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

Para 4.7 Decision

MEETING NUMBER : 33/82-ALC4/2007 **MEETING DATE** : 18.12.2007

The Meeting No.33/08 for the licensing year 2007-08 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2004-09 pertaining to Pharma Products was held on 18.12.2007 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No.31/08 dated 04.12.2007 and Meeting No.32/08 held on 11.12.2007were ratified by the Committee.

Case No.B-436	M/S Merck Ltd
Norms Committee Meeting No.33/08	F.No.01/82/50/884/AM06/DES-III
Meeting Date:18.12.2007	RLA F.No.03/95/40/908/AM06
Advance licence No.0310354793 dated 07.11.2005	
Committee considered case as per agenda for ratification of norms for export product Thiamine Disulfide under para 4.7 of HBP. Committee decided to link this case with original file and to check the quantities applied by firm for obtaining Advance Authorisation. Accordingly, case was deferred for four weeks.	

Case No.B-437	M/S M.J. Biopharma Pvt. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/17/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/95/40/21/AM08
Advance licence 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. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 18.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Prednisolone Sodium Phosphate Injection 30mg/ml----------1 Vial	

Import items:
Prednisolone Sodium Phosphate----------46.017mg/Vial

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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-438	M/S Miles International
Norms Committee Meeting No.33/08	F.No.01/82/50/1002/AM07/DES-III
Meeting Date:18.12.2007	RLA F.No.03/95/40/314/AM07
Advance licence No.0310386250 dated 22.06.2007	

Committee considered case as per agenda for ratification of norms for export product Dithronol BP/EP/Dithranol under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 18.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Dithranol BP/EP----------1kg.

Import item:
1,8 dihydroxy anthraquinone----------1.47kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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-439	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/1663/AM05/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/40/2256/AM05
Advance licence No.0310313830 dated	

27.01.2005	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explained their case. They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export Product: Oxytocin Solution

Sl.No.	Description of import item	Lower Qty. as per C.E. Data
1.	Amino Acid-L-Leucine	2.863kg/1000MIU
2.	Amino Acid-L-Proline	1.797kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.09kg/1000MIU
4.	Carbobenzoxyl-L-Asparagine	4.00kg/1000MIU
5.	Carbobenzoxyl-L-Glutamine	3.485kg/1000MIU
6.	S-Benzyl L-Cysteine	4.36kg/1000MIU
7.	L-Tyrosine Ethyl Ester	2.42kg/1000MIU
8.	Glycine Ethyl Ester Hcl	3.504kg/1000MIU
9.	Benzyl chloroformate (97% stabilized)	9.42liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	18.58kg/1000MIU
11.	4-Nitrophenol	8.49kg/1000MIU
12.	Glacial Acetic Acid	89.42kg/1000MIU
13.	Diethyl Ether Dried	532.09kg/1000MIU
14.	Iso Amyl Nitrite	2.30liter/1000MIU
15.	Hydrogen bromide gas	20.56kg/1000MIU
16.	Hydrogen chloride gas	1.36kg/1000MIU

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

Case No.B-440	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/338/AM05/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/40/65/AM05
Advance licence No.0310265856 dated 28.04.2004	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explained their case.

They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export Product: Oxytocin Solution

Sl.No.	Description of import item	Lower Qty. as per C.E. Data
1.	Amino Acid-L-Leucine	2.863kg/1000MIU
2.	Amino Acid-L-Proline	1.797kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.09kg/1000MIU
4.	Carbobenzoxyl-L-Asparagine	4.00kg/1000MIU
5.	Carbobenzoxyl-L-Glutamine	3.485kg/1000MIU
6.	S-Benzyl L-Cysteine	4.36kg/1000MIU
7.	L-Tyrosine Ethyl Ester	2.42kg/1000MIU
8.	Glycine Ethyl Ester Hcl	3.504kg/1000MIU
9.	Benzyl chloroformate (97% stabilized)	9.42liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	18.58kg/1000MIU
11.	4-Nitrophenol	8.49kg/1000MIU
12.	Glacial Acetic Acid	89.42kg/1000MIU
13.	Diethyl Ether Dried	532.09kg/1000MIU
14.	Iso Amyl Nitrite	2.30liter/1000MIU
15.	Hydrogen bromide gas	20.56kg/1000MIU
16.	Hydrogen chloride gas	1.36kg/1000MIU

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

Case No.B-441	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/1439/AM05/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/41/156/AM05
Advance licence No.0310302356 dated 17.11.2004	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explained their case. They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export product:Oxytocin Powder

Sl.No.	Description of import item	Lowest Qty. as per C.E. Data
1.	Amino Acid-L-Leucine	3.77kg/1000MIU
2.	Amino Acid-L-Proline	2.48kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.54kg/1000MIU
4.	Carbobenzoxy-l-Asparagine	5.67kg/1000MIU
5.	Carbobenzoxy-L-Glutamine	4.96kg/1000MIU
6.	S-Benzyl L-Cysteine	5.97kg/1000MIU
7.	L-Tyrosine Ethyl Ester Hcl	3.34kg/1000MIU
8.	Glycine Ethyl Ester Hcl	4.63kg/1000MIU
9.	Benzyl chloroformate stabilized 97%	13.52liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	26.65kg/1000MIU
11.	4-Nitrophenol	12.17kg/1000MIU
12.	Glacial Acetic Acid	120.21kg/1000MIU
13.	Diethyl Ether Dried Max 0.02% H20	715.81kg/1000MIU
14.	Iso Amyl Nitrite 97% stabilized with 0.2% anhydrous sodium carbonate	3.14liter/1000MIU
15.	Hydrogen bromide gas	27.37kg/1000MIU
16.	Hydrogen chloride gas	1.89kg/1000MIU
17.	Kromasil	0.52kg/1000MIU

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

Case No.B-442	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/464/AM02/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/40/1025/AM02
Advance licence No.0310110660 dated 19.11.2001	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explain their case. They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export Product: Oxytocin Powder

Sl.N	Description of import item	Lowest Qty. as per C.E. Data

o.		
1.	Amino Acid-L-Leucine	3.77kg/1000MIU
2.	Amino Acid-L-Proline	2.48kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.54kg/1000MIU
4.	Carbobenzoxyl-L-Asparagine	5.67kg/1000MIU
5.	Carbobenzoxyl-L-Glutamine	4.96kg/1000MIU
6.	S-Benzyl L-Cysteine	5.97kg/1000MIU
7.	L-Tyrosine Ethyl Ester Hcl	3.34kg/1000MIU
8.	Glycine Ethyl Ester Hcl	4.63kg/1000MIU
9.	Benzyl chloroformate 50% in Toluene Pract.	31.122liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	26.65kg/1000MIU
11.	4-Nitrophenol	12.17kg/1000MIU
12.	Glacial Acetic Acid	120.21kg/1000MIU
13.	Diethyl Ether Dried Max 0.02% H20	715.81kg/1000MIU
14.	Iso Amyl Nitrite 97% stabilized with 0.2% anhydrous sodium carbonate	3.14liter/1000MIU
15.	Hydrogen bromide gas	27.37kg/1000MIU
16.	Hydrogen chloride gas	1.89kg/1000MIU
17.	Kromasil	0.52kg/1000MIU

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

Case No.B-443	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/477/AM04/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/42/281/AM04
Advance licence No.0310219238 dated 18.08.2003	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explained their case. They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export Product: Oxytocin Solution

Sl.N	Description of import item	Lower Qty. as per C.E. Data

o.		
1.	Amino Acid-L-Leucine	2.863kg/1000MIU
2.	Amino Acid-L-Proline	1.797kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.09kg/1000MIU
4.	Carbobenzoxyl-L-Asparagine	4.00kg/1000MIU
5.	Carbobenzoxyl-L-Glutamine	3.485kg/1000MIU
6.	S-Benzyl L-Cysteine	4.36kg/1000MIU
7.	L-Tyrosine Ethyl Ester	2.42kg/1000MIU
8.	Glycine Ethyl Ester Hcl	3.504kg/1000MIU
9.	Benzyl chloroformate (97% stabilized)	9.42liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	18.58kg/1000MIU
11.	4-Nitrophenol	8.49kg/1000MIU
12.	Glacial Acetic Acid	89.42kg/1000MIU
13.	Diethyl Ether Dried	532.09kg/1000MIU
14.	Iso Amyl Nitrite	2.30liter/1000MIU
15.	Hydrogen bromide gas	20.56kg/1000MIU
16.	Hydrogen chloride gas	1.36kg/1000MIU

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

Case No.B-444	M/S Hemmo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/478/AM05/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/40/582/AM05
Advance licence No.031019241 dated 18.08.2003	

Committee considered case as per agenda for enhancement of quantity of inputs under para 4.7 of HBP.

Shri Suresh Vazirani, General manager and Dr. D.R.S. Kushwaha, Technical Director of the Company appeared for personal hearing and explained their case. They requested that they may be given the lowest quantity certified by Central Excise Authorities or as applied by them whichever is lower.

After detailed deliberations, Committee decided to allow quantity of inputs as per details below;

Export Product: Oxytocin Powder

Sl.No.	Description of import item	Lowest Qty. as per C.E. Data
1.	Amino Acid-L-Leucine	3.77kg/1000MIU
2.	Amino Acid-L-Proline	2.48kg/1000MIU
3.	Amino Acid-L-Isoleucine	1.54kg/1000MIU

4.	Carbobenzoxyl-L-Asparagine	5.67kg/1000MIU
5.	Carbobenzoxyl-L-Glutamine	4.96kg/1000MIU
6.	S-Benzyl L-Cysteine	5.97kg/1000MIU
7.	L-Tyrosine Ethyl Ester Hcl	3.34kg/1000MIU
8.	Glycine Ethyl Ester Hcl	4.63kg/1000MIU
9.	Benzyl chloroformate (97% stabilized)	13.52liter/1000MIU
10.	N,N. Dicyclo Hexyl Carbodimide	26.65kg/1000MIU
11.	4-Nitrophenol	12.17kg/1000MIU
12.	Glacial Acetic Acid	120.21kg/1000MIU
13.	Diethyl Ether Dried Max 0.02% H20	715.81kg/1000MIU
14.	Iso Amyl Nitrite 97% stabilized with 0.2% anhydrous sodium carbonate	3.14liter/1000MIU
15.	Hydrogen bromide gas	27.37kg/1000MIU
16.	Hydrogen chloride gas	1.89kg/1000MIU
17.	Kromasil	0.52kg/1000MIU

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

Case No.B-445	M/S Aurobindo Pharma Ltd.
Norms Committee Meeting No.33/08	F.No.01/87/50/641/AM07/DES-III F.No.01/87/50/400/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/134/AM07 RLA F.No.09/24/40/50/AM08
Advance licence No.0910027866 dated 18.10.2006 Advance licence No.0910030397 dated 31.05.2007	

Committee considered case as per agenda for modification of norms for export product Metformin Hcl under para 4.7 of HBP.

Committee observed that Central Excise certified production and consumption data has been called for from firm vide letter dated 06.12.2007 which has not been received. Committee, therefore, decided to await data. Accordingly, case was deferred for four weeks.

Case No.B-446	M/S Gulf Oil Corporation Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/1215/AM07/DES-III

Meeting Date:18.12.2007	RLA F.No.09/24/40/194/AM07
Advance licence 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 in light of written comments forwarded by PI Division vide their U.O. No.35011/95/2007-PI-III dated 18.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Sodium Cromo Glycate----------1kg.

Import items:

1. 2,6-dihydroxy acetophenone-----1.85kg/kg
2. Epichlorohydrin----------0.61kg/kg
3. Sodium Metal----------Not allowed as shown neither in manufacturing process nor in Literature

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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-447	M/S KDL Biotech Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/1415/AM05/DES-III
Meeting Date:18.12.2007	RLA F.No.03/24/40/1364/AM05
Advance licence No.0310301988 dated 11.11.2004	

Committee considered case as per agenda for ratification of norms for export product Immobilized Pencillin G Amidase Enzyme under para 4.7 of HBP.

Committee observed that Deptt. of Bio-technology have issued NOC for import/export of Bio-technology items, but they have not furnished their comments for ratification of norms. Committee, therefore, decided to remind DBT to furnish their comments. Accordingly case was deferred for four weeks.

Case No.B-448	M/S Dalas Biotech Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/223/AM08/DES-III

Meeting Date:18.12.2007	RLA F.No.05/24/40/1078/AM07
Advance licence No.0510203062 dated 27.04.2007	

Committee considered case as per agenda for modification of norms for export product 7 AVCA under para 4.7 of HBP.

Committee observed that Central Excise Data has been called for from major exporters of 7 AVCA, but same has not been received. Committee, therefore, decided to await data. Accordingly, case was deferred for four weeks.

Case No.A-899	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/228/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/236/AM08
Advance licence No.0910031322 dated 30.08.2007	

Committee considered case as per agenda for ratification of norms for export product Candesartan Cilexetil-4mg, 8mg, 16mg and 32mg Tablets under para 4.7 of HBP.

Committee in consultation with technical authority present in meeting decided to ratify norms with 2% wastage or as applied by firm whichever is lower subject to confirmation of DML and other relevant documents by RA.

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

Case No.A-900	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/227/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/204/AM08
Advance licence No.0910031354 dated 31.08.2007	

Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate 300mg and Lamivudine 300mg Tablets 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-901	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/233/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/196/AM08
Advance licence No.0910031321 dated 30.08.2007	

Committee considered case as per agenda for ratification of norms for export product Emitricitabine 200mg and Tenofovir Disoproxil Furarate 300mg tablets 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-902	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/234/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/188/AM08
Advance licence No.0910031126 dated 13.08.2007	

Committee considered case as per agenda for ratification of norms for export product Valsartan Tablets 40mg 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-903	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/232/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/216/AM08
Advance licence No.0910031186 dated 21.08.2007	

Committee considered case as per agenda for ratification of norms for export product Citalopram Tablets 10mg, 20mg, 30mg, 40mg and 60mg 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-904	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/226/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/192/AM08
Advance licence No.0910031252 dated 27.08.2007	

Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate 300mg Tablets 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-905	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/231/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/191/AM08
Advance licence No.0910031127 dated 13.08.2007	

Committee considered case as per agenda for ratification of norms for export product Quetiapine Fumarate Tablets 25mg 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-906	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/229/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/202/AM08
Advance licence No.0910031202 dated 24.08.2007	

Committee considered case as per agenda for ratification of norms for export product Didanosine Delayed Release Capsules 125mg, 200mg, 250mg and 400mg Capsules 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-907	M/S Matrix Lab. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/230/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/187/AM08

Advance licence No.0910031251 dated 27.08.2007	

Committee considered case as per agenda for ratification of norms for export product Abacavie Sulfate 300mg Tablets 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 six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-908	M/S Amoli Organics Pvt. Ltd.
Norms Committee Meeting No.33/08	F.No.01/87/50/606/AM07/DES-III
Meeting Date:18.12.2007	RLA F.No.03/94/40/411/AM07
Advance licence No.0310380982 dated 24.07.2006	

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

Committee decided to withdraw case as same has been considered by NC in its meeting held on 11.12.2007.

Case No.A-909	M/S Cipla Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/212/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/94/40/590/AM08
Advance licence No.0310442077 dated 06.09.2007	

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

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-910	M/S Lyka BDR Intl. Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/89/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/95/40/1309/AM07
Advance licence No.0310419266 dated 12.02.2007	

Committee considered case as per agenda for ratification of norms for export product Clobetasole Propionate Cream 10GM (Dermotyl Cream 10GM), Clobetasole Propionate Cream 15gm (Dermotyl Cream 15gm), Clobetasole Propionate Cream 30gm (Dermotyl Cream 30gm), Clobetasol Propionate Topical Solution 0.05%W/V and Clobetasol Propionate Topical Solution 0.05W/V (Dermotyl Lotion 30ml)BP/USP under para 4.7 of HBP.

Committee decided to call for a copy of Drug Manufacturing Licence from firm. Accordingly, case was deferred for six weeks.

Case No.A-911	M/S Lupin Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/119/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/95/40/293/AM08
Advance licence No.0310433980 dated 26.06.2007	

Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriazone Sodium 1gm Injection, Sterile Ceftriaxone Sodium 2 gm Injection and Sterile Ceftriaxone Sodium 250mg Injection under para 4.7 of HBP.

Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.

Case No.A-912	M/S Cipla Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/233/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.09/24/40/196/AM08
Advance licence No.0910031321 dated 30.08.2007	

Committee considered case as per agenda for ratification of norms for various

export product s under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-913	M/S Cipla Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/168/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/94/40/17/AM08
Advance licence No.0310426065 dated 10.04.2007	

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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-914	M/S Cipla Ltd.

Norms Committee Meeting No.33/08	F.No.01/82/50/223/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/94/40/706/AM08
Advance licence No.0310445735 dated 09.10.2007	

Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablets/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 Baby Tablets Lamivudine and Stavudine Tables, 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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-915	M/S Cipla Ltd.
Norms Committee Meeting No.33/08	F.No.01/82/50/224/AM08/DES-III
Meeting Date:18.12.2007	RLA F.No.03/94/40/708/AM08
Advance licence 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 Nevimyne under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-916	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/155/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/473/AM08
Adv. Lic. No.0310438672 dt.07.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200 MG Tablets/Nevirapine 200MG Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-917	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/153/AM 08
Meeting Date 18.12.2007	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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-918	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/152/AM 08
Meeting Date 18.12.2007	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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-919	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/194/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/582/AM08
Adv. Lic. No.0310441827 dt.05.09.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200 MG Tablets/Nevirapine 200MG Tablets (2) Nevirapine Oral Suspension 50 MG/5 ML/Nevimune under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-920	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/188/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/554/AM08
Adv. Lic. No.0310441419 dt.30.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lopinavir and Ritonavir Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-921	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/136/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/383/AM08
Adv. Lic. No.0310436156 dt.13.07.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Stavir 15MG Capsules/Stavudine Capsule 15 MG under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-922	M/s Wockhardt Ltd.
M.No.33/08	F.No.01/82/162/1115/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/95/40/810/AM08
Adv. Lic. No.0310450400 dt.15.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Flu Strenght Hot Powder 5GM Sachet each MG Sachet Contains under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/84/2007-PI-III dated 18.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Flu Strength Hot Lemon Powder in 5gm. Sachet
(each 5gm. Sachet contain Paracetamol Ph. EUR)

Import item:
Paracetamol Ph. EUR----------1.01gm/5gm Sachet

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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-923	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/160/AM 08

Meeting Date 18.12.2007	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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-924	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/193/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/540/AM08
Adv. Lic. No.0310440643 dt.23.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Cyproterone Acetate Tablets 100MG/Cyproterone Acetate Tablets 50 MG under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-925	M/s Cipla Ltd.

M.No.33/08	F.No.01/82/50/158/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/535/AM08
Adv. Lic. No.0310440429 dt.22.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Budccort 200 Inhaler (200 MD) Aerobud Inhaler (200 MD)/Budesonide Generis 200 Inhaler (200 MD) under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-926	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/210/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/578/AM08
Adv. Lic. No.0310441906 dt.21.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lamivir 150MG Tablets/Lamivudine Tablets 150 MG under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-927	M/s Cipla Ltd.

M.No.33/08	F.No.01/82/50/211/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/553/AM08
Adv. Lic. No.0310440694 dt.27.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lamivir 150MG Tablets/Lamivudine Tablets 150 MG under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-928	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/213/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/534/AM08
Adv. Lic. No.0310440647 dt.23.08.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Efavir Capsules 200MG/Efavirenz 200 Capsules (2) Efavir 600 MG Tablets/Efavirenz 600MG Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-929	M/s Cipla Ltd.

M.No.33/08	F.No.01/82/50/214/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/674/AM08
Adv. Lic. No.0310445040 dt.03.10.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Telmisartan and Amlodipin Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-930	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/215/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/621/AM08
Adv. Lic. No.0310443538 dt.18.09.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lamivir Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-931	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/216/AM 08

Meeting Date 18.12.2007	RLA F. No. 03/94/40/688/AM08
Adv. Lic. No.0310445044 dt.03.10.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Nevimune Tablets/Nevirapine Oral Suspension under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-932	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/169/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/250/AM08
Adv. Lic. No.0310432136 dt.08.06.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Stavir 15 MG Capsules under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-933	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/251/AM 08
Meeting Date 18.12.2007	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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-934	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/250/AM 08
Meeting Date 18.12.2007	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.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-935	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/264/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/865/AM08
Adv. Lic. No.0310450789	

dt.20.11.2007	

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

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-936	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/265/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/857/AM08
Adv. Lic. No.0310450548 dt.16.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 1. Irinotecan Hydrochloride Injection 40mg/2ml (each Vial 2ml) 2. Irinotecan Hydrochloride Injection 100mg/5ml (each Vial 5ml) para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-937	M/s Cipla Ltd.
M.No.33/08	F.No.01/82/50/270/AM 08

Meeting Date 18.12.2007	RLA F. No. 03/94/40/860/AM08
Adv. Lic. No.0310450692 dt.19.11.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 1. Irinotecan Hydrochloride Injection 40mg/2ml (each Vial 2ml) 2. Irinotecan Hydrochloride Injection 100mg/5ml (each Vial 5ml) under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

Case No.A-938	M/s Arch Pharma Labs Ltd.
M.No.33/08	F.No.01/82/50/268/AM 08
Meeting Date 18.12.2007	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,S,5 R)-Methyl-5S-(Cytosine-I-YL) 1-3-Oxathiolane –2R-Carboxylate/CME Compound under para 4.7 of HBP.

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-939	M/s Arch Pharma Labs Ltd.
M.No.33/08	F.No.01/82/50/269/AM 08
Meeting Date 18.12.2007	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.

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-940	M/s Aurobindo Pharma Ltd.
M.No.33/08	F.No.01/82/50/266/AM 08
Meeting Date 18.12.2007	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.

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-941	M/s Glenmark Pharmaceuticals Ltd.
M.No.33/08	F.No.01/82/50/267/AM 08
Meeting Date 18.12.2007	RLA F. No. 03/94/40/805/AM08
Adv. Lic. No.0310450439 dt.16.11.2007	

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

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

Case No.A-942	M/s Cadila Healthcare Ltd.
M.No.33/08	F.No.01/82/50/191/AM 08
Meeting Date 18.12.2007	RLA F. No. 08/24/40/150/AM08
Adv. Lic. No.0810067103 dt.11.09.2007	

The Committee considered the case as per agenda for ratification of norms for the export product 62/0Hydroxychloroquine Sulfate 200MG Tab. 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.A-943	M/s Cadila Healthcare Ltd.

M.No.33/08	F.No.01/82/50/192/AM 08
Meeting Date 18.12.2007	RLA F. No. 08/24/40/158/AM08
Adv. Lic. No. 0810067315 dt.24.09.2007	
The Committee considered the case as per agenda for ratification of norms for the export product 62/0 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. Committee, accordingly, decided to defer case for four weeks.	

Case No.A-944	M/s Aurobindo Pharma Ltd.
M.No.33/08	F.No.01/82/50/127/AM 08
Meeting Date 18.12.2007	RLA F. No. 09/24/40/469/AM08
Adv. Lic. No.0910030086 dt.24.04.2007	

The Committee considered the case as per agenda for ratification of norms for the export product Sterile Ampicillin Sodium 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 10.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Sterile Ampicillin Sodium + Salbactam Sodium (2:1)---------1kg.

Import items:

1. 6 APA----------1.039kg/kg
2. Pivaloyl chloride----------0.283kg/kg
3. Triethylamine----------0.0171kg/kg
4. Methylene chloride----------0.745kg/kg
5. D(-)Alpha Phenyl glycine Base----------0.374kg/kg
6. Ethyl Aceto acetate----------0.358kg/kg
7. Sodium Thiocynate----------0.189kg/kg
8. Acetonitrile----------1.342kg/kg
9. Isopropyl Alcohol----------1.684kg/kg
10. Acetone----------0.501kg/kg
11. Pot. Carbonate----------0.149kg/kg
12. 2-Ethyl Hexanoic Acid----------0.016kg/kg
13. Potassium Permaganate----------0.449kg/kg
14. Activated Carbon----------0.074kg/kg
15. Hydrobromic acid 48%----------1.39kg/kg
16. Aluminium Canisters----------As per packing policy

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

1	**Case No.:31/30/87-ALC1/2005**	Party Name:ALKALOIDS CORP	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/87/050/00870/AM06/	RLA File : 02/24/040/00154/AM06/	Lic.No/Date:0210082777 17.10.2005	Defer Date:29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Cascara Dry Extract under para 4.7 of HBP.			

	Committee decided to defer case for six weeks for comments of Department of MSME.

2	**Case No.:28/29/82-ALC1/2006**	Party Name:INNOVASSYNTH TECHNOLOGIES (INDIA) LTD.	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Transferred**
	HQ File : 01/82/050/01009/AM07/	RLA File : 03/94/040/00602/AM07/	Lic.No/Date:0310400932 25.09.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product 5-O-Dimethoxyltrityl-2-O-tert-butyldimethylsilyl-Uridine/DMT-rU-TBDMS Solid under para 4.7 of HBP. Representative of PI Division informed Committee that export item is used as Oligonucelotide intermediates which has been classified as RNA amidites. He has further stated that M/S innovysyth techlologies is an R&D company and the export item may be customer's specific biomolity. Committee, accordingly, decided to transfer the case to DES-IV.			

3	**Case No.:803/21/82-ALC4/2007**	Party Name:GLOCHEM INDUSTRIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/01546/AM07/	RLA File : 09/24/040/00403/AM07/	Lic.No/Date:0910028964 10.01.2007	Defer Date: 15.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Amlodipine Maleate Solid under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.			

4	**Case No.:16/49/82-ALC1/2006**	Party Name:LUPIN LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 15.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriazone Sodium – Non infringing under para 4.7 of HBP. Committee decided to examine case on file from policy view point as there is non-infringing process involved.			

5	**Case No.:425/24/83-ALC1/2007**	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Rejected**
	HQ File : 01/83/050/01203/AM07/	RLA File : 09/24/040/00466/AM07/	Lic.No/Date:0910029229 07.02.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 5-Methoxy-2-((4-Methoxy-3,5-Dimethyl-2Pyridinyl)Methyl]Thio-1H-Benzimidazole under para 4.7 of HBP. Committee observed that firm was requested to furnish technical details vide letter dated 13.11.2007, but same has not been received. Committee, therefore, decided to close the case as norms may not be ratified in absence of technical details. RA concerned may take further necessary action as per above decision of Norms Committee.			

6	**Case No.:4/9/82-ALC4/2007**	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 01.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium USP under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division for his comments. Accordingly, case was deferred for two weeks.			

7	**Case No.:3/19/82-ALC4/2007**	Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
	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 six weeks. Committee, accordingly, decided to defer case for six weeks.			

8	**Case No.:852/21/82-ALC4/2007**	Party Name:METROCHEM API PVT. LTD.	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/01678/AM07/	RLA File : 09/24/040/00436/AM07/	Lic.No/Date:09100294 25 22.02.2007	Defer Date: 29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Lansoprazole Pellets 11.2% under para 4.7 of HBP. Committee decided to remind Jt. DGFT, Hyderabad through D.O. letter at the appropriate level for furnishing a copy of application alongwith a copy of Advance Authorisation. Accordingly, case was deferred for six weeks.			

9	**Case No.:879/21/82-ALC4/2007**	Party Name:LAKE CHEMICALS PRIVATE LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
	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 six weeks. Committee, accordingly, decided to defer case for six weeks.			

10	**Case No.:6/9/82-ALC4/2007**	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Approved**
	HQ File : 01/82/050/01728/AM07/	RLA File : 09/24/040/00488/AM07/	Lic.No/Date:09100295 04 01.03.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 18.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Cefdinir----------1kg. Import items:			

1. 7-Phenylacetamideo-3-Chloromethyl Cephalosporanic Acid Para Methoxybenzyl Ester (GCLE)----------2.44kg/kg
2. Ethyl-(Z)-2-Hydroxyimino-2-(2-Aminothiazole-4-YL) Acetone (EHATA)----------1.896kg/kg
3. Methylene chloride----------16.88kg/kg
4. Tetrahydrofuran----------2.34kg/kg
5. Dicyclo Hexylamine----------0.62kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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.:7/2/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
11	**Decision :** Committee considered case as per agenda for ratification of norms for export product Triomune30/Lamivudine, Stavudine and Nevirapine Tablets and Triomune 40/Lamivudine, Stavudine and nevirapine Tablets under para 4.7 of HBP. Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information. 1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs. 2. %yield on molar basis for each step. 3. Requirement and recovery of Solvents. 4. Raw material composition for each bulk drugs in multi component form. The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.			

12	**Case No.:17/9/82-ALC4/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**

	HQ File : 01/82/050/01837/AM07/	RLA File : 03/94/040/01468/AM07/	Lic.No/Date:0310423777 21.03.2007	Defer Date: 29.01.2008

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

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

13	**Case No.:25/14/83-ALC1/2007**	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/00016/AM08/	RLA File : 04/24/040/00501/AM07/	Lic.No/Date:0410088727 02.04.2007	Defer Date: 29.01.2008

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 six weeks. Committee, accordingly, decided to defer case for six weeks.

14	**Case No.:26/9/82-ALC4/2007**	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Rejected**
	HQ File : 01/82/050/00010/AM08/	RLA File : 09/24/040/00555/AM07/	Lic.No/Date:0910029933 10.04.2007	

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

Committee observed that firm was requested to furnish technical

details vide letter dated 13.11.2007, but same has not been received. Committee, therefore, decided to close the case as norms may not be ratified in absence of technical details.

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

	Case No.:9/13/83-ALC1/2007	Party Name:KUMAR ORGANIC PRODUCTS LIMITED,	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Approved**
	HQ File : 01/83/050/00105/AM08/	RLA File : 07/24/040/00020/AM08/	Lic.No/Date:07100512 16 13.04.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/240/2004-PI-III dated 18.12.2007 and in consultation with technical authority 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.

15 Export product:
Minoxidil----------1kg.

Import items:
1. 2,4-Diamino-6-chloro pyrimidine----------1.737kg/kg
2. Phthalic Anhydride----------3.474kg/kg
3. Piperidine----------2.78kg/kg

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

16	**Case No.:566/24/83-ALC1/2007**	Party Name:MOREPEN LABORATORIES LTD.,	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008

	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 six weeks. Committee, accordingly, decided to defer case for six weeks.

17	**Case No.:614/24/83-ALC1/2007**	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Ultrazyme Tablets (7458X) [Contact Lens Cleaning Tablets) under para 4.7 of HBP. Committee decided to defer case for six weeks for comments of Department of Bio-technology.			

18	**Case No.:642/24/83-ALC1/2007**	Party Name:DEVATS (INDIA) PVT.LTD	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/00422/AM08/	RLA File : 05/24/040/00921/AM07/	Lic.No/Date:0510204173 29.05.2007	Defer Date: 15.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Nystatin Oral Suspension (USP) under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.			

19	**Case No.:712/24/83-ALC1/2007**	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/00584/AM08/	RLA File : 03/94/040/00192/AM08/	Lic.No/Date:0310432914 18.06.2007	Defer Date: 29.01.2008
	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 six			

	weeks. Committee, accordingly, decided to defer case for six weeks.

	Case No.:829/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/00821/AM08/	RLA File : 09/24/040/00042/AM08/	Lic.No/Date:09100309 72 23.07.2007	Defer Date: 15.01.2008
20	**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. 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.:95/21/82-ALC4/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00144/AM08/	RLA File : 03/95/040/00389/AM08/	Lic.No/Date:03104375 08 26.07.2007	Defer Date: 29.01.2008
21	**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 decided to remind concerned RA for furnishing copy of application and Advance Authorisation. Accordingly, case was deferred for six weeks.			

22	**Case No.:3/18/82-ALC4/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00142/AM08/	RLA File : 03/94/040/00455/AM08/	Lic.No/Date:03104384 06 06.08.2007	Defer Date: 29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir Arved Tablets under para 4.7 of HBP. Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.			

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

23	**Case No.:113/21/82-ALC4/2007**	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00157/AM08/	RLA File : 22/24/040/00030/AM08/	Lic.No/Date:2210006984 20.08.2007	Defer Date: 01.01.2008

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

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

24	**Case No.:989/24/83-ALC1/2007**	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Approved**
	HQ File : 01/83/050/01007/AM08/	RLA File : 22/24/040/00034/AM08/	Lic.No/Date:2210006991 21.08.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/67/2007-PI-III dated 18.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Cefprozil Monohydrate----------1kg.

Import items:
1. 7-Phenylacetamido-3-chloromethyl Cephalasporanic Acid P-Methoxybenzyl Ester (GCLE)----------3.323kg/kg
2. Ethylenediamine Tetra Acetic Acid Disodium Salt------0.0137kg/kg
3. D(-)Alpha para hydroxyl phenylglycine Methyl Potassium Dane Salt----------1.050kg/kg

4. Acetone----------2.410kg/kg
5. Dimethyl Aniline----------Not allowed as not shown in process.
6. Methanol----------0.680kg/kg
7. Methylene chloride----------19.50kg/kg
8. Dimethyl Formamide----------4.910kg/kg
9. Hexamethyl Disilazane----------0.418kg/kg
10. Trimethyl Chlorosilane----------0.273kg/kg
11. Ethyl Acetate----------1.920kg/kg
12. N.O-Bis (Trimethysilane) Acetamide-------Not allowed as not shown in process.
13. Ethyl Chloro Formate----------0.406kg/kg
14. Trifluoro Acetic acid----------0.548kg/kg
15. Iso Propyl Alcohol----------7.380kg/kg
16. Triphenyl Phosphine----------1.96kg/kg
17. N-Methyl Morpholine----------0.0066kg/kg
18. Phosphorous Pentachloride----------Not allowed as not shown in process.
19. Ammonia----------0.500kg/kg
20. Caustic Soda----------0.670kg/kg
21. Phenol----------Not allowed as specific use not indicated.
22. N-Butyl Acetate----------2.24kg/kg
23. Activated Carbon----------0.100kg/kg

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

25	**Case No.:5/22/82-ALC4/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00175/AM08/	RLA File : 03/94/040/00571/AM08/	Lic.No/Date:0310441556 31.08.2007	Defer Date: 29.01.2008

Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/Duovir/Bivir/Arved Tablets under para 4.7 of HBP.

Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head

	of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information. 1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs. 2. %yield on molar basis for each step. 3. Requirement and recovery of Solvents. 4. Raw material composition for each bulk drugs in multi component form. The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

26	**Case No.:12/27/83-ALC1/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/01086/AM08/	RLA File : 03/94/040/00555/AM08/	Lic.No/Date:0310441561 31.08.2007	Defer Date: 29.01.2008
	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. Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information. 1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs. 2. %yield on molar basis for each step. 3. Requirement and recovery of Solvents. 4. Raw material composition for each bulk drugs in multi component form. The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.			

27	**Case No.:72/27/83-ALC1/2007**	Party Name:LUPIN LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/01146/AM08/	RLA File : 03/95/040/00570/AM08/	Lic.No/Date:0310442436 11.09.2007	Defer Date: 15.01.2008

	Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriazone Sodium Non infringing under para 4.7 of HBP. Committee decided to examine case on file on policy view point as there is non-fringing process involved.

28	**Case No.:10/22/82-ALC4/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP. Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information. 1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs. 2. %yield on molar basis for each step. 3. Requirement and recovery of Solvents. 4. Raw material composition for each bulk drugs in multi component form. The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.			

29	**Case No.:2/25/82-ALC4/2007**	Party Name:CIPLA LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP. Shri R.N. Kankan, Corporate R&D (API) and Shri Rajesh S. Ghangurde, Head of Imports of company appeared before Committee and explained their case. They stated that they will import raw material and first manufacture Bulk Drugs from Raw Material and thereafter they will manufacture Formulation from Bulk			

Drugs. After detailed deliberations, Committee asked the representatives to furnish the following information.

1. Wastage to be shown separately for manufacture of Bulk Drugs and Formulations from raw material and from Bulk Drugs.
2. %yield on molar basis for each step.
3. Requirement and recovery of Solvents.
4. Raw material composition for each bulk drugs in multi component form.

The representatives of company promised to furnish above information within 15 days. Accordingly, case was deferred for six weeks.

30	**Case No.:7/25/82-ALC4/2007**	Party Name:MADAUS PHARMACEUTICALS PRIVATE LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00201/AM08/	RLA File : 17/24/040/00068/AM08/	Lic.No/Date:1710001775 09.10.2007	Defer Date: 15.01.2008

Decision : Committee considered case as per agenda for ratification of norms for export product Agiolax (Bulk Granular Lasative Formulation) under para 4.7 of HBP.

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

31	**Case No.:8/25/82-ALC4/2007**	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Withdrawn**
	HQ File : 01/82/050/00202/AM08/	RLA File : 04/24/040/00253/AM08/	Lic.No/Date:0410091459 10.10.2007	

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 withdraw case as same has already been approved in its 32/08 meeting held on 11.12.2007.

32	**Case No.:9/25/82-ALC4/2007**	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/82/050/00203/AM08/	RLA File : 04/24/040/00254/AM08/	Lic.No/Date:0410091460 10.10.2007	Defer Date: 15.01.2008

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 hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.

	Case No.:10/25/82-ALC4/2007	Party Name:SHASUN CHEMICALS & DRUGS LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 15.01.2008
33	**Decision :** Committee considered case as per agenda for ratification of norms for export productSpironolactone Tablets (100mgs) under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.			

	Case No.:53/30/83-ALC1/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**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: 29.01.2008
34	**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.			

35	**Case No.:52/30/83-ALC1/2007**	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Withdrawn**
	HQ File : 01/83/050/01421/AM08/	RLA File : 09/24/040/00280/AM08/	Lic.No/Date:09100318 80 24.10.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP. Committee decided to withdraw case as same has already been			

	approved in 32/08 meeting held on 11.12.2007.

36	**Case No.:14/32/83-ALC1/2007**	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Deferred**
	HQ File : 01/83/050/01436/AM08/	RLA File : 03/94/040/00662/AM08/	Lic.No/Date:0310447885 25.10.2007	Defer Date: 15.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 6-Methoxy-2-Naphthaldehyde under para 4.7 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

37	**Case No.:73/32/83-ALC1/2007**	Party Name:ARCH PHARMALABS LTD	Meet No/Date:33/82-ALC4/2007 18.12.2007	**Status:Case Approved**
	HQ File : 01/83/050/01495/AM08/	RLA File : 05/24/040/00551/AM08/	Lic.No/Date:0510211499 02.11.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Dihydroartemisinin NLT 99% under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/245/2006/PI-III dated 18.12.2007 in the case of M/S Calyx Chemicals & Pharmaceuticals Ltd decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Dihydro Artemisinin----------1kg. Import items: Artemisinin----------1.12kg/kg Sodium Borohydride----------0.14kg/kg Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file 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.			