

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

Para 4.7 Decision

MEETING NUMBER : 29/82-ALC4/2007 MEETING DATE : 20.11.2007

Case No.B-403	M/S Alkem Laboratories Ltd.	
NC Meeting No.29/08	F.No.01/83/50/409/AM08	
Meeting Date: 20.11.2007	RLA F.No.03/94/40/187/AM08	
Adv.Lic.No.0310430680 dated 25.05.2007		
Committee considered case as per agenda for ratification of norms for export product Sucralose USP under para 4.7 of HBP.		
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.		
Export product: Sucralose USP-----1kg.		
Import items:		
Sl.No.	Description of import items	Quantity allowed
1.	Acetic Acid	38.93kg/kg
2.	Dimethyl formamide	0.37lts/kg
3.	Ethylene dichloride	10.22lts/kg
4.	Methanol	2.31lts/kg
5.	Pharma grade sugar	3.18kg/kg
6.	Pet Ether 60/80	1.26Lts/kg
7.	Pyridine	1.49Lts/kg
8.	Sulphuryl chloride	4.71Lts/kg
9.	Toluene	0.97Lts/kg
10.	Trityl chloride	1.56kg/kg
Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms.		
RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.		

Case No.B-404	M/S Process Chemicals Co.
NC Meeting No.29/08	F.No.01/83/50/485/AM07
Meeting Date: 20.11.2007	
Adv.Lic.No.0210092098 dated 1.8.06 Adv.Lic.No.0210083908 dated 1.12.05 Adv.Lic.No.0210083906 dated 1.12.05	
Committee considered case as per agenda for enhancement in the quantity of input Potassium Hydroxide Flakes 90% for export product Monopotassium Glucarate and Calcium D-Saccharate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/101/2007-PI-III dated 14.11.2007 (2 Nos) decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Calcium D-Saccharate-----1Kg. Import item: Potassium Hydroxide Flakes 90%-----1.01kg/kg Export product: Monopotassium Glucarate-----1Kg. Import item: Potassium Hydroxide Flakes 90%-----1.31kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.B-405	M/S Miles International
NC Meeting No.29/08	F.No.01/82/50/1002/AM07
Meeting Date: 20.11.2007	RLA F.No.03/95/40/314/AM07
Adv.Lic.No.0310386250 dated 22.06.2007	
Committee considered case as per agenda for ratification of norms for export product Dithranol BP/EP/Dithranol under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four	

weeks. Committee accordingly decided to defer case for four weeks.

Case No.B-406	M/S M.J. Biopharma Pvt. Ltd.
NC Meeting No.29/08	F.No.01/82/50/17/AM08
Meeting Date: 20.11.2007	RLA F.No.03/95/40/21/AM08
Adv.Lic.No.0310427662 dated 23.04.2007	
Committee considered case as per agenda for ratification of norms for export product Prednilolone Sodium Phosphate Inj. 30mg/1ml under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee accordingly decided to defer case for two weeks.	

Case No.B-407	M/S Neuland Laboratories Ltd.				
NC Meeting No.29/08	F.No.01/83/50/167/AM08				
Meeting Date: 20.11.2007	RLA F.No.09/24/40/214/AM08				
Adv.Lic.No.0910031312 dated 29.08.2007					
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. as per details below:- <table><tr><th>From</th><th>To</th></tr><tr><td>Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl</td><td>Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl /[(S,S)-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride].</td></tr></table> RA concerned may take further necessary action as per above decision of Norms Committee.		From	To	Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl	Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl /[(S,S)-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride].
From	To				
Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl	Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hcl /[(S,S)-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride].				

Case No.B-408	M/S Gulf Oil Corporation Ltd.
NC Meeting No.29/08	F.No.01/82/50/1215/AM07
Meeting Date: 20.11.2007	RLA F.No.09/24/40/194/AM07
Adv.Lic.No.0910028005 dated 31.10.2006	
Committee considered case as per agenda for ratification of norms for export product Sodium Cromo Glycate under para 4.7 of HBP. Committee decided to hand over case file to representative of PI Division present in meeting for their comments. Accordingly, case was deferred for four weeks.	

Case No.B-409	M/S Alchem International Ltd.
NC Meeting No.29/08	F.No.01/87/50/1374/AM05
Meeting Date: 20.11.2007	RLA F.No.05/24/40/542/AM05
Adv.Lic.No.0510148830 dated 17.01.2005	
Committee considered case as per agenda for ratification of norms for export product Hyoscine-N-Butyl Bromide or Hyoscine Hydro Bromide under para 4.7 of HBP. Committee decided to constitute a committee to visit plant of firm to verify the inputs and quantity actually required. Accordingly, case was deferred for six weeks.	

Case No.B-410	M/S Rashmi Pharma Ltd.
NC Meeting No.29/08	F.No.01/83/50/1327/AM07 F.No.01/83/50/836/AM08 01/83/50/486/AM08
Meeting Date: 20.11.2007	RLA F.No.09/24/40/506/AM07 RLA F.No.09/24/40/163/AM08 RLA F.No.09/24/40/88/AM08
Adv.Lic.No.0910029625 dated 09.03.2007 Adv.Lic.No.0910030992 dated 24.07.2007 Adv.Lic.No.0910030478 dated	

07.06.2007	
Committee considered case as per agenda for enhancement in the quantity of input under para 4.7 of HBP. Committee observed that quantity of input has already been allowed correctly and therefore request of firm for enhancement has no merit. Committee, therefore, decided to maintain status quo.	

Case No.B-411	M/S Wockhardt Ltd.
NC Meeting No.29/08	F.No.01/82/162/215/AM08
Meeting Date: 20.11.2007	
Committee considered case as per agenda for fixation of value addition for DEPB rate for export product Dextropropoxyphene Napsylate USP (SION at Sl.No.A-175) Committee decided to refer the case to DEPB Committee recommending 425% value addition.	

Case No.B-412	M/S Wockhardt Ltd.
NC Meeting No.29/08	F.No.01/82/162/548/AM07
Meeting Date: 20.11.2007	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product Oxyphene Base (Powder) (SION at Sl.No.A-166). Committee decided to defer case for four weeks for want of comments of Department of Revenue in respect of value addition .	

Case No.B-413	M/S Merck Ltd.
NC Meeting No.29/08	F.No.01/82/50/884/AM06
Meeting Date: 20.11.2007	RLA F.No.03/95/40/908/AM06
Adv.Lic.No.0310375053 dated 05.04.2006	
Committee considered case as per agenda for modification of norms for	

export product Thiamine Disulfide 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 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Thiamine Disulfide-----1Kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	Thiamine Hcl IP/BP/USP (Vitamin B1 Hcl)	1.4199kg/kg
2.	Sodium Hydroxide Pellets	0.4634kg/kg
3.	Potassium Hexacyanoferrate (III) GR	0.0022kg/kg
4.	Hydrochloric Acid fuming 37%	0.3356kg/kg
5.	Hydrogen Peroxide Solution 35% extra pure	0.2157kg/kg
6.	Acetone	0.8702ltrs/kg

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

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

Case No.A-845	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/175/ASM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/571/AM08 /615/AM08 /650/AM08 /553/AM08 /578/AM08 /534/AM08 /688/AM08 /1267/AM07 /674/AM08 /535/AM08 /383/AM08 /250/AM08 /524/AM08
Adv.Lic.No.0310441556 dated 31.08.2007 0310442878 dated 12.09.2007 0310444204 dated 25.09.2007	

27.08.2007	0310440694 dated	
05.09.2007	0310441096 dated	
23.08.2007	0310440647 dated	
03.10.2007	0310445044 dated	
19.09.2007	0310443538 dated	
03.10.2007	0310445040 dated	
22.08.2007	0310440229 dated	
13.07.2007	0310436156 dated	
08.06.2007	0310432136 dated	
21.08.2007	0310440273 dated	
Committee considered cases as per agenda for ratification of norms for export product under para 4.7 of HBP. Committee decided to call for the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.		

Case No.A-846	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/211/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/553/AM08
Adv.Lic.No.0310440694 dated 27.08.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablets, Lamivir S-30 Tablets, Lamivir S-40 Tablets and Lamivudine Oral Solution/Lamivir under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-847	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/210/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/578/AM08

Adv.Lic.No.0310441906 dated 05.09.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablets, Lamivir S-30 Tablets, Lamivir S-40 Tablets and Lamivudine Oral Solution/Lamivir under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-848	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/213/AM08
Meeting Date: 20.11.2007	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/Efavirenz 200mg Capsules and Efavir 600mg Tablet/Efavirenz 600mg Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-849	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/216/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/688/AM08
Adv.Lic.No.0310445044 dated 03.10.2007	
Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-850	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/215/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/621/AM08
Adv.Lic.No.0310443358 dated 18.09.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir HBV Tablets 100mg/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, lamivudine, Zidovudine and Nevirapine Tablets Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-851	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/214/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/674/AM08
Adv.Lic.No.0310445040 dated 03.10.2007	
Committee considered case as per agenda for ratification of norms for export product Telmisartan and Amlodipin Tablets 40/10mg, Telmisartan and Amlodipin Tablets 80/10mg, Telmisartan and Amlodipin Tablets 40/5mg and Telmisartan and Amlodipin Tablets 80/5mg under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-852	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/158/ASM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/535/AM08
Adv.Lic.No.0310440429 dated 22.08.2007	
Committee considered case as per agenda for ratification of norms for export product Budecort 200 Inhaler (200MD)/Aerobud Inhaler (200MD)/Budesonide Generis 200 Inhaler (200MD) and Budecort 100 Inhaler (200MD)/Budesonida 100mcg Inhaler (200MD)/Sycort 100mcg HFA Inhaler (200MD) under para 4.7 of HBP.	

Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.

Case No.A-853	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/162/169/ASM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/250/AM08
Adv.Lic.No.0310432136 dated 08.06.2007	
Committee considered case as per agenda for ratification of norms for export product Stavir 15mg Capsules /Stavudine Capsules 15mg, Stavir 20mg Capsules/Stavudine Capsules 20mg, Stavir 30mg Capsules/Stavudine Capsules 30mg, Stavir 40mg Capsules/Stavudine Capsules 40mg, Lamivir S 30 Lamivudine and Stavudine Tablets and Lamivir S 40 Lamivudine and Stavudine Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-854	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/160/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/524/AM08
Adv.Lic.No.0310440273 dated 21.08.2007	
Committee considered case as per agenda for ratification of norms for export product Irinotecan Hcl Injection 40mg/2ml and Irinotecan Hcl Injection 100mg/5ml under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-855	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/136/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/383/AM08

Adv.Lic.No.0310436156 dated 13.07.2007	
Committee considered case as per agenda for ratification of norms for export product Stavir 15mg Capsules, Stavir 20mg Capsules, Stavir 30mg Capsules, Stavir 40mg Capsules, Lamivir S 30 and Lamivir S 40 under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-856	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/224/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/708/AM08
Adv.Lic.No.0310445737 dated 09.10.2007	
Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-857	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/223/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/706/AM08
Adv.Lic.No.0310445735 dated 03.10.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivir HBV Tablets 100mg, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamivudine, Zidovudine and Nevirapine Tablets Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-858	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/155/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/473/AM08
Adv.Lic.No.0310438672 dated 07.08.2007	
Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-859	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/152/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/437/AM08
Adv.Lic.No.0310437618 dated 27.07.2007	
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 observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-860	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/188/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/554/AM08
Adv.Lic.No.0310441419 dated 30.08.2007	
Committee considered case as per agenda for ratification of norms for export product Lopinavir and Ritonavir Tablets 200/50mg/Lopimune Tables/Lopinavir and Lopinavir and Ritonavir Capsules/Lopimune Capsules/Lopinavir under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal	

hearing on 18.12.2007. Accordingly, case was deferred for four weeks.

Case No.A-861	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/168/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/17/AM08
Adv.Lic.No.0310426065 dated 10.04.2007	
Committee considered case as per agenda for ratification of norms for export product Triomune 30/Lamivudine, Stavudine and Vevirapine Tablets and Triomune 40/Lamivudine. Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-862	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/153/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/485/AM08
Adv.Lic.No.0310439033 dated 09.08.2007	
Committee considered case as per agenda for ratification of norms for export product Gemcitabine Okasa Pharma (Gemcicross)1g Injection/Gemcitabine Hydrochloride Injection 1000mg/Oncogem 1000Injection and Gemcitabine 200mg Injection/Gemcitabine Hydrochloride Injection 200mg/Oncogem 200 Injection under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-863	M/S Cadila Healthcare Ltd.
NC Meeting No.29/08	F.No.01/82/50/191/AM08
Meeting Date: 20.11.2007	RLA F.No.08/24/40/150/AM08
Adv.Lic.No.0810067103 dated 11.09.2003	
Committee considered case as per agenda for ratification of norms for export product Hydroxychloroquine Sulfate 200mg Tabs under para 4.7 of HBP.	

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.

Case No.A-864	M/S Cadila Healthcare Ltd.
NC Meeting No.29/08	F.No.01/82/50/192/AM08
Meeting Date: 20.11.2007	RLA F.No.08/24/40/158/AM08
Adv.Lic.No.0810067315 dated 24.09.2007	
Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate Pharma Grade under para 4.7 of HBP.	
Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.	

Case No.A-865	M/S Aurobindo Pharma Ltd.
NC Meeting No.29/08	F.No.01/82/50/127/AM08
Meeting Date: 20.11.2007	RLA F.No.09/24/40/469/AM08
Adv.Lic.No.0910030086 dated 24.04.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Sulbactam Sodium (2:1) under para 4.7 of HBP.	
Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.	

Case No.A-866	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/193/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/540/AM08
Adv.Lic.No.0310440643 dated 23.08.2007	
Committee considered case as per agenda for ratification of norms for export product Cyproterone Acetate Tablets 100mg and 50mg under para 4.7 of HBP.	
Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-867	M/S Cipla Ltd.
NC Meeting No.29/08	F.No.01/82/50/194/AM08
Meeting Date: 20.11.2007	RLA F.No.03/94/40/582/AM08
Adv.Lic.No.0310441827 dated 05.09.2007	
Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.	

Case No.A-868	M/S Granules India Ltd.
NC Meeting No.29/08	F.No.01/82/50/393/AM08
Meeting Date: 20.11.2007	RLA F.No.09/24/40/46/AM08
Adv.Lic.No.0910030337 dated 24.05.2007	

Committee considered case as per agenda for ratification of norms for export product Compresso ANG90 (Metamizole Sodium Granules DC Grade 90%) under para 4.7 of HBP.

Committee in consultation with technical authorities and in light of its earlier decision taken in its 9/82 meeting held on 31.05.2006 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:
Compresso ANG 90 (Metamizole Sodium Granules DC Grade 90%-----1Kg.

Import items:

Sl.No.	Description of import items	Quantity allowed
1.	Metamizole Sodium	0.909kg/kg
2.	Maize Starch	0.060kg/kg
3.	Povidone	0.010kg/kg
4.	Sodium Starch Glycollate	0.020kg/kg
5.	Magnesium Stearate	0.010kg/kg

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

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

Case No.A-869	M/S Lyka BDR Int. Ltd
NC Meeting No.29/08	F.No.01/82/50/89/AM08
Meeting Date: 20.11.2007	RLA F.No.03/95/40/1309/AM07
Adv.Lic.No.0310419266 dated 12.02.2007	
Committee considered case as per agenda for ratification of norms for export product Clobetasole Propionate Cream 10GM, Clobetasole Propionate Cream 15gm, Clobetasole Propionate Cream 30gm, Clobetasol Propionate Topical Solution 0.05% W/V and Clobetasol Propionate topical Solution 0.05%W/V under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.	

Case No.A-870	M/S Lupin Ltd.
NC Meeting No.29/08	F.No.01/82/50/119/AM08
Meeting Date: 20.11.2007	RLA F.No.03/95/40/293/AM08
Adv.Lic.No.0310433980 dated 26.06.2007	
Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium 1gm Inj., 2gm Inj. And 250mg Injection under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.	

Case No.A-871	M/S Ranbaxy Lab. Ltd.
NC Meeting No.29/08	F.No.01/82/50/206/AM08
Meeting Date: 20.11.2007	RLA F.No.05/24/40/401/AM08
Adv.Lic.No.0310445044 dated 03.10.2007	
Committee considered case as per agenda for ratification of norms for export product Citalopram Hydrobromide Tablets 10mg, 20mg and 40mg under para 4.7 of	

HBP.

Committee perused comments of PI Division forwarded by their U.O. No.35011/85/2007-PI-III dated 20.11.2007 and decided to call for the country of export from firm and whether the application is based on non-infringing process. Accordingly, case was deferred for six weeks.

1	Case No.: 31/30/87- ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Ca se Deferred
	HQ File : 01/87/050/00870/AM06/	RLA File : 02/24/040/00154/AM06/	Lic.No/Date:02100827 77 17.10.2005	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cascara Dry Extract (Powdered) under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of MSME.			

2	Case No.: 3/46/87- ALC1/2005	Party Name:SNEHAL PHARMA CHEM	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Ca se Transferr ed
	HQ File : 01/87/050/01278/AM06/	RLA File : 34/24/040/00237/AM06/	Lic.No/Date:34100153 24 25.01.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-N-Butyl Benzofuran Clear Liquid under para 4.7 of HBP. Committee in view of written comments forwarded by PI Division vide their U.O. No.35011/98/2006-PI-III and in consultation with representative of DCGI decided to transfer case to DES-IV as Benzofuran derivatives have been indicated in the literature to be used in artificial flavours.			

3	Case No.: 39/9/82- ALC1/2006	Party Name:KDL BIOTECH LIMITED	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Ca se Rejected
	HQ File : 01/82/050/00209/AM07/	RLA File : 03/94/040/00021/AM07/	Lic.No/Date:03103798 82 10.05.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Flu-Cloxacillin Sodium BP/USP/EP under para 4.7 of HBP.			

Committee observed that firm and Pharmexcil were requested to furnish data, but same has not been received. Since data is not forthcoming, Committee decided to close the case.

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

4	Case No.:2/34/82-ALC1/2006	Party Name:DISHMAN PHARMACEUTICALS & CHEMICALS LTD	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00593/AM07/	RLA File : 08/24/040/00247/AM06/	Lic.No/Date:08100583 23 24.07.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 1-Carbethoxy Ethylidene Triphenyl Phosphorane under para 4.7 of HBP.			
	Committee decided to withdraw case as same has already been transferred to DES-IV.			

5	Case No.:375/24/83-ALC1/2007	Party Name:RA CHEM PHARMA LIMITED.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/83/050/00935/AM07/	RLA File : 09/24/040/00205/AM07/	Lic.No/Date:09100282 85 21.11.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Metaxalone under para 4.7 of HBP.			
	Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/66/2007-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Metaxalone-----1Kg. Import items: 1. 3,5-dimethyl phenol-----0.86kg/kg 2. Epichlorohydrin-----1.93kg/kg 3. Sodium hydroxide flakes-----0.83kg/kg 4. Polyethylene with glycol-----2.50kg/kg 5. Toluene-----2.43kg/kg			

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

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

6	Case No.:16/49/82-ALC1/2006	Party Name:LUPIN LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	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: 18.12.2007
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 observed that export product is Sterile Ceftriazone Sodium Non Infringing which is required to be examined from policy view point. It was therefore decided to examine the case on file.				

7	Case No.:437/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/83/050/01236/AM07/	RLA File : 09/24/040/00377/AM07/	Lic.No/Date:0910029305 12.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product N-Carbethoxy-4-Piperidinol (OR) 4-Hydroxy-N-Carbethoxy Peperidine (OR) N-Carbethoxy-4-Hydroxy Piperidine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: N-carboethoxy-4-piperidinol (Or) 4-hydroxy-N-carbethoxy Piperidine-----1Kg. Import items: 1. Methanol-----0.90kg/kg 2. Methyl Acrylate-----2.06kg/kg				

3. Sodium methoxide-----0.91kg/kg
4. Chloroform-----0.67kg/kg
5. Ethyl chloro formate-----0.75kg/kg
6. Triethyl amine-----0.34kg/kg
7. Di isopropyl ether-----1.05kg/kg
8. Carbon-----0.039kg/kg

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

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

8	Case No.:4/9/82-ALC4/2007	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01644/AM07/	RLA File : 03/94/040/01206/AM07/	Lic.No/Date:0310419586 14.02.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium USP under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.			

9	Case No.:3/19/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01663/AM07/	RLA File : 05/24/040/00951/AM07/	Lic.No/Date:0510199828 21.02.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Nalidixic Acid under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.			

10	Case No.:874/21/82-ALC4/2007	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
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HQ File : 01/82/050/01710/AM07/	RLA File : 05/24/040/00972/AM07/	Lic.No/Date:05102001 16 27.02.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Azacyclonol under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/260/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Azacyclonol-----1Kg. Import items: 1. THF-----2.81kg/kg 2. Gamma Picoline-----0.74kg/kg 3. Magnesium Turning-----0.30kg/kg 4. Toluene-----0.405kg/kg 5. Iodine Crystal-----Not shown in reaction. Hence not allowed. 6. Monochloro Benzene-----1.40kg/kg 7. Bromo Benzene-----Not shown in reaction. Hence not allowed. 8. Methanol-----0.375kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

Case No.:879/21/82-ALC4/2007	Party Name:LAKE CHEMICALS PRIVATE LIMITED	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/82/050/01714/AM07/	RLA File : 07/24/040/00780/AM07/	Lic.No/Date:07100503 14 27.02.2007	Defer Date: 18.12.2007
11	Decision : Committee considered case as per agenda for ratification of norms for export product Dorzolamide Hcl under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.		

12	Case No.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	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: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP. Committee observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.			

13	Case No.:1/17/82-ALC4/2007	Party Name:BIOLOGICAL E LTD	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/82/050/01860/AM07/	RLA File : 09/24/040/00481/AM07/	Lic.No/Date:0910029748 23.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Noscapine Hcl para 4.7 of HBP. Committee in light of its earlier decision taken in its 9/82 meeting held on 03.07.2007 vide Case No.15/9/82 in the case of M/S Indo German Alkaloids decided to ratify norms as per details below or as applied by firm whichever is lower. Export product: Noscapine Hcl-----1Kg. Import item: Noscapine Base-----0.9kg/kg Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action as per above decision of Norms Committee.			

14	Case No.:2/3/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
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HQ File : 01/82/050/00005/AM08/	RLA File : 34/24/040/00301/AM07/	Lic.No/Date:34100184 54 30.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Step IV (Azithromycin Crude Purity NLT 94.5%) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Azithromycin Step IV (Azithromycin Crude Purity NLT 94.5%)-----1kg. Import items: 1. Erythromycin base-----1.75kg/kg 2. Acetone-----6.45kg/kg 3. Ethyl Alcohol-----2.81kg/kg 4. Hydroxylamine Hcl-----0.91kg/kg 5. Methane sulfonyl chloride-----0.72kg/kg 6. Methanol-----2.72kg/kg 7. Platinum Catalyst with base of activated carbon (5% Platinum on carbon)-----1.00gm/kg 8. Hyflo-----Not a raw material, hence not Allowed Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman within the validity period of such adhoc norms. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

15	Case No.:25/14/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:29/82- ALC4/2007 20.11.2007	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: 18.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Allylestrenol under para 4.7 of HBP.				

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.

16	Case No.:26/9/82-ALC4/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00010/AM08/	RLA File : 09/24/040/00555/AM07/	Lic.No/Date:09100299 33 10.04.2007	Defer Date: 18.12.2007
	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 observed that firm has been requested to furnish certain technical information vide letter dated 05.11.2007, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.			

17	Case No.:566/24/83-ALC1/2007	Party Name:MOREPEN LABORATORIES LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00239/AM08/	RLA File : 05/24/040/00080/AM08/	Lic.No/Date:05102032 07 03.05.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.			

18	Case No.:8/13/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/82/050/00038/AM08/	RLA File : 34/24/040/00028/AM08/	Lic.No/Date:34100187 60 17.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm			

whichever is lower.

Export product:

Clarithromycin USP-----1Kg.

Import items:

1. Clarithromycin crude, purity
not more than 90% by HPLC-----1.02kg/kg
2. Activated Carbon-----0.06kg/kg
3. Ethyl alcohol-----2.50kg/kg
4. Hyflo-----Not a raw material. Hence not
allowed.

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

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

Case No.:614/24/83-ALC1/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/83/050/00369/AM08/	RLA File : 03/95/040/01471/AM07/	Lic.No/Date:0310430058 21.05.2007	Defer Date: 01.01.2008
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 observed that Department of Biotechnology has been requested to indicate whether NOC is required for export of Ultrazyme Tablets (7458X) (Contact Lens Cleaning Agent), but no information has been received. Committee, therefore, decided to remind DBT for their comments. Accordingly, case was deferred for six weeks.			

20 Case No.:628/24/83-ALC1/2007	Party Name:INVENTIS DRUG DELIVERY SYSTEMS PVT LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Withdrawn
HQ File : 01/83/050/00397/AM08/	RLA File : 09/24/040/00047/AM08/	Lic.No/Date:0910030344 25.05.2007	

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

Committee decided to withdraw this case as same has already been rejected in its 28/08 meeting held on 13.11.2007.

Case No.:35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
HQ File : 01/82/050/00051/AM08/	RLA File : 34/24/040/00035/AM08/	Lic.No/Date:34100188 54 28.05.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Step 3 under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 28/82 meeting held on 13.11.2007 vide Case No.101/21/82 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Azithromycin Step 3 (AZA Azithromycin)-----1kg.

21 Import items:

1. Erythromycin base-----1.86kg/kg
2. Acetone-----1.27kg/kg
3. Ethyl Alcohol-----3.00Ltr/kg
4. Hydroxylamine Hcl-----0.97kg/kg
5. Methane sulfonyl chloride-----0.69kg/kg
6. Methanol-----1.09kg/kg
7. Platinum Catalyst with base of activated carbon
(5% Platinum on carbon)-----1.00gm/kg

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

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

22	Case No.:38/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/82/050/00061/AM08/	RLA File : 34/24/040/00039/AM08/	Lic.No/Date:34100188 74 01.06.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Clarithromycin USP-----1Kg.

Import items:

1. Clarithromycin crude, purity
not more than 90% by HPLC-----1.02kg/kg
2. Activated Carbon-----0.06kg/kg
3. Ethyl alcohol-----2.50kg/kg
4. Hyflo-----Not a raw material. Hence not allowed.

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

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

23	Case No.:712/24/83-ALC1/2007	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00584/AM08/	RLA File : 03/94/040/00192/AM08/	Lic.No/Date:03104329 14 18.06.2007	Defer Date: 18.12.2007

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

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, case was deferred for four weeks.

24	Case No.:747/24/83-ALC1/2007	Party Name:RASULA PHARMACEUTICALS & FINE CHEMICALS	Meet No/Date:29/82- ALC4/2007 20.11.2007	Status:Case Transferred
	HQ File : 01/83/050/00669/AM08/	RLA File : 09/24/040/00121/AM08/	Lic.No/Date:09100307 61	

		05.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Propyl Paraben Sodium BP/USP under para 4.7 of HBP.			
Committee decided to transfer the case to DES-IV as export product pertains to Chemical Sector.			

25	Case No.:829/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00821/AM08/	RLA File : 09/24/040/00042/AM08/	Lic.No/Date:0910030972 23.07.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cis-4-Amino-3-Methoxy-Piperidine-1-Carboxylic Acid Ethyl Ester Monohydrochloride under para 4.7 of HBP. Committee observed that certain technical information has been called for from firm which has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.			

26	Case No.:95/21/82-ALC4/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	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: 01.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocare Tablets (Contact Lens Cleaning Tablets) under para 4.7 of HBP. Committee observed that Department of Biotechnology has been requested to indicate whether NOC is required for export of Hydrocare Tablets (Contact Lens Cleaning tablets), but no information has been received. Committee, therefore, decided to remind DBT for their comments. Accordingly, case was deferred for six weeks.			

27	Case No.:3/18/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	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: 18.12.2007
	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 observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.

Case No.:9/27/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/83/050/01083/AM08/	RLA File : 03/95/040/00534/AM08/	Lic.No/Date:03104415 37 31.08.2007	Defer Date: 01.01.2008

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 call for following information from firm and to defer the case for six weeks.

1. Percentage yield on molar basis for each step of manufacturing process.
2. Technical literature in support of the yields envisaged in the application.
3. Whether the import item No.1 is Sorbitol or Sorbitol 70% especially when the reaction scheme shown the input as Sorbitol 70%?
4. Specific use of Dioxabicyclo octan in step I and technical justification for its requirement.
5. Whether a fresh charge of this item can be utilized for a number of batches. Recovery after use may be elaborated?
6. In the process flow chart export product has been shown as diluted mixture of ISMN with Dextrose. As per the norms applied the percentage of Dextrose works out to 62%. Actual proportion in the export envisaged may be clarified and accordingly the export description should be amended.
7. Copy of valid DML for above export product.

Accordingly, deferred for six weeks.

29	Case No.:5/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:03104415	Defer

01/82/050/00175/AM08/	03/94/040/00571/AM08/	56 31.08.2007	Date: 18.12.2007
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 observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.			

Case No.:72/27/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/83/050/01146/AM08/	RLA File : 03/95/040/00570/AM08/	Lic.No/Date:03104424 36 11.09.2007	Defer Date: 18.12.2007
30	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 firm has applied for export of Sterile Ceftriaxone Sodium-Non Infringing. The case was deferred for four weeks.			

Case No.:10/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	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: 18.12.2007
31	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 observed that firm was called for personal hearing to explain their case, but they have sought the date of personal hearing after 15.12.2007 vide their letter dated 15.11.2007. Committee, therefore, decided to call the firm for personal hearing on 18.12.2007. Accordingly, case was deferred for four weeks.			

Case No.:17/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
HQ File : 01/82/050/00187/AM08/	RLA File : 03/94/040/00650/AM08/	Lic.No/Date:03104442 04 25.09.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Tenofovir Disoproxil Fumarate-----1Kg.

Import items:

1. 9-[2-(Phosphonyl Methoxy) Propyl] Adenine-----0.8026kg/kg
2. Chloromethyl Isopropyl carbonate-----2.08670kg/kg

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

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

33	Case No.:176/27/83-ALC1/2007	Party Name:RASHMI PHARMA PVT LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/83/050/01250/AM08/	RLA File : 09/24/040/00281/AM08/	Lic.No/Date:0910031662 28.09.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Orlistat Pellets 50% (Tetrahydro Lipstatin Pettets (Anti Obesity) under para 4.7 of HBP.

Committee in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Orlistat Pellets 50% (Tetrahydro Lipstatin Pellets (Anti Obesity)-----1kg.

Import item:

Orlistat powder-----0.505kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman

within the validity period of such adhoc norms.

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

Case No.:175/27/83-ALC1/2007	Party Name:RASHMI PHARMA PVT LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
HQ File : 01/83/050/01249/AM08/	RLA File : 09/24/040/00282/AM08/	Lic.No/Date:09100316 61 28.09.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Orlistat Pellets 60% (Tetrahydro Lipstatin_ (Pellets (Anti Obesity) under para 4.7 of HBP.

Committee in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Orlistat Pellets 60% (Tetrahydro Lipstatin Pellets (Anti Obesity)-----1kg.

Import item:

Orlistat powder-----0.606kg/kg

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

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

Case No.:1/25/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/82/050/00195/AM08/	RLA File : 13/24/040/00019/AM08/	Lic.No/Date:13100250 71 01.10.2007	Defer Date:01.01.20 08

Decision : Committee considered case as per agenda for ratification of norms for export product Alpha Lipoic Acid Granules 95% under para 4.7 of HBP.

Committee observed that copy of application and copy of Advance Authorisation were called far from RA, but same has not been received. Committee, therefore, decided to remind RA and defer case for six weeks.

Decision : Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets 25mgs 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 two weeks.

Case No.:9/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/82/050/00203/AM08/	RLA File : 04/24/040/00254/AM08/	Lic.No/Date:04100914 60 10.10.2007	Defer Date: 04.12.2007

41 **Decision :** Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (50mgs) 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 two weeks.

Case No.:10/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Deferred
HQ File : 01/82/050/00204/AM08/	RLA File : 04/24/040/00255/AM08/	Lic.No/Date:04100914 62 10.10.2007	Defer Date: 04.12.2007

42 **Decision :** Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (100mgs) 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 two weeks.

Case No.:37/30/83-ALC1/2007	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
HQ File : 01/83/050/01406/AM08/	RLA File : 09/24/040/00317/AM08/	Lic.No/Date:09100318 63 23.10.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/125/2006-PI-III dated 20.11.2007 decided to ratify

norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Hydroxy Chloroquine Sulfate-----1kg.

Import items:

1. 4,7-Dichloro quinoline-----0.77kg/kg
2. 4-amino-N-Ethyl-(2-Hydroxy Ethyl)-Pentylamine-----1.06kg/kg
3. Sodium Hydroxide Micropearls-----0.75kg/kg

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

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

44	Case No.:38/30/83-ALC1/2007	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
	HQ File : 01/83/050/01407/AM08/	RLA File : 09/24/040/00260/AM08/	Lic.No/Date:0910031864 23.10.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/25/2006-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Labetalol hydro chloride-----1kg.

Import items:

1. 3-Amino-1-Phenyl Butane/1-Methyl-3-Phenyl propylamine-----
2.70kg/kg
2. 5-(bromocetyl) salicylamide-----
2.48kg/kg
3. Sodium borohydride-----0.20kg/kg
4. Methanol-----6.00kg/kg

Committee also decided to approve on file all the pending cases for the above export product with same inputs with approval of Chairman

within the validity period of such adhoc norms.

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

Case No.:49/30/83-ALC1/2007	Party Name:SHILPA MEDICARE LTD.,	Meet No/Date:29/82-ALC4/2007 20.11.2007	Status:Case Approved
HQ File : 01/83/050/01418/AM08/	RLA File : 07/24/040/00420/AM08/	Lic.No/Date:0710054000 24.10.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product 3A 7B Dioxy Cholanic Acid under para 4.7 of HBP.

Committee in light of written comments forwarded by DC(SSi) vide their U.O. No.5(4)/2000-Chem dated 09.09.2003 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

45 3a, 7b Dioxy Cholanic Acid-----1kg.

Import items:

1. Cholic Acid-----2.55kg/kg
2. Dimethyl Amino Pyridine-----0.048kg/kg
3. 2-Methoxy Ethanol-----8.50kg/kg
4. Hydrazine Hydrate 80%-----2.55kg/kg
5. Sodium Bromate-----0.96kg/kg
6. Sodium Metal-----1.24kg/kg

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

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

Outside Agenda

Committee considered case out side agenda and decided to modify norms earlier fixed by NC in its 25/08 meeting held on 23.10.2007 as per details below;

Case No.A-783	M/S Ranbaxy Laboratoreis Ltd.
NC Meeting No.25/08	F.No.01/82/50/205/AM'08
Meeting Date: 23.10.2007	RLA F.No.05/24/40/305/AM08
Adv.Lic.No.0510207201 dated 06.08.2007	
Committee considered case as per agenda for ratification of norms for export product Simvastatin Tablets 10mg, 20mg and 40mg under para 4.7 of HBP. The Committee in light of the written comments of the Deptt. of C&PC forwarded vide their U.O.No.35011/224/2006-PI-III dated 30.5.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower. Export product Simvastatin tablets 10/20/40 Mg. Import items For export of Simvastatin 10mg tablets - Simvastatin - 10.20mg/tablet For export of Simvastatin 20mg tablets - Simvastatin - 20.40mg/tablet For export of Simvastatin 40mg tablets - Simvastatin - 40.80mg/tablet Lovastatin-----1.648 Kg./kg of Simvastatin Acetone-----1.042 Kg./kg of Simvastatin Activated Carbon-----0.035 Kg./kg of Simvastatin Cyclohexane-----1.33 Kg./kg of Simvastatin Cycloproxylamine-----1.23 Kg./kg of Simvastatin Methanol-----19.82 Kg./kg of Simvastatin N Butyl Lithium-----2.382 Kg./kg of Simvastatin Pyrrolidine-----1.53 Kg./kg of Simvastatin Tetrahydrofuran-----6.58 Kg./kg of Simvastatin Caustic flakes-----1.484 Kg./kg of Simvastatin Iodine-----0.5917 Kg./kg of Simvastatin Ethyl acetate-----4.49 Kg./kg of Simvastatin RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Committee also decided to modify norms earlier fixed in its meeting No.25/08 dated 23.10.2007 vide case No.31/9/82 as per details below.

29	Case No.:31/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:25/82-ALC4/2007 23.10.2007	Status:Case Approved
	HQ File : 01/82/050/00042/AM08/	RLA File : 34/24/040/00031/AM08/	Lic.No/Date:34100188 11 21.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Cefepime (For Injection USP) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/182/2005-PI-III dated 23.10.2007 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: Cefepime for Injection USP (Cefepime + Arginine Sterile)-----1Kg. Import items: 7 Amino Cephalospoonic Acid-----0.84kg/kg - Trimethylsilyl iodide-----1.59kg/kg - Hexamethyl Disilazane-----0.88kg/kg - N-Methyl Pyrrolidine-----0.588kg/kg - Methylene Chloride-----3.60kg/kg - Cyclohexane-----3.98kg/kg - Acetone-----13.80kg/kg - Isopropyl Alcohol-----3.50kg/kg 2-Mercapto Benzothiazolyl (Z)-2-(2-Amino Thiazoyl-4-YL)-2-Methoxy Imino acetate-----0.76kg/kg - Triethyl amine-----0.147kg/kg - Dimethyl Formamide-----1.82kg/kg - Activated Carbon-----0.100kg/kg - Methanol-----3.09kg/kg - L-Arginine(non sterile)-----				

0.40kg/kg

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