

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

Para 4.7 Decision

MEETING NUMBER : 32/82-ALC4/2007 MEETING DATE : 11.12.2007

The Meeting No.32/08 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 11.12.2007 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No.29/08 dated 20.11.2007 and Meeting No.30/08 held on 27.11.2007 were ratified by the Committee.

Case No.B-422	M/s. Glenmark Pharma
Meeting No.32/08	01/82/50/1484/AM-06
Date 11/12/2007	RLA File No.3/94/40/1347/AM06
Adv.Lic.No.0310372003 dt.17.3.2006	
Committee considered case as per agenda for ratification of norms for 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. Accordingly, Committee decided to defer case for six weeks.	

Case No.B-423	M/s. Glenmark Pharma
Meeting No.32/08	01/82/50/285/AM-08
Date 11/12/2007	RLA File No.9/24/40/178/AM03
Adv.Lic.No.0310295800 dt.7.10.2004	
Committee considered case as per agenda for ratification of norms for 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. Accordingly, Committee decided to defer case for six weeks.	

Case No.B-424	M/s. Arvindo Pharma
Meeting No.32/08	H.Q. File No.01/87/50/677/AM-07
Date 11/12/2007	RLA File No.9/24/40/273/AM07
Adv.Lic.No.0910028051 dt.2.11.2006	

Committee considered case as per agenda for ratification of norms for export product Mica Ester (Mica Thioester) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 11.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Mica Ester (Mica Thioester)-----1kg.

Import items:

1. Mica Acid-----0.83kg/kg
2. Methanol-----1.94kg/kg
3. Triethylamine-----0.322kg/kg
4. Triphenyl Phosphine-----0.911kg/kg
5. Methylene chloride-----2.00kg/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-425	M/s. Aurbindo Pharma
Meeting No.32/08	H.Q. File No.01/87/50/230/AM-07
Date 11/12/2007	RLA File No.9/24/40/11/AM07
Adv.Lic.No.0910026489dt.2.6.2006	
Committee considered case as per agenda for ratification of norms for export product Indinavir Sulfate under para 4.7 of HBP. Committee observed that revised application has been received from concerned RA which has been forwarded to PI Division for their comments. Accordingly, Committee decided to defer case for four weeks.	

Case No.B-426	M/s. Bajaj Health Care Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/1012/AM-07
Date 11/12/2007	RLA File No.3/94/40/539/AM07
Adv.Lic.No.0310401076 dt.25.9.2006	

Committee considered case as per agenda for ratification of norms for export product Carbamazepine BP (Micronized) under para 4.7 of HBP.

Committee observed that firm was requested to furnish complete analysis of particle size in export/import substance vide letter dated 19.03.2007, but firm had not furnished the same and accordingly case was rejected by Committee in its 2/82 meeting held on 16.05.2007. Committee also observed that firm has not furnished above information even now. It was, therefore, decided to maintain status quo.

Case No.B-427	M/s. Artemis Biotech
Meeting No.32/08	H.Q. File No.01/87/50/1324/AM-05
Date 11/12/2007	RLA File No.3/24/41/175/AM05
Adv.Lic.No.03102310813 dt.5.1.2005	
Committee considered case as per agenda for ratification of norms for export product Losarton Potassium under para 4.7 of HBP. Committee observed that technical details submitted by firm vide their letter dated 04.10.2005 are not related with this case. Committee, therefore, decided to maintain status quo.	

Case No.B-428	M/s. Ind-Swift Laboratories Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/179/AM-07
Date 11/12/2007	RLA File No.22/24/40/18/AM07
Adv.Lic.No.2210005501 dt.4.5.2006	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/77/2004-PI-III dated 11.12.2007 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:

Clopidogrel Hydrogen Sulphate-----1kg.

Import items:

1. Alpha Bromo-2-(2-chloro Phenyl) Acetic Acid—1.18kg/kg
2. Methylene chloride-----2.41kg/kg
3. Dimethyl formamide-----3.39kg/kg
4. Acetone-----3.91kg/kg
5. Thiophene-2-Ethanol-----1.00kg/kg
6. L(-)Camphor Sulphonic Acid-----0.70kg/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-429	M/s. Neuland Laboratories Ltd.
Meeting No.32/08	H.Q. File No.01/83/50/941/AM-07
Date 11/12/2007	RLA File No.9/24/40/285/AM07
Adv.Lic.No.0910028291 dt.21.11.2006	
Committee considered case as per agenda for amendment in import item No.1 namely Racemie-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride under para 4.7 of HBP. Committee in consultation with representative of PI Division present in meeting decided to allow amendment in description of import item No.1 to read as “Racemic-2-azabicyclo (3.3.0) octane-3-carboxylic acid benzylester Hydrochloride//(S,S)-2-azabicyclo (3.3.0)octane-3-carboxylic acid benzylester Hydrochloride’. RA concerned may take further necessary action as per above decision of Norms Committee.	

Case No.B-430	M/s. Lupin Ltd.
Meeting No.32/08	H.Q. File No.01/83/50/1432/AM-07
Date 11/12/2007	RLA File No.3/95/40/1111/AM07

Adv.Lic.No.0310412093 dt.13.12.2006	
Committee considered case as per agenda for ratification of norms for export product Cephalexin USP Premix 83% under para 4.7 of HBP. Committee in consultation with representative of PI Division present in meeting decided to ratify norms as per revised SION at Sl.No.A-116 published vide Public Notice No.2 dated 19.04.2007. RA concerned may calculate quantities of inputs on 83% pro-rata basis of the SION.	

Case No.B-431	M/s. Lupin Ltd.
Meeting No.32/08	H.Q. File No.01/83/50/2810/AM-06
Date 11/12/2007	RLA File No.3/95/40/1052/AM06
Adv.Lic.No.0310358437 dt.6.12.2005	
Committee considered case as per agenda for ratification of norms for export product Cilazapril under para 4.7 of HBP. Committee in consultation with representative of PI Division present in meeting observed that both the import items namely ‘D(-) para hydroxyl phenyl glycine methyl/ethyl potassium dane salt’ and “D(-) Alpha para hydroxyl phenyl glycine methyl/ethyl potassium dane salt” are same. Committee, therefore, decided to maintain status quo.	

Case No.B-432	M/s. Shilpa Medicare Ltd.
Meeting No.32/08	H.Q. File No.01/87/50/1517/AM-06
Date 11/12/2007	RLA File No.7/24/40/1025/AM06
Adv.Lic.No.0710043911 dt.23.3.2006	
Committee considered case as per agenda for ratification of norms for export product N-[B-Dribofuranosyl]-5-Hydroxyimindiazole-4-Carboxamide Technical 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 six weeks. Accordingly, Committee decided to defer case for six weeks.	

Case No.B-433	M/s.Sun Pharma Inds. Ltd.
Meeting No.32/08	H.Q. File No.01/87/50/1662/AM-05
Date 11/12/2007	RLA File No.3/24/40/2810/AM05
Adv.Lic.No.031022837 dt.23.3.2005	

Committee considered case as per agenda for ratification of norms for export product 3-Chloro 5 Acetyl Iminodibenzyl (Pure) under para 4.7 of HBP.

Committee in consultation with representatives of 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:

3-Chloro 5 Acetyl Iminodibenzyl (Pure)-----1kg.

Import item:

3-Chloro 5 Acetyl Iminodibenzyl (Crude)-----Net to Net with nil wastage

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-434	M/s. Wockhardt Ltd.
Meeting No.32/08	H.Q. File No.01/82/162/548/AM-08
Date 11/12/2007	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product D-Oxyphene Base (Powder).	
Committee in consultation with representative of Department of Revenue present in meeting decided to defer the case for two weeks for their comments.	

Case No.B-435	M/s.Penam Laboratories Ltd.
Meeting No.32/08	H.Q. File No.01/82/162/450/AM-08
Date 11/12/2007	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 6-Amino Penicillanic Acid.	
Committee in consultation with representative of Department of Revenue present in meeting decided to defer the case for two weeks for their comments.	

Case No.C-27	M/s.S.M. Herbals Pvt. Ltd.
Meeting No.32/08	H.Q. File No.01/82/162/443/AM-08
Date 11/12/2007	

Committee considered case as per agenda for fixation of SION in respect of export product Camptothecin.

Committee observed that till date no adhoc norms have been fixed for above export product . No All Industry Data is available. Committee, therefore, decided to reject request of firm.

Case No.A-884	M/s.Gland Pharma Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/257/AM-08
Date 11/12/2007	RLA F.No.9/24/40/356/AM08
Adv.Lic.No.0910032089 dt. 14.11.2007	
Committee considered case as per agenda for ratification of norms for export product Adenosine Injection USP Prefilled Syringe 30mg/ml, 2ml in a PFS 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, Committee decided to defer case for four weeks.	

Case No.A-885	M/s.Cipla Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/256/AM-08
Date 11/12/2007	RLA F.No.3/94/40/797/AM08
Adv.Lic.No.0310448512 dt. 31.10.2007	
Committee considered case as per agenda for ratification of norms for export product Efavir Capsules 200mg/Efavirenz 200mg Capsules and Efavir 600mg Tablets/Efavirenz 600mg Tablets under para 4.7 of HBP. Committee decided to call for the representative of firm for personal hearing on 18.12.2007.	

Case No.A-886	M/s.Cipla Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/255/AM-08
Date 11/12/2007	RLA F.No.3/94/40/798/AM08
Adv.Lic.No.0310448930 dt. 2.11.2007	

Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg tablets/Lamivudine Tablets 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets/Lamivudine and Stavudine Tablets, Lamivir S Baby Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 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 decided to call for the representative of firm for personal hearing on 18.12.2007.

Case No.A-887	M/s.Cadila Healthcare Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/189/AM-08
Date 11/12/2007	RLA F.No.8/24/40/159/AM08
Adv.Lic.No.0810067316 dt. 24.7.2007	
Committee considered case as per agenda for ratification of norms for export product Paroxetine Hcl 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 two weeks. Accordingly, Committee decided to defer case for two weeks.	

Case No.A-888	M/s.Aurobindo Pharma Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/225/AM-08
Date 11/12/2007	RLA F.No.9/24/40/194/AM08
Adv.Lic.No.0910031159 dt. 16.8.2007	

Committee considered case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium + Salbactam Sodium (2:1) 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 Permanganate-----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.

Case No.A-889	M/s.Astrix Laboratories Ltd.
Meeting No.32/08	H.Q. File No.01/83/50/266/AM-08
Date 11/12/2007	RLA F.No.9/24/40/502/AM08
Adv.Lic.No.0910030196 dt. 7.5.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/80/2007-PI-III dated 06.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Stavudine-----1kg.

Import items:

1. 5-Methyl Uridine-----3.15kg/kg
2. N-Methyl Morpholine-----1.23kg/kg
3. Methane sulfonyl chloride-----2.40kg/kg
4. Acetic Acid-----0.49kg/kg
5. N-Methyl Pyrrolidinone-----1.40kg/kg
6. Methanol-----1.17kg/kg
7. Dimethyl Formamide-----1.13kg/kg
8. Ethyl Acetate-----5.87kg/kg
9. Acetone-----2.24kg/kg
10. Iso Propyl Alcohol-----1.75kg/kg
11. Activated carbon-----0.10kg/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.A-890	M/s.Medreich Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/48/AM-08
Date 11/12/2007	RLA F.No.7/24/40/810/AM08
Adv.Lic.No.0710050467 dt. 6.3.2007	
Committee considered case as per agenda for ratification of norms for export product Paracetamol 450mg + Caffeine 45mg +Codeine Phosphate 10mg tablets 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.	

Case No.A-891	M/s.Medreich Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/1790/AM-08
Date 11/12/2007	RLA F.No.7/24/40/718/AM08
Adv.Lic.No.0710049763 dt. 24.1.2007	

Committee considered case as per agenda for ratification of norms for export product Paracetamol 450mg + Doxylamine Succinate 5mg +Caffeine 45mg + Codeine Phosphate 10mg Tablets, Paracetamol 450mg +Doxylamine Succinate 5mg + Caffeine 50mg + Codeine Phosphate 10mg Tablets and Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 30mg + Codeine Phosphate 10mg Tablets under para 4.7 of HBP.

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

Case No.A-892	M/s.Nicholas Piramal India Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/261/AM-08
Date 11/12/2007	RLA F.No.3/95/40/1401/AM07
Para 4.4.2	

Committee considered case as per agenda for ratification of norms for export product Vitamin A Palmitate 1.7 MIU/gm. under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/226/2006-PI-III dated 11.12.2007 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:

Vitamin A Palmitate 1.7 MIU/gm-----1kg.

Import items:

1. Aldehyde Collidine-----0.079kg/kg
2. Methanol-----0.88kg/kg
3. Betaionone-----0.5478kg/kg
4. Dimethyl Sulfoxide-----0.190kg/kg
5. Ethyl Bromide-----0.678kg/kg
6. Lithium Metal-----0.053kg/kg
7. Methylene chloride-----0.45kg/kg
8. Paraformaldehyde-----0.427kg/kg
9. Magnesium-----0.153kg/kg
- 10.Sod. Methylate-----0.330kg/kg
- 11.N-Hexane-----1.161kg/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.A-893	M/s.Hetero Drugs Ltd.
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Meeting No.32/08	H.Q. File No.01/82/50/263/AM-08
Date 11/12/2007	RLA F.No.9/95/40/247/AM08
Adv.Lic.No.0910032132 dt. 22.11.2007	
Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/87/2007-PI-III dated 03.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Lamivudine-----1kg. Import items: 1. Glyoxylic acid 50%-----1.80kg/kg. 2. 1,4-dithiane-2,5-dihydroxy-----0.739kg/kg 3. Cytosine-----0.955kg/kg 4. Hexamethyl disilazane-----1.89kg/kg 5. Salicylic acid-----0.79kg/kg 6. Sodium borohydride-----0.48kg/kg 7. Dimethyl formamide-----0.83kg/kg 8. N-Hexane-----3.75kg/kg 9. Methylene dichloride-----5.75kg/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.A-894	M/s.Matrix Labs Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/260/AM-08
Date 11/12/2007	RLA F.No.7/24/40/221/AM08
Adv.Lic.No.0710031767 dt. 15.10.2007	
Committee considered case as per agenda for ratification of norms for export product L-Menthyl Glyoxylate Hydrate (MGH) 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, Committee decided to defer case for four weeks.	

Case No.A-895	M/s.Karnataka antibiotics & Pharma Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/262/AM-08

Date 11/12/2007	RLA F.No.7/24/40/533/AM08
Adv.Lic.No.0710054149 dt. 26.10.2007	
Committee considered case as per agenda for ratification of norms for export product Ceftazidime 1gm Injection under para 4.7 of HBP. Committee in light of its earlier decision taken in its 26/82 meeting held on 30.10.2007 vide Case No.1/26/82 and in consultation with representative of PI Division present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export Product: Ceftazidime 1gm. Injection Import item: Sterile Ceftazidime USP as Pentahydrate With minimum 8.33% Sodium Carbonate-----1.32gm/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.A-896	M/s.Mission Pharma Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/258/AM-08
Date 11/12/2007	RLA F.No.3/95/40/563/AM08
Adv.Lic.No.0310445307 dt. 5.10.2007	
Committee considered case as per agenda for ratification of norms for export product Levamisole Hydrochloride Tabs USP 40MG (KYMORM) and Levamisole Syrup (KYMORM) 15ml Bottle 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, Committee decided to defer case for four weeks.	

Case No.A-897	M/s.Matrix Labs. Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/261/AM-08
Date 11/12/2007	RLA F.No.9/95/40/255/AM08
Adv.Lic.No.0910031766 dt. 15.10.2007	

Committee considered case as per agenda for ratification of norms for export product Levetiracetam 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, Committee decided to defer case for four weeks.

Case No.A-898	M/s.Matrix Labs. Ltd.
Meeting No.32/08	H.Q. File No.01/82/50/259/AM-08
Date 11/12/2007	RLA F.No.9/95/40/243/AM08
Adv.Lic.No.0910031765 dt. 15.10.2007	

Committee considered case as per agenda for ratification of norms for export product Efavirenz Stage-V ((S)-5-Chloro-(cyclopropylethynyl)-2-amino-(trifluoromethyl) Benxenemethanol) MMAA-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, Committee decided to defer case for four weeks.

1	Case No.:2/35/82-ALC1/2004	Party Name:MADHUR PHARMA & RESEARCH LABORATORIES PVT.LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/82/050/01467/AM05/	RLA File : 07/24/040/00492/AM05/	Lic.No/Date:0710034246 23.11.2004	Defer Date:11.12.2007
Decision :Committee considered case as per agenda for ratification of norms for export product Herpasil Capsules and Stimmune Capsules under para 4.7 of HBP. Committee in light of written comments forwarded by Department of MSME vide their U.O. No.5(9)/2005-Chem dated 28.11.2007 and 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: 1. Herpasil Capsules-----3,00,000 Nos. 2. Stimmue Capsules-----3,00,000 Nos. Import items: 1. Prunella Vulgaris-----105kg. 2. Astralafus Membranaceous-----30kg.				

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.

2	Case No.:9/22/83-ALC1/2006	Party Name:PARABOLIC DRUGS LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Added
	HQ File : 01/83/050/00293/AM07/	RLA File : 22/24/040/00056/AM07/	Lic.No/Date:2210005639 15.06.2006	Defer Date:
Decision : Committee considered case as per agenda for ratification of norms for export product Cloxacillin Sodium form Pen G Route under para 4.7 of HBP. Committee decided to ratify norms as per revised SION at Sl.No.A-152 published vide Public Notice No.45 dated 06.09.2007. RA concerned may take further necessary action as per above decision of Norms Committee.				

3	Case No.:11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/87/050/00566/AM07/	RLA File : 02/24/040/00189/AM07/	Lic.No/Date:0210094006 25.09.2006	Defer Date:11.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Senega Soft Extract under para 4.7 of HBP. Representative of Department of MSME 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.				

4	Case No.:631/24/87-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/87/050/00972/AM07/	RLA File : 09/24/040/00440/AM07/	Lic.No/Date:0910029251 08.02.2007	Defer Date:11.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine (Cyclohexyl Ester Route) under para 4.7 of HBP.				

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/80/2007-PI-III dated 06.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Lamivudine (Cyclohexyl Ester Route)-----1kg.

Import items:

1. Cyclohexyl ester-----2.19kg/kg
2. Sodium Borohydride-----0.48kg/kg
3. Methanol-----0.290kg/kg
4. Toluene-----0.350kg/kg
5. Triethylamine-----2.00kg/kg
6. Isopropyl Alcohol-----2.51kg/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.

5	Case No.:8/2/83-ALC1/2007	Party Name:PAB ORGANICS PVT.LTD,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deffered and Re-indexed
	HQ File : 01/83/050/01256/AM07/	RLA File : 34/24/040/00259/AM07/	Lic.No/Date:3410018108 19.02.2007	Defer Date:11.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product 5-Bromo Phthalide under para 4.7 of HBP. Committee noted that this case has been received from DES-IV Section in September, 2007. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for six weeks. Accordingly, Committee decided to defer case for six weeks.				

6	Case No.:445/24/83-ALC1/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01268/AM07/	RLA File : 09/24/040/00478/AM07/	Lic.No/Date:0910029428 22.02.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of				

norms for export product {3-5[Bromo-1-(fluorophenyl)(1,3-dihydro isobenzofuranyl)]propyl] dimehylamine oxalate under para 4.7 of HBP.

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

7	Case No.:12/7/83-ALC1/2007	Party Name:RANTUS PHARMA PVT LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/00083/AM08/	RLA File : 09/24/040/00433/AM07/	Lic.No/Date:09100299 34 10.04.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Tramadol Base under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				

8	Case No.:6/4/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/82/050/00031/AM08/	RLA File : 03/95/040/00095/AM08/	Lic.No/Date:03104289 99 10.05.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Diprosone Lotion 30ml under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				

9	Case No.:34/18/83-ALC1/2007	Party Name:HARMAN FINOCHEM LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/00471/AM08/	RLA File : 03/94/040/01379/AM07/	Lic.No/Date:03104311 13 30.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Xipamide under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/99/2007-PI-III dated 26.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm				

whichever is lower.

Export product:

Xipamide-----1kg.

Import items:

1. 4-chloro salicylic acid-----1.64kg/kg
2. Methyl Iso Butyl Ketone-----4.95kg/kg
3. 2.6 Xylidine-----1.80kg/kg
4. Iso Propyl Alcohol-----1.31kg/kg
5. Methanol-----2.00kg/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.

10	Case No.:821/24/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:32/82- ALC4/2007 11.12.2007	Status:Case Withdrawn
	HQ File : 01/83/050/00807/AM08/	RLA File : 03/94/040/00375/AM08/	Lic.No/Date:03104361 63 13.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product 2-Dimethyl Amino Isopropyl Chloride Hydrochloride or DMAIPC Or 2 Chloro-1-Dimethylamino Propane Hydrochloride under para 4.7 of HBP. Committee decided to withdraw this case as same has been decided by NC in its 26/08 meeting held on 30.10.2007.				

11	Case No.:797/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:32/82- ALC4/2007 11.12.2007	Status:Deffered and Re-indexed
	HQ File : 01/83/050/00755/AM08/	RLA File : 05/24/040/00286/AM08/	Lic.No/Date:05102063 21 16.07.2007	Defer Date:11.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Citalopram Hydrobromide under para 4.7 of HBP. Committee observed that non infringing process is involed in				

manufacture of export product. Committee, therefore, decided to examine case on file on policy view point.

12	Case No.:3/20/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/82/050/00146/AM08/	RLA File : 03/95/040/00277/AM08/	Lic.No/Date:03104375 31 26.07.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Epiderm Lotion 30ml under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				

13	Case No.:894/24/83-ALC1/2007	Party Name:DOCTORSORGANIC CHEMICALS LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/00902/AM08/	RLA File : 26/24/040/00001/AM08/	Lic.No/Date:26100063 18 07.08.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Clopidogrel hydrogen Sulphate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2004-PI-III dated 06.12.2007 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: Clopidogrel Hydrogen Sulphate-----1kg. Import items: 1. DL-2 chloro phenyl glycine -----1.05kg/kg 2. 2-Thiophene ethanol-----0.61kg/kg 3. L+ tartaric acid-----0.70kg/kg 4. Toluene-----6.75kg/kg 5. Acetonitrile-----0.280kg/kg 6. Isopropyl alcohol-----1.01kg/kg 7. Methanol-----0.33kg/kg 8. Acetone-----0.82kg/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.

14	Case No.:5/20/82-ALC4/2007	Party Name:RICHY GOLD INTERNATIONAL	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/82/050/00162/AM08/	RLA File : 03/95/040/00461/AM08/	Lic.No/Date:03104394 44 14.08.2007	Defer Date: 22.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Oral Rehydration Salt BP under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for six weeks. Accordingly, Committee decided to defer case for six weeks.				

15	Case No.:972/24/83-ALC1/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/83/050/00988/AM08/	RLA File : 09/24/040/00554/AM07/	Lic.No/Date:09100311 78 21.08.2007	Defer Date:11.12.20 07
Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Epoxy-2-(2,4-Difluorophenyl)-3(1(H)-Triazole-1YL) Propane Methane Sulphonate 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. According, Committee decided to defer case for four weeks.				

16	Case No.:973/24/83-ALC1/2007	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/83/050/00990/AM08/	RLA File : 09/24/040/00139/AM08/	Lic.No/Date:09100311 79 21.08.2007	Defer Date:11.12.20 07
Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Epoxy-2-(2,4-Difluorophenyl)-3(1(H)-Triazole-1YL) Propane Methane Sulphonate 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. According, Committee decided to defer case for four weeks.

Case No.:1005/24/83-ALC1/2007	Party Name:CALYX CHEMICALS & PHARMACEUTICALS LTD.	Meet No/Date:32/82- ALC4/2007 11.12.2007	Status:Case Approved
HQ File : 01/83/050/01023/AM08/	RLA File : 03/94/040/00234/AM08/	Lic.No/Date:03104406 40 23.08.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Dihydro Artemisinin 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 26.11.2007 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: Dihydro Artemisinin-----1kg Import items: 1. Artemisinin-----1.12kg/kg 2. 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.			

Case No.:1000/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:32/82- ALC4/2007 11.12.2007	Status:Case Deferred
HQ File : 01/83/050/01018/AM08/	RLA File : 09/24/040/00185/AM08/	Lic.No/Date:09100312 01 24.08.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product 8-Chloro-5,6-Dihydro-11h-benzo(5,6)cyclohepta(1,2-b)pyridence-11-one under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

19	Case No.:6/25/83-ALC1/2007	Party Name:BIOCHEMICAL & SYNTHETIC PRODUCTS LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01031/AM08/	RLA File : 09/24/040/00055/AM08/	Lic.No/Date:09100313 13 29.08.2007	Defer Date: 08.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product 4-Acetamido-5-Bromo-2-Methoxy Benzoic Acid Methyl Ester (Bromomethopabate under para 4.7 of HBP. Committee in light of its earlier decision taken in its 01/2005 held on 07.04.2004 vide Case No.A-15 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: 4-Actamido-5-Bromo-2-Methoxy Benzioc Acid Methyl Ester-----1kg. Import items: 1. Meta Amino Phenol-----0.86kg/kg 2. Potassium Carbonate-----1.94kg/kg 3. Bromine-----0.59kg/kg RA concerned may take further necessary action as per above decision of Norms Committee.			

20	Case No.:7/25/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01032/AM08/	RLA File : 09/24/040/00231/AM08/	Lic.No/Date:09100313 14 29.08.2007	Defer Date: 22.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Didanosine under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for six weeks. Accordingly, Committee decided to defer case for six weeks.			

21	Case No.:42/25/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:03104414	Defer

01/83/050/01067/AM08/	03/94/040/00299/AM08/	32 30.08.2007	Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Nitazoxanide under para 4.7 of HBP.			
Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

22	Case No.:5/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01079/AM08/	RLA File : 09/24/040/00234/AM08/	Lic.No/Date:09100313 29 31.08.2007	Defer Date: 08.01.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Florfenicol under para 4.7 of HBP.			
	Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

23	Case No.:24/27/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01098/AM08/	RLA File : 09/24/040/00226/AM08/	Lic.No/Date:09100313 83 03.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Dibenzosuberone under para 4.7 of HBP.				
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/77/2007-PI-III dated 11.12.2007 decided to ratify norms on repeat under para 4.7 of HBP as per details below or as applied by firm whichever is lower.				
Export product: Dibenzosuberone-----1kg.				
Import items: 1. Methanol-----0.627kg/kg 2. Acetonitrile-----0.75kg/kg 3. Phosphorous Pentaoxide-----0.758kg/kg 4. Phosphoric acid-----0.523kg/kg 5. Tetrahydrofuran-----0.25kg/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.

24	Case No.:29/27/83-ALC1/2007	Party Name:AVENTIS PHARMA LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01103/AM08/	RLA File : 03/94/040/00521/AM08/	Lic.No/Date:0310441708 03.09.2007	Defer Date:
	Decision : Committee considered case as per agenda for ratification of norms for export product under para 4.7 of HBP. Committee decided to withdraw this case as agenda was generated in the case of M/S Aventis Pharma Ltd while RA has furnished application of M/S Dalas Ltd.			

25	Case No.:36/27/83-ALC1/2007	Party Name:BAJAJ HEALTHCARE LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Deferred and Re-indexed
	HQ File : 01/83/050/01110/AM08/	RLA File : 03/94/040/00486/AM08/	Lic.No/Date:0310441914 05.09.2007	Defer Date:11.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Carbamazepine BP (Micronized) under para 4.7 of HBP. Committee observed that firm was requested to furnish complete analysis of particle size in export/import substance vide letter dated 19.03.2007, but firm had not furnished the same and accordingly case was rejected by Committee in its 2/82 meeting held on 16.05.2007. Committee also observed that firm has not furnished above information even now. It was, therefore, decided to maintain status quo.			

26	Case No.:30/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01104/AM08/	RLA File : 09/24/040/00239/AM08/	Lic.No/Date:0910031400 05.09.2007	
	Decision : Committee considered case as per agenda for ratification of			

norms for export product Stavudine under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Stavudine-----1kg.

Import items:

1. Acetic Acid-----1.11kg/kg
2. Acetone-----3.63kg/kg
3. Beta Thymidine-----2.36kg/kg
4. Carbon enoanticromos-----0.100kg/kg
5. Isopropyl alcohol-----11.64kg/kg
6. Methane sulfonyl chloride-----2.40kg/kg
7. Methanol-----2.22kg/kg
8. N-Methyl pyddolidine-----1.45kg/kg
9. Pyridine-----5.80kg/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.:54/27/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01128/AM08/	RLA File : 03/94/040/00525/AM08/	Lic.No/Date:0310441978 06.09.2007	Defer Date: 08.01.2008
27	Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			
28	Case No.:61/27/83-ALC1/2007	Party Name:APITHECARY PHARMA PVT LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred

HQ File : 01/83/050/01135/AM08/	RLA File : 09/24/040/00147/AM08/	Lic.No/Date:09100314 43 07.09.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Omeprazole Sulphide or 5-Methoxy-2-[[4-Methoxy-3,5-Dimethyl-2-Pyridine-2-Methyl]Thio]-1H-Benzimidazole under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

Case No.:94/27/83-ALC1/2007	Party Name:ENVEE DRUGS PVT LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
HQ File : 01/83/050/01168/AM08/	RLA File : 34/24/040/00082/AM08/	Lic.No/Date:34100196 47 14.09.2007	Defer Date: 08.01.2008
29	Decision : Committee considered case as per agenda for ratification of norms for export product Betamethasone Valerate BP/USP under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.		

30	Case No.:116/27/83-ALC1/2007	Party Name:VITAL HEALTHCARE PVT.LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01190/AM08/	RLA File : 03/95/040/00584/AM08/	Lic.No/Date:03104433 65 17.09.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Dihydro Artemisinin 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 11.12.2007 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: Dihydro Artemisinin-----1kg. Import items:			

1. Artemisinin-----1.12kg/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.:132/27/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
HQ File : 01/83/050/01206/AM08/	RLA File : 05/24/040/00489/AM08/	Lic.No/Date:05102091 50 18.09.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 11.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Lorazepam-----1kg.

31 Import items:

1. 2,Amino-2,5-dichloro benzophenone-----1.60kg/kg
2. Chloro acetaldehyde demethyl acetal-----0.82kg/kg
3. Methanol-----6.16kg/kg
4. Isopropyl alcohol-----1.91kg/kg
5. Methylene chloride-----7.74kg/kg
6. Toluene-----1.11kg/kg
7. Acetone-----2.67kg/kg
8. Activated Carbon-----0.0687kg/kg
9. Cyclohexane-----1.71kg/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.

32	Case No.:12/22/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/82/050/00182/AM08/	RLA File : 03/94/040/00638/AM08/	Lic.No/Date:0310443698 19.09.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				

33	Case No.:14/29/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01279/AM08/	RLA File : 03/94/040/00630/AM08/	Lic.No/Date:0310444397 26.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Cilostazol under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/243/2006-PI-III dated 05.12.2006 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: Cilostazol-----1kg. Import items: 1. 5-(4-chlorobutyl)-1-cyclohexyl-1H-Tetrazole----0.88kg/kg 2. 6-Hydroxy-3,4-Dihydro-1H-Quinolin-2-one-----0.59kg/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.				

34	Case No.:24/29/83-	Party Name:CIPLA LIMITED	Meet No/Date:32/82-	Status:Ca
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ALC1/2007		ALC4/2007 11.12.2007	se Approved
HQ File : 01/83/050/01289/AM08/	RLA File : 03/94/040/00651/AM08/	Lic.No/Date:03104445 71 28.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Trimetazidine Dihydrochloride under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/231/2005-PI-III dated 11.12.2007 in the case of M/S Alcon Biosciences Pvt. Ltd and 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: Trimetazidine Dihydrochloride-----1kg. Import items: 1. 2,3,4 Trimethoxy Benzaldehyde----0.80kg/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.:26/29/83- ALC1/2007	Party Name:INDO GERMAN ALKALOIDS	Meet No/Date:32/82- ALC4/2007 11.12.2007	Status:Ca se Deferred
HQ File : 01/83/050/01291/AM08/	RLA File : 03/94/040/00663/AM08/	Lic.No/Date:03104450 49 03.10.2007	Defer Date: 08.01.2008
35	Decision : Committee considered case as per agenda for ratification of norms for export product Ipecacuanha Tincture BP/EP under para 4.7 of HBP. Committee decided to refer the case to Deptt. of MSME alongwith DGFT Technical Report, Report of the Central Council for Research in Ayurveda and Siddha dated 24.01.2007 and copy of D.O. letter received from Deptt. of Ayush. Accordingly, case was deferred for four weeks.		

36	Case No.:25/29/83-	Party Name:CIPLA LIMITED	Meet No/Date:32/82-	Status:Ca
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ALC1/2007		ALC4/2007 11.12.2007	se Added
HQ File : 01/83/050/01290/AM08/	RLA File : 03/94/040/00684/AM08/	Lic.No/Date:03104450 36 03.10.2007	Defer Date:
Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

Case No.:9/29/83-ALC1/2007	Party Name:HETERO LABS LTD.	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
HQ File : 01/83/050/01274/AM08/	RLA File : 09/24/040/00278/AM08/	Lic.No/Date:09100317 04 04.10.2007	Defer Date: 08.01.2008
37	Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.		

38	Case No.:31/29/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01296/AM08/	RLA File : 03/94/040/00659/AM08/	Lic.No/Date:03104452 95 05.10.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Bupropion Hcl BP under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/191/2006-PI-III dated 11.12.2007 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: Bupropion Hcl. BP-----1kg.			

Import items:

1. M-chloro propiophenone-----0.85kg/kg
2. Methanol-----Not allowed as not shown in process/material balance
3. Methelene chloride/Methelene Cichloride/DMC-----2.00kg/kg
4. Acetonitrile-----1.00kg/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.

39	Case No.:39/29/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01304/AM08/	RLA File : 03/94/040/00643/AM08/	Lic.No/Date:0310445399 08.10.2007	Defer Date: 22.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for six weeks. Accordingly, Committee decided to defer case for six weeks.				

40	Case No.:71/29/83-ALC1/2007	Party Name:HONEST BIO-VET PVT. LTD	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01336/AM08/	RLA File : 08/24/040/00174/AM08/	Lic.No/Date:0810067747 11.10.2007	Defer Date: 08.01.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Menadione Sodium Bisulphite Complex (MSB 65%) under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.				

41	Case No.:44/30/83-ALC1/2007	Party Name:INDO GERMAN ALKALOIDS	Meet No/Date:32/82-ALC4/2007	Status:Case
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		11.12.2007	Approved
HQ File : 01/83/050/01413/AM08/	RLA File : 03/94/040/00717/AM08/	Lic.No/Date:03104469 75 18.10.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Ipecacuanha Extract BP/USP under para 4.7 of HBP. Committee in light of its earlier decision taken in its 2/82 meeting held on 16.05.2007 vide Case No.38/31/82 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 for by firm whichever is lower. Ipecacuanha Extract BP/IP-----1kg. Import item: Ipecacuanha Roots-----4.10kg/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.:50/30/83-ALC1/2007	Party Name:JUPITER BIOSCIENCE LIMITED,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Deferred
	HQ File : 01/83/050/01419/AM08/	RLA File : 09/24/040/00336/AM08/	Lic.No/Date:09100318 78 24.10.2007	Defer Date: 08.01.2008
42	Decision : Committee considered case as per agenda for ratification of norms for export product N-T-Boc-L-Phyenylalanine 99% purity under para 4.7 of HBP. Representative of PI Division informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

43	Case No.:54/32/83-ALC1/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01476/AM08/	RLA File : 03/95/040/00727/AM08/	Lic.No/Date:03104486 29	

	01.11.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Artesunate under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/297/2005-PI-III dated 11.09.2007 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: Artesunate-----1kg. Import items: 1. Artemisinin-----0.9259kg/kg 2. Sodium borohydride-----0.150kg/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.		

44	Case No.:83/32/83-ALC1/2007	Party Name:HETERO DRUGS LIMITED,	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01505/AM08/	RLA File : 09/24/040/00344/AM08/	Lic.No/Date:09100319 92 05.11.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Lisinopril under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/219/2005-PI-III dated 11.12.2007 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: Lisinopril-----1kg. Import items: 1. N 2-[(1-S)-Ethoxy Carbonyl-3-Phenyl Propyl]-N 6-trifluoro acetyl-L-lysine benzyl ester-----2.58kg/kg				

2. Palladium on carbon 5%-----0.011kg/kg
3. L-Proline-----0.927kg/kg
4. Methanol-----5.45kg/kg
5. Methylene chloride-----10.77kg/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.

45	Case No.:86/32/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:32/82-ALC4/2007 11.12.2007	Status:Case Approved
	HQ File : 01/83/050/01508/AM08/	RLA File : 03/95/040/00776/AM08/	Lic.No/Date:03104493 60 06.11.2007	

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/99/2007-PI-III dated 26.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:
Cefixime Trihydrate-----1kg.

Import items:

1. GCLE-----1.555kg/kg
2. PGTA disodium-----0.020kg/kg
3. DATMA-----0.923kg/kg
4. Methanol-----3.69kg/kg
5. Methylene chloride-----16.57kg/kg
6. Dimethyl formamide-----0.49kg/kg
7. Ethyl acetate-----5.98kg/kg
8. MIBK-----0.42kg/kg
9. Dimethylamine-----0.62kg/kg
10. Formaldehyde-----1.7419kg/kg
11. N-methyl morpholine-----0.12kg/kg
12. Activated Carbon-----0.100kg/kg
13. Ammonia-----0.65kg/kg
14. Celite-----Not a raw material.

Hence not allowed.

15. Phosphorus pentachloride-----0.88kg/kg
16. Sodium bicarbonate-----0.6471kg/kg
17. Sodium carbonate-----0.2686kg/kg
18. Sodium hydrosulphite-----0.001kg/kg
19. Triphenyl phosphine-----1.22kg/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.

Outside agenda:

Case No. Outside Agenda-1	M/S Covalent Laboratories Pvt. Ltd.
Norms Committee Meeting No.32/08	F.No.01/83/50/1421/AM08
Meeting Date:11.12.2007	RLA F.No.09/24/40/280/AM08
Adv.Lic.No.0910031880 dated 24.10.2007	
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 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: 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. Methanol-----4.68kg/kg 6. 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.

Case No. Outside Agenda-2	M/S Divis Labs Ltd.
Norms Committee Meeting No.32/08	F.No.01/82/50/56/AM07
Meeting Date:11.12.2007	RLA F.No.09/24/40/182/AM01
Adv.Lic.No.0910019924 dated 30.08.2004	
Committee considered case as per agenda for ratification of norms for export product Capecitabine 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 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: Capecitabine-----1kg. Import items: 1. D-Ribose-----8.57kg/kg 2. 2,2 Dimethoxy Propane-----11.88kg/kg 3. Methanol-----11.61kg/kg 4. 4-amino-5-fluoro-2-hydroxy pyrimidine---Not required in process. Hence not allowed. 5. Sodium Boro hydride-----0.74kg/kg 6. P-toluene sulfonyl chloride-----6.53kg/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. Outside Agenda-3	M/S Surya Pharmaceutical Ltd
Norms Committee Meeting No.32/08	F.No.01/83/50/1135/AM07
Meeting Date:11.12.2007	RLA F.No.22/24/40/291/AM07
Adv.Lic.No.2210006400 dated 17.01.2007	
Committee considered case as per agenda for ratification of norms for export product Sultamicillin Tosylate 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 10.12.2007 and 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: Sultamicillin Tosylate-----1kg. Import items: 1. Salbactam Sodium-----0.90kg/kg 2. Ampicillin Anhydrous-----0.80kg/kg 3. Chloromethyl chloro sulphate-----0.58kg/kg 4. Tetrabutyl ammonium hydrogen sulphate-----0.144kg/kg 5. Sodium Iodide-----0.34kg/kg 6. Sodium Thiosulphate-----Not shown in reaction. Hence not allowed. 7. Para Toluene Sulfonic acid-----0.33kg/kg 8. Potassium carbonate-----0.295kg/kg 9. Methylene chloride-----2.159kg/kg 10. Isopropyl alcohol-----1.31kg/kg 11. Acetone-----1.05kg/kg 12. Dimethyl formamide-----0.58kg/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. Outside Agenda-4	M/S Shasun Chemicals & Drugs Ltd.
Norms Committee Meeting No.32/08	F.No.01/82/50/202/AM08/DES-III
Meeting Date:11.12.2007	RLA F.No.04/24/40/253/AM08
Adv.Lic.No.0410091459 dated 10.10.2007	

Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets 25mg 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 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:

Spiromolactone tablets 25mg.

Import items:

1. Spironolactone EP-----25.50mg/tablet
2. Lactose Monohydrate-----125.00mg/tablet
3. Povidone EP-----3.00mg/tablet
4. Hydroxy Propyl methyl Cellulose 6000EP-----6.00mg/tablet

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. Outside Agenda-5	M/S Amoli Organics Ltd
Norms Committee Meeting No.32/08	F.No.01/87/50/606/AM07
Meeting Date:11.12.2007	RLA F.No.03/94/40/411/AM07
Adv.Lic.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 in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 10.12.2007 decided to call for following details/clarification from firm. 1. Whether the export product is a chemically bonded product or a physical mixture of Noscapine and Resin. 2. In case if the export product is formed by chemical reaction, molecular weight of resin and the export product with percentage yield of molar basis be furnished. Otherwise proportion of Noscapine and Resin in the export product be given in the process along with wastage claimed. Export product may also be suitably amended. 3. Complete chemical description of resin along with technical catalogue	

may be furnished.

4. Whereas no moisture content is shown in the application or in the licence, the firm is showing a large content of 68% moisture in resin in the process details and accordingly have worked out the requirement. Technical justification along with documentary evidence may be furnished on the above. Whether the dowex resin is in powder form or paste may be clarified.

Accordingly, case was deferred for six weeks.