82-ALC4/2007	Party Name:KUDUES CHEMIE LTD.,	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Deferred
	HQ File : 01/82/050/00459/AM08/	RLA File : 22/24/040/00065/AM08/	Lic.No/Date:22100074 51 13.02.2008	Defer Date: 22.04.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Synthetic Caffeine under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of PI Division.			

34	Case No.:2/43/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:43/82-ALC4/2007	Status:Case Approved
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		26.02.2008		
HQ File : 01/82/050/00460/AM08/	RLA File : 22/24/040/00063/AM08/	Lic.No/Date:22100074 55 14.02.2008		
Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate Through Enzymatic Route under para 4.7 of HBP.				
Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 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 the firm whichever is lower:-				
Export product	Export Qty.	Sl.No	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
		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.				

35	Case No.:3/43/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Approved
	HQ File : 01/82/050/00461/AM08/	RLA File : 22/24/040/00064/AM08/	Lic.No/Date:22100074 57 14.02.2008	

Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Trihydrate through Enzymatic Route under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 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 the firm whichever is lower:-

Export product	Export Qty.	Sl.No	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
		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.:4/43/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:43/82-ALC4/2007 26.02.2008	Status:Case Approved
HQ File : 01/82/050/00462/AM08/	RLA File : 22/24/040/00061/AM08/	Lic.No/Date:22100074 58 14.02.2008	

36

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

Committee in light of written comments forwarded by PI Division vide

their U.O. No.35011/165/2006-PI-III dated 09.03.2007 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 Quantity	Sl.No.	Import items	Qty. allowed per unit of export product
6-Amino Penicillin Acid (6 APA)	1kg.	1.	Penicillin G Pot. 1 st crystal	2.92BOU/kg
		2.	Penicillin G Amidase Enzyme	0.096gm/kg
		3.	Boric Acid	0.055kg/kg
		4.	Methanol-	0.04kg/kg
		5.	Butyl Acetate	0.214kg/kg
		6.	P.T. Resin	0.004ltd/kg

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