

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

Para 4.7 Decision

MEETING NUMBER : 27/82-ALC4/2007 MEETING DATE : 06.11.2007

Minutes of NC-III meeting No.27/08 held on 07.11.2007

The Meeting No.27/08 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 07.11.2007 in the chamber of Export Commissioner under the Chairmanship of Shri Sanjay Rastogi.

At the outset minutes of Norms Committee Meeting No.25/08 dated 23.10.2007 and Meeting No.26/08 dated 30.10.2007 were ratified by the Committee.

Case No.B-376	M/s. Cadila Pharma Ltd
M.No.27/08	F.No.01/82/50/1433/AM 05
Meeting Date 06.11.2007	RLA F. No. 08/24/40/95/AM05
Adv.Lic. No. 0810041718 dt. 06.09.2004 Adv.Lic. No. 0810036678 dt. 05.03.2004	
The Committee considered case as per agenda for ratification of norms for the export product Carbinoxamine under para 4.7 of HBP.	
Committee observed that case has already been approved by NC in its 1/08 meeting held on 09.05.2007. Committee, therefore, decided to withdraw case.	

Case No.B-377	M/s.Bajaj Healthcare Ltd.
M.No.27/08	F.No.01/82/50/1012/AM 07
Meeting Date 06.11.2007	RLA F. No. 03/94/40/539/AM07
Adv. Lic No. 0310401076 dt. 25.09.2006	
The Committee considered case as per agenda for ratification of norms for the export product Carbamazepine BP under para 4.7 of HBP.	
Committee in consultation with technical authorities present in the meeting decided to call for specification of import item and particle size from the supplier. Accordingly, case was deferred for six weeks.	

Case No.B-378	M/s. Aurobindo Pharma Ltd
M.No.27/08	F.No.01/87/50/677/AM 07
Meeting Date 06.11.2007	RLA F. No. 09/24/40/273/AM07

Adv. Lic No. 0910028051 dt. 02.11.2006	
The Committee considered case as per agenda for ratification of norms for the export product Mica Ester (Mica Thioester) under para 4.7 of HBP.	
Committee decided to call for upto date details of actual import from concerned RA. Accordingly case was deferred for six weeks.	

Case No.B-379	M/s. Aurobindo Pharma Ltd
M.No.27/08	F.No.01/87/50/230/AM 07
Meeting Date 06.11.2007	RLA F. No. 09/24/40/11/AM07
Adv. Lic. No. 0910026489 dt. 02.06.2006	
The Committee considered case as per agenda for ratification of norms for the export product Indinavir Sulfate under para 4.7 of HBP.	
Committee decided to call for a copy of revised application from RA. Accordingly case was deferred for six weeks.	

Case No.B-380	M/s.Advy Chemical
M.No.27/08	F.No.01/87/50/313/AM 07
Meeting Date 06.11.2007	RLA F. No. 03/94/40/310/AM07
Adv. Lic No. 0310387468 dt. 29.06.2006	
The Committee considered case as per agenda for ratification of norms for the export product HbsAG Subtypes ad Reagent (4000 mgs) (Hepatitis B Surface Antigen-Subtypes as) under para 4.7 of HBP.	
Committee decided to forward a copy of application alongwith a copy of representation of firm to DBT for their comments. Accordingly, case was deferred for four weeks.	

Case No.B-381	M/s. Dalas Biotech Ltd
M.No.27/08	F.No.01/82/50/223/AM 08
Meeting Date 06.11.2007	RLA F. No. 05/24/40/1078/AM07
Adv. Lic. No. 0510203062 dt. 27.04.2007	
The Committee considered case as per agenda for ratification of norms for the export product 7 Amino-3-vinyl-cephalosporanic acid (7AVCA) under para 4.7 of HBP.	
Committee decided to call for Central Excise certified consumption and production data from M/S Dalas Biotech Ltd,, M/S Dhanuka, M/S Covalent, M/S Nectar and M/S Surya Pharma for the above export product. Accordingly, case was deferred for six weeks.	

Case No.B-382	M/s. Shilpa Medicare Ltd.
M.No.27/08	F.No.01/82/162/354/AM 08
Meeting Date 06.11.2007	RLA F. No. 07/24/40/180/AM04
Adv.Lic. No. 0710022461 dt. 16.07.2003	

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

Committee decided to maintain rejection as the molecular structure furnished by firm of import product and export product in reaction it is same.

Case No.C-19	M/s. IPCA Labs. Ltd.
M.No.27/08	F.No.01/82/162/329/AM 08
Meeting Date 06.11.2007	
Committee considered the case as per agenda and observed that data of import/export certified by Central Excise Authorities was called from Pharmexcil. The same has not been received so far. In view of data not forthcoming from Pharmexcil, Committee decided to reject firm's request for fixation of SION.	

Case No.C-20	M/s. IPCA Labs. Ltd.
M.No.27/08	F.No.01/82/162/330/AM 08
Meeting Date 06.11.2007	
Committee considered the case as per agenda and observed that data of import/export certified by Central Excise Authorities was called from Pharmexcil. The same has not been received so far. In view of data not forthcoming from Pharmexcil, Committee decided to reject firm's request for fixation of SION.	

Case No.C-21	M/s. IPCA Labs. Ltd.
M.No.27/08	F.No.01/82/162/331/AM 08
Meeting Date 06.11.2007	
Committee considered the case as per agenda and observed that data of import/export certified by Central Excise Authorities was called from Pharmexcil. The same has not been received so far. In view of data not forthcoming from Pharmexcil, Committee decided to reject firm's request for fixation of SION.	

Case No.C-22	M/s. IPCA Labs. Ltd.
M.No.27/08	F.No.01/82/162/328/AM 08
Meeting Date 06.11.2007	
Committee considered the case as per agenda and observed that data of import/export certified by Central Excise Authorities was called from Pharmexcil. The same has not been received so far. In view of data not forthcoming from Pharmexcil, Committee decided to reject firm's request for fixation of SION.	

Case No.C-23	M/s. New Medichem . Ltd.
M.No.27/08	F.No.01/82/162/309/AM 08
Meeting Date 06.11.2007	

Committee considered the case as per agenda and observed that data of import/export certified by Central Excise Authorities was called from Pharmexcil. The same has not been received so far. In view of data not forthcoming from Pharmexcil, Committee decided to reject firm's request for fixation of SION.

1	Case No.:1/6/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00389/AM04/	RLA File : 09/24/040/00068/AM04/	Lic.No/Date:0910015288 05.08.2003	Defer Date:13.11.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product N,N-Dimethyl Amino Ethoxy Benzyl Amino (DEBA) under para 4.7 of HBP. Committee decided to defer case for one week for want of comments of PI Division.			

2	Case No.:195/21/82-ALC4/2007	Party Name:FDC LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00256/AM05/	RLA File : 03/24/040/02006/AM04/	Lic.No/Date:0310254462 24.02.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Timolol Maleate under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 24.02.2004 and no reminder has been received from firm or RLA. No record are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

3	Case No.:196/21/82-ALC4/2007	Party Name:FDC LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00257/AM05/	RLA File : 03/24/040/02253/AM04/	Lic.No/Date:0310254464 24.02.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Miconazole Base under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 24.02.2004 and no reminder has been received from firm or RLA. No record are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

4	Case No.:197/21/82-ALC4/2007	Party Name:FDC LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00258/AM05/	RLA File : 03/24/040/02041/AM04/	Lic.No/Date:03102544 69 24.02.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Econazole Nitrate BP/EP/USP under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 25.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Econazole Nitrate BP/USP-----1Kg. Import items: 1. 2,2,4-Trichloro Acetophenone-----0.98kg/kg 2. Sodium Borohydride-----0.085kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

5	Case No.:84/21/82-ALC4/2007	Party Name:KAMUD DRUGS PVT.LIMITED.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00135/AM05/	RLA File : 31/24/040/00269/AM04/	Lic.No/Date:31100148 04 08.03.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Timolol Maleate USP 26 under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 08.03.2004 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

6	Case No.:175/21/82-ALC4/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00224/AM05/	RLA File : 03/24/040/02221/AM04/	Lic.No/Date:03102624 02 05.04.2004	
	Decision : Committee considered case as per agenda for ratification of			

norms for export product N Cyano Ethyl-N-Hydroxy Ethyl-Meta Amino Acetanilide under para 4.7 of HBP.

Committee observed that Advance Authorisation was issued on 05.04.2004 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.

7	Case No.:220/21/82-ALC4/2007	Party Name:MECK PHARMACEUTICALS AND CHEMICALS PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00294/AM05/	RLA File : 08/81/040/00504/AM04/	Lic.No/Date:08100378 89 16.04.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Glucosamine Sulphate Potassium Chloride under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 16.04.2004 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

8	Case No.:291/21/82-ALC4/2007	Party Name:LI TAKA PHARMACEUTICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00427/AM05/	RLA File : 31/80/040/00077/AM05/	Lic.No/Date:31100156 41 14.05.2004	
	Decision : Committee considered case as per agenda for ratification of norms for export product Tablets/Capsules Pyraxel 500 under para 4.7 of HBP. Committee in consultation with technical authorities present in meeting decided to ratify norms as per SION A-412 with 2% wastage subject to verification of DML and other relevant documents by concerned RA. RA concerned may take further necessary action as per above decision of Norms Committee.			

9	Case No.:333/21/82-ALC4/2007	Party Name:M.J.BIOPHARM PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00520/AM05/	RLA File : 03/24/040/00372/AM05/	Lic.No/Date:03102703 91 24.05.2004	

Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Cefotaxime Sodium Injection 1 gm. under para 4.7 of HBP.

Committee in consultation with technical authority present in meeting decided to ratify norms as per SION at Sl.No.A-206 with 5% wastage subject to verification of DML and other relevant documents by concerned RA.

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

Case No.:634/21/82-ALC4/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
HQ File : 01/82/050/01245/AM05/	RLA File : 03/24/040/00965/AM05/	Lic.No/Date:0310283208 27.07.2004	

10 **Decision :** Committee considered case as per agenda for ratification of norms for export product N Acetoxy Ethyl N Cyano Ethyl Meta Amino Acetanilide (1-Acetylamino-3-N-(2 Acetoxy Ethyl-3-N(2 Cyano Ethyl) under para 4.7 of HBP.

Committee observed that Advance Authorisation was issued on 27.07.2004 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.

11 Case No.:799/21/82-ALC4/2007	Party Name:KWALITY PHARMACEUTICALS PVT.LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/82/050/01541/AM05/	RLA File : 12/80/040/00047/AM05/	Lic.No/Date:1210003366 08.12.2004	

Decision : Committee considered case as per agenda for ratification of norms for export product Pilocarpine Nitrate Eye Drops 1%, 10ml under para 4.7 of HBP.

Committee in consultation with technical authority present in meeting decided to ratify norms with 1% wastage as per details below or as applied by firm whichever is lower subject to verification of DML and other relevant documents by concerned RA.

Export product:
Pilocarpine Nitrate Eye Drops 1%, 10ml

Each 10ml Vial contains Pilocarpine Nitrate 100mg

Import item:

Piocarpine Nitrate-----1.01kg/kg

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

Case No.:997/21/82-ALC4/2007	Party Name:HY-GRO CHEMICALS PHARMTEK PVT LTD.	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Rejected
HQ File : 01/82/050/01872/AM05/	RLA File : 09/24/040/00354/AM05/	Lic.No/Date:09100218 34 09.02.2005	
12	Decision : Committee considered case as per agenda for ratification of norms for export product Citadiol under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 09.02.2005 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.		

Case No.:1030/21/82-ALC4/2007	Party Name:BROWN & BURK PHARMACEUTICAL LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Rejected
HQ File : 01/82/050/01910/AM05/	RLA File : 07/24/040/00667/AM05/	Lic.No/Date:07100361 16 16.02.2005	
13	Decision : Committee considered case as per agenda for ratification of norms for export product Bactoclav 625mg tablets under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 16.02.2005 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.		

14	Case No.:1041/21/82-ALC4/2007	Party Name:HY-GRO CHEMICALS PHARMTEK PVT LTD.	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01971/AM05/	RLA File : 09/24/040/00380/AM05/	Lic.No/Date:09100221 34 04.03.2005	
Decision : Committee considered case as per agenda for ratification of norms for export product Citadiol under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 04.03.2005				

and no reminder has been received from firm or RLA. No record are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.

15	Case No.:27/21/82-ALC4/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00053/AM06/	RLA File : 09/24/040/00007/AM06/	Lic.No/Date:09100226 02 20.04.2005	
	Decision : Committee considered case as per agenda for ratification of norms for export product N-Triphenyl Methyl-2-Amino Ethanol under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 20.04.2005 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

16	Case No.:10/20/87-ALC1/2005	Party Name:ALKALOIDS CORP	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/87/050/00429/AM06/	RLA File : 02/24/040/00081/AM06/	Lic.No/Date:02100800 76 15.07.2005	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms. Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.			

17	Case No.:263/21/82-ALC4/2007	Party Name:LI TAKA PHARMACEUTICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00380/AM06/	RLA File : 31/80/040/00160/AM06/	Lic.No/Date:3110021264 19.07.2005	
	Decision : Committee considered case as per agenda for ratification of norms for export product Tetracycline BP 500mg under para 4.7 of HBP. Committee in consultation with technical authorities present in the meeting decided to ratify norms as per SION A-412 with 2% wastage subject to verification of DML and other relevant documents by concerned RA. RA concerned may take further necessary action as per above decision of Norms Committee.			

18	Case No.:463/21/82-ALC4/2007	Party Name:BENZO CHEM INDUSTRIES PRIVATE LIMITED,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00872/AM06/	RLA File : 03/94/040/00770/AM06/	Lic.No/Date:0310354462 31.10.2005	
	Decision : Committee considered case as per agenda for ratification of norms for export product 4-Methoxy Phenyl Acetone under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 31.10.2005 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.			

19	Case No.:5/37/82-ALC1/2005	Party Name:FDC LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00946/AM06/	RLA File : 03/94/040/00798/AM06/	Lic.No/Date:0310356218 22.11.2005	
	Decision : Committee considered case as per agenda for ratification of norms for export product Econazole Nitrate BP/JP/USP under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 25.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.			

Export product:
Econazole Nitrate BP/USP-----1Kg.

Import items:

3. 2,2,4-Trichloro Acetophenone-----0.98kg/kg

4. Sodium Borohydride-----0.085kg/kg

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

20	Case No.:620/21/82-ALC4/2007	Party Name:BENZO CHEM INDUSTRIES PRIVATE LIMITED,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01228/AM06/	RLA File : 03/94/040/01142/AM06/	Lic.No/Date:03103635 69 17.01.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product 4-Methoxy Phenyl Acetone under para 4.7 of HBP. Committee observed that Advance Authorisation was issued on 17.01.2006 and no reminder has been received from firm or RLA. No records are also available. Committee, therefore, decided to close the case. In case, any representation/reminder is received, case will be re-opened for a decision.				

21	Case No.:31/47/82-ALC1/2005	Party Name:CALYX CHEMICALS & PHARMACEUTICALS PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01335/AM06/	RLA File : 03/94/040/01210/AM06/	Lic.No/Date:03103656 92 03.02.2006	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Coenzyme Q10 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.				

22	Case No.:745/21/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/01444/AM06/	RLA File : 22/24/040/00088/AM06/	Lic.No/Date:22100052 93 06.03.2006	

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

The Committee decided to ratify the norms of the export product as per revised SION at Sl.No.A-6 published vide Public Notice No.58 dated 26.09.2006 or as applied by the firm whichever is lower.

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

Case No.:8/10/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/87/050/00096/AM07/	RLA File : 02/24/040/00020/AM07/	Lic.No/Date:0210088734 28.04.2006	Defer Date: 04.12.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP.

23 Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms.

Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.

24 Case No.:1/23/87-ALC1/2006	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/87/050/00336/AM07/	RLA File : 05/24/040/00255/AM07/	Lic.No/Date:0510185276 21.06.2006	Defer Date: 04.12.2007

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

Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms.

Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.

Case No.:361/21/82-ALC4/2007	Party Name:HINDUSTAN ANTIBIOTICS LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
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HQ File : 01/82/050/00577/AM07/	RLA File : 31/80/040/00161/AM06/	Lic.No/Date:31100256 28 19.07.2006	
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Decision : Committee considered case as per agenda for ratification of norms for export product Fortified Procaine Pencillin 0.4 Mega Inj BP under para 4.7 of HBP.

25 Committee in light of its earlier decision taken in its 16/82 meeting held on 21.08.2007 vide Case No.8/38/83 in the case of M/S SKM Pharma (P) 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:

Fortified Procaine Penicillin 4 Mega Injection 20ml-----1No.
Procaine penicillin and benzyl penicillin sodium 3:1)

Import item:

Fortified Procaine Penicillin (Procaine Penicillin
/Benzyl Penicillin Sodium-3:1)-----0.00346 BOU with 4% wastage

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

26	Case No.:2/34/82-ALC1/2006	Party Name:DISHMAN PHARMACEUTICALS &	Meet No/Date:27/82-ALC4/2007	Status:Case
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	CHEMICALS LTD	06.11.2007	Deferred
HQ File : 01/82/050/00593/AM07/	RLA File : 08/24/040/00247/AM06/	Lic.No/Date:08100583 23 24.07.2006	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product 1-Carbethoxy Ethylidene Triphenyl Phosphorane under para 4.7 of HBP. 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.:377/21/82-ALC4/2007	Party Name:CADILA PHARMACEUTICALS LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/82/050/00629/AM07/	RLA File : 08/24/040/00095/AM07/	Lic.No/Date:08100585 31 28.07.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Cilostazol under para 4.7 of HBP. The Committee in light of its earlier decision taken in its 2/82 meeting held on 16.05.2007 vide Case No.27/48/82 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm which ever is lower. Export product Cilostazol-----1kg Import items 1. 5-(4-chlorobutyl)-cyclohexyl-1H-Tetrasole-----0.88kg 2. 6-Hydroxy-3, 4-Dihydro-1H-Quinolin-2-one-----0.59kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

28	Case No.:16/27/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/87/050/00419/AM07/	RLA File : 02/24/040/00123/AM07/	Lic.No/Date:02100921 25 02.08.2006	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Kola Extract under para 4.7 of HBP.			

Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms.

Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.

Case No.:17/31/82-ALC1/2006	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/82/050/00911/AM07/	RLA File : 03/94/040/00615/AM07/	Lic.No/Date:0310399069 12.09.2006	

Decision : Committee considered case as per agenda for ratification of norms for export product Terbinafine Hydrochloride Tablets 250mg 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 07.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Terbinafine Hcl tablets 250mg-----72,00,000 Nos.

Terbinafine Hcl tablets 250mg-----12,00,000 Nos.

Import items:

1. N-Methyl-1-Napthalenemethylamine Hcl-----2077.74kg

2. (Trans)-2-chloro-6,6-dimethyl-2-Heptane-4-YNE-2420.46Kg.

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

30	Case No.:489/21/82-ALC4/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
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HQ File : 01/82/050/00941/AM07/	RLA File : 09/24/040/00138/AM07/	Lic.No/Date:09100275 77 15.09.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/145/2005-PI-III dated 07.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Montelukastt Sodium-----1kg. Import items: 1. 7-chloro quinaldine-----8.07kg/kg 2. Iso Phthalaldehyde-----10.406kg/kg 3. Vinyl magnesium bromide-----29.80kg/kg 4. Methyl-2-iodo benzoate-----7.45kg/kg 5. Palladium acetate-----0.100kg/kg 6. (-)Di isopino camphenyl chloro borane-----13.80kg/kg 7. Cerium (III) chloride-----2.466kg/kg 8. Methyl magnesium bromide-----34.50kg/kg 9. Methane sulfonyl chloride-----3.74kg/kg 10. N-Butyl Lithium-----3.53kg/kg 11. Ethylene di chloride-----36.00kg/kg 12. Potassium Carbonate-----20.53kg/kg 13. Sodium Borohydride-----5.65kg/kg 14. Thionyl Chloride-----8.07kg/kg 15. Dimethy formamide-----2.36kg/kg 16. Potassium Permanganate-----5.78kg/kg 17. Potassium thio acetate-----3.96kg/kg 18. Methanol-----47.86kg/kg 19. Methylene chloride-----43.93kg/kg 20. Tetrahydrofuran-----19.40kg/kg 21. Acetonitrile-----13.27kg/kg 22. N-heptane-----5.80kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

31	Case No.:2/31/83- ALC1/2006	Party Name:PRADEEP SHETYE PVT. LTD.	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Ca se Rejected
	HQ File : 01/83/050/00707/AM07/	RLA File : 03/95/040/00433/AM07/	Lic.No/Date:03104006 43	

		22.09.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product Micronized Rifaxanide under para 4.7 of HBP. Committee observed that firm was requested to furnish technical specification including particle size, analysis for both import and export items vide letter dated 07.08.2007, but same has not been received. Committee, therefore, decided to close the case. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

	Case No.:555/21/82-ALC4/2007	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01110/AM07/	RLA File : 09/24/040/00247/AM07/	Lic.No/Date:0910027792 09.10.2006	Defer Date: 04.12.2007
32	Decision : Committee considered case as per agenda for ratification of norms for export product Amoxycillin Capsules 500mg under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for six weeks.			

	Case No.:2/46/87-ALC1/2006	Party Name:AVON ORGANICS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/87/050/00663/AM07/	RLA File : 09/24/040/00271/AM07/	Lic.No/Date:0910027981 30.10.2006	Defer Date: 04.12.2007
33	Decision : Committee considered case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidaxolone (AABZ) (OR) 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) 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.			

34	Case No.:606/21/82-ALC4/2007	Party Name:DR REDDYS LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
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HQ File : 01/82/050/01216/AM07/	RLA File : 09/24/040/00277/AM07/	Lic.No/Date:09100280 07 31.10.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product Finasteride under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/130/2006-PI-III dated 07.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Finasteride-----1Kg. Import items: 1. 3-oxo-4-Aza-5-Alphs-androstane-17-b-carbocyclic acid-----2.38kg/kg 2. Benzene Selenic Anhydride-----3.80kg/kg 3. Methylene chloride-----7.5-kg/kg 4. Cyclohexane-----12.50kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

Case No.:3/44/82-ALC1/2006	Party Name:GULF OIL CORPORATION LIMITED.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/82/050/01214/AM07/	RLA File : 09/24/040/00174/AM07/	Lic.No/Date:09100280 04 31.10.2006	
Decision : Committee considered case as per agenda for ratification of norms for export product Fexofenadine Hydrochloride under para 4.7 of HBP. Committee in light of its earlier decision taken in its 26/08 meeting held on 30.10.2007 vide Case No.A-819 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: Fexofenadine Hcl-----1Kg. Import items: 1. Methacrylic acid-----1.462kg/kg 2. Dimethoxy Ethane-----1.12kg/kg 3. Tetrahydrofuran-----3.00kg/kg 4. Sodium Borohydride-----0.332kg/kg 5. Azacyclonol-----1.035kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

36	Case No.:12/45/87-ALC1/2006	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/87/050/00747/AM07/	RLA File : 09/24/040/00128/AM07/	Lic.No/Date:0910028249 17.11.2006	Defer Date: 04.12.2007
	Decision : 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. 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.			

37	Case No.:2/46/82-ALC1/2006	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01441/AM07/	RLA File : 09/24/040/00390/AM07/	Lic.No/Date:0910028634 13.12.2006	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-Lysine-Praline (Lyspro Isolated) 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.			

38	Case No.:779/21/82-ALC4/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01495/AM07/	RLA File : 03/95/040/01117/AM07/	Lic.No/Date:0310413350 22.12.2006	
	Decision : Committee considered case as per agenda for ratification of norms for export product Amodiaquine Base under para 4.7 of HBP. Committee observed that SION for this export product were deleted and All Industry Data was called for from Pharmexcil, but they have not furnished the same. In view of data not forthcoming from Pharmexcil, Committee decided to close case.			

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

39	Case No.:803/21/82-ALC4/2007	Party Name:GLOCHEM INDUSTRIES LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	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: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Amilodipine Maleate Solid under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

40	Case No.:2/48/83-ALC1/2006	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01135/AM07/	RLA File : 22/24/040/00291/AM07/	Lic.No/Date:2210006400 17.01.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Sultamicillin Tosylate 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.			

41	Case No.:425/24/83-ALC1/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01203/AM07/	RLA File : 09/24/040/00466/AM07/	Lic.No/Date:0910029229 07.02.2007	Defer Date: 18.12.2007
	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 in light of written comments forwarded by PI Division vide their U.O. No.35011/97/2007-PI-III dated 18.10.2007 decided to call for following information from firm.			

1. Complete and balanced chemical reactions for each step of manufacturing process alongwith molecular weight and % yield of molar basis.
2. Material balance for the entire process based on the latest batch record.
3. Requirement and recovery of solvents at each step of manufacturing process.
4. Copy of technical literature in support of the yields envisaged in each step.

Accordingly, case was deferred for six weeks.

42	Case No.:500/24/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00062/AM08/	RLA File : 22/24/040/00297/AM07/	Lic.No/Date:22100064 82 13.02.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ezetimibe under para 4.7 of HBP. Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for four weeks.			

43	Case No.:4/3/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/01267/AM07/	RLA File : 03/95/040/01424/AM07/	Lic.No/Date:03104204 07 21.02.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee observed that firm has given incomplete and mis-leading information. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms committee.			

44	Case No.:852/21/82-ALC4/2007	Party Name:METROCHEM API PVT. LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/01678/AM07/	RLA File : 09/24/040/00436/AM07/	Lic.No/Date:09100294 25	Defer Date:

		22.02.2007	04.12.2007
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 call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for six weeks.			

45	Case No.:861/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/01692/AM07/	RLA File : 03/94/040/01323/AM07/	Lic.No/Date:0310420518 22.02.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Sulfamethazine & Trimethoprim Oral Powder/Cobalt Powder under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.			

46	Case No.:1/11/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/01270/AM07/	RLA File : 03/95/040/01095/AM07/	Lic.No/Date:0310420522 22.02.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP. Committee observed that firm was requested to furnish certain technical information vide letter dated 27.08.2007, but same has not been received. Committee, therefore, decided to close case. RA concerned may take further necessary action as per above decision of Norms Committee.			

47	Case No.:4/21/82-ALC4/2007	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File :	RLA File :	Lic.No/Date:22100065	Defer

01/82/050/00006/AM08/	22/24/040/00295/AM07/	38 27.02.2007	Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Cephalothin for Injection under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

Case No.:6/9/82-ALC4/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/82/050/01728/AM07/	RLA File : 09/24/040/00488/AM07/	Lic.No/Date:09100295 04 01.03.2007	Defer Date: 04.12.2007
48	Decision : Committee considered case as per agenda for ratification of norms for export product Cefdinir 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.:907/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case withdrawn
HQ File : 01/82/050/01750/AM07/	RLA File : 03/94/040/01374/AM06/	Lic.No/Date:03104219 56 06.03.2007	
49	Decision : Committee considered case as per agenda for ratification of norms for export product Asthalin inhaler under para 4.7 of HBP. Committee was informed that firm had filed application for Advance Authorisation under para 4.4.2 of HBP and after fixation of norms by NC, Advance Authorisation was issued to firm. Committee, accordingly, decided to withdraw case.		

Case No.:4/9/83-ALC1/2007	Party Name:ZANDU CHEMICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Transferred
HQ File : 01/83/050/01315/AM07/	RLA File : 03/95/040/01260/AM07/	Lic.No/Date:03104220 65 06.03.2007	
50			

Decision : Committee considered case as per agenda for ratification of norms for export product 2 Methyl 4,6 Bis (Trichloromethyl)1,3,5 Triazine (TAZ) under para 4.7 of HBP.

Committee decided to transfer case to DES-IV as export product pertains to Chemical Sector end use being fungicide/herbicide.

Case No.:943/21/82-ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Withdrawn

HQ File :
01/82/050/01803/AM07/

RLA File :
03/94/040/01439/AM07/

Lic.No/Date:0310422963
13.03.2007

51

Decision : Committee considered case as per agenda for ratification of norms for export product Sulfamethazine & Trimethoprim Oral Powder/Cobalt Powder under para 4.7 of HBP.

Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

Case No.:3/1/87-ALC1/2007

Party Name:AVON ORGANICS LTD.,

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/87/050/01107/AM07/

RLA File :
09/24/040/00487/AM07/

Lic.No/Date:0910029668
14.03.2007

Defer Date:
04.12.2007

52

Decision : Committee considered case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidazolone (AABZ) (OR) 5-aceto Acetyl Amino Benzimidazolone-2 (AABI) 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.:950/21/82-ALC4/2007

Party Name:LAKE CHEMICALS PRIVATE LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/01812/AM07/

RLA File :
07/24/040/00829/AM07/

Lic.No/Date:0710050672
15.03.2007

Defer Date:
04.12.2007

53

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

Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.

Case No.:954/21/82-ALC4/2007

Party Name:MERCK LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/01815/AM07/

RLA File :
03/95/040/01559/AM07/

Lic.No/Date:03104232
60
15.03.2007

Defer
Date:
04.12.2007

54 **Decision :** Committee considered case as per agenda for ratification of norms for export product DL-Alpha Tocopheryl Acetate USP under para 4.7 of HBP.

Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.

Case No.:17/9/82-ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/01837/AM07/

RLA File :
03/94/040/01468/AM07/

Lic.No/Date:03104237
77
21.03.2007

Defer
Date:
04.12.2007

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

55 Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 23.10.2007 decided to call for following information from firm.

1. Step wise chemical reactions showing molecular weight and percentage yield on molar basis for each step.
2. Material balance for a recent batch.
3. Technical literature in support of yields envisaged in the application.
4. Copy of valid DML for the above export product.
5. Pharmacoepl references for the above export product.

Accordingly, case was deferred for four weeks.

56 **Case No.:19/9/82-ALC4/2007**

Party Name:DIVIS LABORATORIES LTD.,

Meet No/Date:27/82-ALC4/2007

Status:Case

		06.11.2007	Approved
HQ File : 01/82/050/01846/AM07/	RLA File : 09/24/040/00523/AM07/	Lic.No/Date:09100297 39 22.03.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/249/2006-PI-III dated 07.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Carvedilol-----1Kg. Import items: 1. N-Benzyl Carvedilol-----1.50kg/kg 2. Iso Propyl Alcohol-----2.89kg/kg 3. 5% Palladium on Activated Carbon Water Wet-----0.100kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

	Case No.:20/9/82-ALC4/2007	Party Name:CONCORD BIOTECH LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/01863/AM07/	RLA File : 08/24/040/00356/AM07/	Lic.No/Date:08100638 62 26.03.2007	
57	Decision : Committee considered case as per agenda for ratification of norms for export product Vamcomycin Hcl under para 4.7 of HBP. Committee observed that firm has sought for import of consumables only and not raw material. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.			

58	Case No.:7/7/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:case Rejected
	HQ File : 01/83/050/01378/AM07/	RLA File : 03/95/040/01605/AM07/	Lic.No/Date:03104246 23 27.03.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.

Committee observed that firm has given mis-leading information. Committee, therefore, decided to reject case.

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

Case No.:1019/21/82-ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Withdrawn

HQ File :
01/82/050/01893/AM07/

RLA File :
03/94/040/01501/AM07/

Lic.No/Date:0310424679
28.03.2007

59 **Decision :** Committee considered case as per agenda for ratification of norms for export product GCS Max Powder 500 gm pack under para 4.7 of HBP.

Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

Case No.:23/9/82-ALC4/2007

Party Name:LUPIN LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/01901/AM07/

RLA File :
03/95/040/01622/AM07/

Lic.No/Date:0310424915
29.03.2007

Defer Date:
04.12.2007

60 **Decision :** Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil 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.:2/3/82-ALC4/2007

Party Name:ALEMBIC LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/00005/AM08/

RLA File :
34/24/040/00301/AM07/

Lic.No/Date:3410018454
30.03.2007

Defer Date:20.11.2007

Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Crude 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.:7/21/82-ALC4/2007

Party Name:CIPLA LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Withdrawn

HQ File :
01/82/050/00008/AM08/

RLA File :
03/94/040/00010/AM08/

Lic.No/Date:0310426066
10.04.2007

62 **Decision :** Committee considered case as per agenda for ratification of norms for export product Asthalin Inhaler (200MD) under para 4.7 of HBP.

Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

Case No.:9/21/82-ALC4/2007

Party Name:AUROBINDO PHARMA LIMITED

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/82/050/00009/AM08/

RLA File :
09/24/040/00543/AM07/

Lic.No/Date:0910029931
10.04.2007

Defer Date:
04.12.2007

63 **Decision :** Committee considered case as per agenda for ratification of norms for export product 7-Amino-3[(Z/E)-1-Propen-1-YL]-3-Cephem-4-Carboxylic Acid (APRA) under para 4.7 of HBP.

Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.

Case No.:9/13/83-ALC1/2007

Party Name:KUMAR ORGANIC PRODUCTS LIMITED,

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/83/050/00105/AM08/

RLA File :
07/24/040/00020/AM08/

Lic.No/Date:0710051216
13.04.2007

Defer Date:18.12.2007

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

65	Case No.:519/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00107/AM08/	RLA File : 05/24/040/00017/AM08/	Lic.No/Date:05102025 04 13.04.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Isotretinoin 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.				

66	Case No.:12/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00015/AM08/	RLA File : 03/94/040/00821/AM07/	Lic.No/Date:03104272 88 19.04.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Asthalin Inhaler (200MD) under para 4.7 of HBP. Committee was informed that firm had filed application for Advance Authorisation under para 4.4.2 of HBP and after fixation of norms by NC, Advance Authorisation was issued to firm. Committee, accordingly, decided to withdraw case.				

67	Case No.:18/7/83-ALC1/2007	Party Name:RESONANCE LABORATORIES PVT LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00171/AM08/	RLA File : 07/24/040/00048/AM08/	Lic.No/Date:07100513 63 23.04.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product 1-[2,6 Dichloro-4(Trifluoromethyl) Phenyl]-5-[Pyridine-2-YL Methylene) Amino] 1H-Pyrazole-3-Carbonitrile (C-6900) 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.

68	Case No.:14/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00019/AM08/	RLA File : 03/94/040/00061/AM08/	Lic.No/Date:03104278 10 25.04.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product GCS Max Powder 500gm pack under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.			

69	Case No.:15/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00020/AM08/	RLA File : 03/94/040/00060/AM08/	Lic.No/Date:03104278 11 25.04.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Asthalin Inhaler (200MD) under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.			

70	Case No.:18/21/82-ALC4/2007	Party Name:KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00025/AM08/	RLA File : 07/24/040/00064/AM08/	Lic.No/Date:07100514 99 03.05.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ceftriazone for Inj 500mg under para 4.7 of HBP.			

Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.

71	Case No.:19/21/82-ALC4/2007	Party Name:KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00026/AM08/	RLA File : 07/24/040/00063/AM08/	Lic.No/Date:07100515 01 03.05.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Ceftriazone for Inj. USP 1 GM Vial under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.				

72	Case No.:574/24/83-ALC1/2007	Party Name:ORGANON (INDIA) LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00261/AM08/	RLA File : 02/24/040/00025/AM08/	Lic.No/Date:02101005 42 04.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Norandrostenedione (Nordion) under para 4.7 of HBP. Committee in light of its earlier decision taken in its 18/83 meeting held on 20.07.2005 vide Case No.24/12/83 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product Norandrostenedione (Not less than 90% purity)-----1Kg. Import items: 1. Sitolactone-----1.26kg/kg 2. Chloroket-----1.17kg/kg 3. Pyridine-----0.56kg/kg 4. Methanol-----2.88kg/kg 5. Toluene-----5.71kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.				

73	Case No.:20/21/82-ALC4/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00028/AM08/	RLA File : 05/24/040/00097/AM08/	Lic.No/Date:0510203344 07.05.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin Carbomer Granules 44% under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

74	Case No.:575/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00265/AM08/	RLA File : 09/24/040/00445/AM07/	Lic.No/Date:0910030195 07.05.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Nelfinavir Mesylate 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.			

75	Case No.:16/12/83-ALC1/2007	Party Name:HONEST BIO-VET PVT. LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/83/050/00272/AM08/	RLA File : 08/24/040/00032/AM08/	Lic.No/Date:0810064691 07.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Menadione Dimethyl Pyrimidinol Bisulphite (MPB 50%) under para 4.7 of HBP. Committee decided to withdraw case as same has already been approved by NC in its Meeting No.24/08 held on 16.10.2007.			

76	Case No.:23/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007	Status:Case
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		06.11.2007	Withdrawn
HQ File : 01/82/050/00033/AM08/	RLA File : 03/94/040/00079/AM08/	Lic.No/Date:03104288 32 08.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Toltrazuril Oral Solution 2.5%/Cipxox 2.5% Solution under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.			

Case No.:577/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/83/050/00273/AM08/	RLA File : 09/24/040/00444/AM07/	Lic.No/Date:09100302 07 08.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Methyl-5S-Cytosine-1 YL-1,3-Oxathiolane-2R Carboxalate (Lamuvudine Intermediate-Stage-III) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/108/2007-PI-III dated 30.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. 77 Export product: Menthyl-5 S-Cytosine-1YL-1,3- Oxathiolane-2R Carboxalate (Lamivudine intermediate State 3)-----1Kg. Import items: 1. Menthol-----0.87kg/kg 2. Glyoxalic acid 50%-----0.90kg/kg 3. 2,5 Dihydroxy-1,4 dithiane-----0.37kg/kg 4. Triethylamine-----0.67kg/kg 5. Cytosine-----0.475kg/kg 6. Hexamethyl disilazane-----0.75kg/kg 7. Dimethyl formamide-----0.31kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

Case No.:578/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/83/050/00274/AM08/	RLA File : 09/24/040/00043/AM08/	Lic.No/Date:09100302 08 08.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Methyl-5S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamuvudine Stage-III) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/108/2007-PI-III dated 30.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. 78 Export product: Menthyl-5 S-Cytosine-1YL-1,3-Oxathiolane-2R Carboxalate (Lamivudine intermediate State 3)-----1Kg. Import items: 8. Menthol-----0.87kg/kg 9. Glyoxalic acid 50%-----0.90kg/kg 10. 2,5 Dihydroxy-1,4 dithiane-----0.37kg/kg 11. Triethylamine-----0.67kg/kg 12. Cytosine-----0.475kg/kg 13. Hexamethyl disilazane-----0.75kg/kg 14. Dimethyl formamide-----0.31kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

79 Case No.:579/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/83/050/00275/AM08/	RLA File : 09/24/040/00039/AM08/	Lic.No/Date:09100302 09 08.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product 5-O-Benzoyl-3-Mesyl-2,2 Anhyfro-5-Methyl Uridine (An Intermediate of Stavudine) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/108/2007-PI-III dated 30.10.2007 decided to ratify			

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

Export product:

5-O-Benzoyl-3-Mesyl-2,2 Anhydro-5-methyl uridine-----1Kg.

Import items:

1. 5-Methyl uridine-----1.327kg/kg
2. N-Methyl Morpholine-----Specific use and recovery of NMM is
not indicated By
firm. Hence not
allowed.
3. Methane sulfonyl chloride-----1.21kg/kg
4. Dimethyl formamide-----1.325kg/kg

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

Case No.:21/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
HQ File : 01/82/050/00032/AM08/	RLA File : 03/94/040/00123/AM08/	Lic.No/Date:0310429101 10.05.2007	
80	Decision : Committee considered case as per agenda for ratification of norms for export product Asthalin Inhaler (200MD)/Asthavent Inhaler (200MD)/Sulbutamol Inhaler (200MD) under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.		

81	Case No.:589/24/83-ALC1/2007	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00308/AM08/	RLA File : 09/24/040/00013/AM08/	Lic.No/Date:0910030250 14.05.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Benzhydryl Thioacetamide 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.

82	Case No.:16/18/83-ALC1/2007	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/83/050/00317/AM08/	RLA File : 04/24/040/00012/AM08/	Lic.No/Date:04100894 21 14.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Clomipramine Hcl under para 4.7 of HBP. Committee decided to withdraw this case as same has already been approved by NC in its meeting No.24/82 held on 16.10.2007.			

83	Case No.:29/9/82-ALC4/2007	Party Name:S.M. HERBALS PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00039/AM08/	RLA File : 05/24/040/01075/AM07/	Lic.No/Date:05102037 51 16.05.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP. Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms. Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.			

84	Case No.:615/24/83-ALC1/2007	Party Name:NICHOLAS PIRAMAL INDIA LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
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HQ File : 01/83/050/00370/AM08/	RLA File : 03/95/040/01389/AM07/	Lic.No/Date:03104300 66 21.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Concept Quick Unit Dose Solution (9247X) (Pack 15ml Vial) under para 4.7 of HBP. Committee observed that export product is Biotechnology item and firm has not obtained 'NOC' from DBT as required under last para of para 4.7 of HBP. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms committee.			

Case No.:37/16/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Approved
HQ File : 01/83/050/00385/AM08/	RLA File : 03/94/040/00170/AM08/	Lic.No/Date:03104304 24 23.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Niclosamide Piperazine Salt under para 4.7 of HBP. The Committee in consultation with technical authorities and in light of its earlier decision taken in its 23/07 meeting held on 13.09.2005 vide Case No.B-636 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. Niclosamide Piperazine salt-----1kg Import items 1. Salicylic Acid-----0.650kg 2. Triethylamine-----0.260kg 3. Piperazine Anhydrous-----0.130kg 4. Isopropyl alcohol-----0.60kg 5. Thionyl Chloride-----0.20kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

86	Case No.:624/24/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:27/82- ALC4/2007	Status:Case
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		06.11.2007	Deferred
HQ File : 01/83/050/00390/AM08/	RLA File : 09/24/040/00040/AM08/	Lic.No/Date:09100303 36 24.05.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product 3-Oxa-4-Aza-5a-Androstane-17b-Carboxylic Acid under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

Case No.:622/24/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/83/050/00388/AM08/	RLA File : 09/24/040/00048/AM08/	Lic.No/Date:09100303 34 24.05.2007	Defer Date: 04.12.2007
87	Decision : Committee considered case as per agenda for ratification of norms for export product 2-(2-Methoxy Phenoxy) Ethylamine 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.:623/24/83-ALC1/2007	Party Name:SHODHANA LABORATORIES LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/83/050/00389/AM08/	RLA File : 09/24/040/00049/AM08/	Lic.No/Date:09100303 35 24.05.2007	Defer Date: 04.12.2007
88	Decision : Committee considered case as per agenda for ratification of norms for export product 4-(2,3-Eposy Propoxy)Carboxole 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.		

89	Case No.:24/21/82-ALC4/2007	Party Name:CE-CHEM PHARMACEUTICALS,	Meet No/Date:27/82-ALC4/2007	Status:Case
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		06.11.2007	Deferred
HQ File : 01/82/050/00046/AM08/	RLA File : 07/24/040/00136/AM08/	Lic.No/Date:07100517 61 25.05.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Pencillin V Pottasium 250mg Tablets under para 4.7 of HBP. Committee observed that firm has been requested to furnish copy of DML which has not been received. Committee, therefore, decided to await reply of firm and to defer case for four weeks.			

	Case No.:628/24/83-ALC1/2007	Party Name:INVENTIS DRUG DELIVERY SYSTEMS PVT LTD.	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/00397/AM08/	RLA File : 09/24/040/00047/AM08/	Lic.No/Date:09100303 44 25.05.2007	
90	Decision : Committee considered case as per agenda for ratification of norms for export product Fenofibrate Pellets under para 4.7 of HBP. Committee observed that firm was requested to furnish copy of DML vide letter dated 13.09.2007, but they have furnished copy of incomplete DML as same does not contain list of approved items. Committee, therefore, decided to close the case. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

	Case No.:35/9/82-ALC4/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00051/AM08/	RLA File : 34/24/040/00035/AM08/	Lic.No/Date:34100188 54 28.05.2007	Defer Date: 20.11.2007
91	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Step 3 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, case was deferred for two weeks.			

92	Case No.:33/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Withdraw
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HQ File : 01/82/050/00062/AM08/	RLA File : 03/94/040/00215/AM08/	Lic.No/Date:03104310 32 29.05.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product GCS Max Powder (per pack 500gm) under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.			

Case No.:642/24/83-ALC1/2007	Party Name:DEVATS (INDIA) PVT.LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/83/050/00422/AM08/	RLA File : 05/24/040/00921/AM07/	Lic.No/Date:05102041 73 29.05.2007	Defer Date: 04.12.2007
93	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 call for a copy of DML from firm. Accordingly, case was deferred for six weeks.		

Case No.:653/24/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/83/050/00456/AM08/	RLA File : 03/95/040/00187/AM08/	Lic.No/Date:03104310 79 30.05.2007	Defer Date: 04.12.2007
94	Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil 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.		

95	Case No.:32/21/82-ALC4/2007	Party Name:NEULAND LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00060/AM08/	RLA File : 09/24/040/00052/AM08/	Lic.No/Date:09100304 10	Defer Date:

		01.06.2007	04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Ramipril under para 4.7 of HBP.			
Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

Case No.:657/24/83-ALC1/2007	Party Name:LEPRO HERBALS PVT. LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
HQ File : 01/83/050/00469/AM08/	RLA File : 05/24/040/00155/AM08/	Lic.No/Date:05102045 04 05.06.2007	Defer Date: 04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Griffonia Dry Extract under para 4.7 of HBP.			
Committee observed that Deptt. of Ayush vide their O.M. No.K.11025/5/2007-DCC(Ayush) dated 08.10.2007 has stated that while considering the cases pertaining to input and output norms fixation, plants like Artemisinin, Griffonia, Simplicifolia, Podophyllum, Cpecacuanha, Mappia Foetida, many of the plants are not mentioned in Ayurveda, Siddha, Unani and Homeopathy systems of medicine. They have further stated that in other cases the product manufacturing technology, resultant product or extractions are not according to the Ayush systems of medicine manufacturing and hence their Department can not suggest the input output norms.			
Committee observed that the unit being an SSI Unit, DC(MSME) can examine the case with reference to input output norms. It was, therefore, decided to forward a copy of application to DC(MSME) for their comments. Accordingly, case was deferred for four weeks.			

97	Case No.:778/24/83-ALC1/2007	Party Name:OM SHREE PHARMACHEM PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/00725/AM08/	RLA File : 03/95/040/00230/AM08/	Lic.No/Date:03104321 41 08.06.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide 5-Mononitrate under para 4.7 of HBP.				
Committee observed that firm has given mis-leading information. Committee, therefore, decided to reject case.				

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

98	Case No.: 661/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00490/AM08/	RLA File : 09/24/040/00094/AM08/	Lic.No/Date:09100304 86 08.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumerate 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.			

99	Case No.: 715/24/83-ALC1/2007	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00590/AM08/	RLA File : 03/94/040/00243/AM08/	Lic.No/Date:03104329 29 18.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Norethisterone 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.			

100	Case No.: 63/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00112/AM08/	RLA File : 03/94/040/00297/AM08/	Lic.No/Date:03104333 63 20.06.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Asthalin Inhaler (200MD)/Asthavent Inhaler (200MD)/Salbutamol Inhaler (200MD) under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under			

para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

10 1	Case No.:696/24/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00551/AM08/	RLA File : 09/24/040/00072/AM08/	Lic.No/Date:09100306 25 21.06.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefadroxil USP/BP under para 4.7 of HBP. Committee decided to ratify norms as per revised SION at SL.No.A-108 published vide Public Notice No.67 dated 12.10.2007. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

10 2	Case No.:706/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00563/AM08/	RLA File : 09/24/040/00080/AM08/	Lic.No/Date:09100306 41 22.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Efavirenz 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.			

10 3	Case No.:789/24/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00742/AM08/	RLA File : 03/95/040/00276/AM08/	Lic.No/Date:03104335 02 22.06.2007	Defer Date: 04.12.2007
	Decision : 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.

104	Case No.:37/21/82-ALC4/2007	Party Name:SARACA LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00075/AM08/	RLA File : 09/24/040/00029/AM08/	Lic.No/Date:0910030654 25.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Gabapentin Hcl (Technical) Powder under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for six weeks.			

105	Case No.:726/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00613/AM08/	RLA File : 04/24/040/00113/AM08/	Lic.No/Date:0410090130 28.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-Fluoro Adenosin Triacetate (2-FAT)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.			

106	Case No.:728/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00615/AM08/	RLA File : 04/24/040/00111/AM08/	Lic.No/Date:0410090132 28.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate 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.
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10 7	Case No.:727/24/83-ALC1/2007	Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00614/AM08/	RLA File : 04/24/040/00112/AM08/	Lic.No/Date:0410090131 28.06.2007	Defer Date: 04.12.2007
	Decision : 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.			

10 8	Case No.:731/24/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00624/AM08/	RLA File : 09/24/040/00425/AM07/	Lic.No/Date:0910030691 29.06.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Sertraline Mandelate 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.			

10 9	Case No.:55/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/82/050/00107/AM08/	RLA File : 03/94/040/00333/AM08/	Lic.No/Date:0310434536 29.06.2007	
	Decision : Committee considered case as per agenda for ratification of			

norms for export product Toltrazuril Oral Solution 2.5%/Cipcox 2.5% Soudution under para 4.7 of HBP.

Committee was informed that Advance Authorisation was issued under para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

110	Case No.:54/21/82-ALC4/2007	Party Name:SRINI PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00104/AM08/	RLA File : 09/24/040/00116/AM08/	Lic.No/Date:0910030710 02.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Levofloxacin Hemihydrate 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. Accordingly, Committee decided to defer case for four weeks.			

111	Case No.:739/24/83-ALC1/2007	Party Name:PONALAB	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00640/AM08/	RLA File : 07/24/040/00223/AM08/	Lic.No/Date:0710052285 03.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product 8-Hydroxyquinoline 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.			

112	Case No.:743/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00665/AM08/	RLA File : 09/24/040/00511/AM07/	Lic.No/Date:0910030757 04.07.2007	Defer Date: 04.12.2007

Decision : Committee considered case as per agenda for ratification of norms for export product 5,11-Dihydro(1)-Benzoxepino(3,4-b)-Pyridine-5-One 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.:746/24/83-ALC1/2007

Party Name:SRINI PHARMACEUTICALS LTD.,

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Approved

HQ File :
01/83/050/00668/AM08/

RLA File :
09/24/040/00134/AM08/

Lic.No/Date:09100307
60
05.07.2007

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/101/2004-PI-III dated 07.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Bicalutamide-----1Kg.

Import items:

1. N-[(4-Cyano-3-Trifluoromethyl)Phenyl]
-2-methyl Oxirane Carboxamide-----1.11kg/kg
2. 4-Fluorobenzothiol-----0.53kg/kg

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

Case No.:757/24/83-ALC1/2007

Party Name:MATRIX LABORATORIES LTD

Meet No/Date:27/82-ALC4/2007
06.11.2007

Status:Case Deferred

HQ File :
01/83/050/00687/AM08/

RLA File :
09/24/040/00112/AM08/

Lic.No/Date:09100308
02
06.07.2007

Defer
Date:
04.12.2007

Decision : Committee considered case as per agenda for ratification of norms for export product L-Methyl 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.

11 5	Case No.:81/21/82-ALC4/2007	Party Name:KOPRAN LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00131/AM08/	RLA File : 03/94/040/00173/AM08/	Lic.No/Date:03104354 12 09.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Azithromycin Dihydrate 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.			

11 6	Case No.:761/24/83-ALC1/2007	Party Name:COVALENT LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00694/AM08/	RLA File : 09/24/040/00100/AM08/	Lic.No/Date:09100308 45 11.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil 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.			

11 7	Case No.:764/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00698/AM08/	RLA File : 05/24/040/00274/AM08/	Lic.No/Date:05102060 46 11.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Fisinopril Sodium under para 4.7 of HBP.			

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

118	Case No.:771/24/83-ALC1/2007	Party Name:PRACHI PHARMACEUTICALS PVT LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00709/AM08/	RLA File : 03/95/040/00308/AM08/	Lic.No/Date:0310435714 11.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Thiamine Hydrochloride BP/USP under para 4.7 of HBP. Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.			

119	Case No.:774/24/83-ALC1/2007	Party Name:ASTRIX LABORATORIES LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00718/AM08/	RLA File : 09/24/040/00118/AM08/	Lic.No/Date:0910030869 12.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Lopinavir 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.			

120	Case No.:768/24/83-ALC1/2007	Party Name:LIQUORS INDIA LTD,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00702/AM08/	RLA File : 09/24/040/00142/AM08/	Lic.No/Date:0910030864 12.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of			

	norms for export product Lovastatin 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.

12 1	Case No.:784/24/83-ALC1/2007	Party Name:KAIVAL CHEMICALS P LTD	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Transferred
	HQ File : 01/83/050/00733/AM08/	RLA File : 34/24/040/00073/AM08/	Lic.No/Date:34100191 92 13.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product L(-)-DI-P-Toluoyl Tartaric Acid under para 4.7 of HBP. Committee decided to transfer case to DES-IV as export product pertains to Chemical Sector.			

12 2	Case No.:797/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00755/AM08/	RLA File : 05/24/040/00286/AM08/	Lic.No/Date:05102063 21 16.07.2007	Defer Date: 04.12.200 7
	Decision : Committee considered case as per agenda for ratification of norms for export product Citalopram hydrobromide 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.			

12 3	Case No.:801/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00760/AM08/	RLA File : 09/24/040/00115/AM08/	Lic.No/Date:09100309 17 18.07.2007	Defer Date: 04.12.200 7
	Decision : Committee considered case as per agenda for ratification of norms for export product (S)-5-Chloro-a-(Cyclopropylethynyl)-2-[(4-			

Methoxy phenyl)methyl)amino]-a-(Trifluoromethyl) Benzene Methanol 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.

12 4	Case No.:905/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00915/AM08/	RLA File : 03/95/040/01473/AM07/	Lic.No/Date:03104368 39 19.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol BP under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

12 5	Case No.:906/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00916/AM08/	RLA File : 03/95/040/01472/AM07/	Lic.No/Date:03104368 43 19.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Setralone (Tetralone) under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

12 6	Case No.:909/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00920/AM08/	RLA File : 03/95/040/01516/AM07/	Lic.No/Date:03104369 93 20.07.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ibuprofen DC Granules 65% under para 4.7 of HBP.			

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

12 7	Case No.:908/24/83-ALC1/2007	Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD)	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00919/AM08/	RLA File : 03/95/040/01517/AM07/	Lic.No/Date:03104369 87 20.07.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ibuprofen DC Granules 90% under para 4.7 of HBP. Committee decided to call for a copy of DML from firm. Accordingly, case was deferred for six weeks.			

12 8	Case No.:817/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00803/AM08/	RLA File : 09/24/040/00151/AM08/	Lic.No/Date:09100309 52 20.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product N-carboethoxy-4-piperidinol (Or) 4-hydroxy-N-carbethoxy Piperidine under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: N-carboethoxy-4-piperidinol (Or) 4-hydroxy-N-carbethoxy Piperidine-----1Kg. Import items: 1. Methanol-----0.90kg/kg 2. Methyl Acrylate-----2.06kg/kg 3. Sodium methoxide-----0.91kg/kg 4. Chloroform-----0.67kg/kg 5. Ethyl chloro formate-----0.75kg/kg 6. Triethyl amine-----0.34kg/kg 7. Di isopropyl ether-----1.05kg/kg 8. Carbon-----0.039kg/kg			

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

12 9	Case No.:816/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00802/AM08/	RLA File : 09/24/040/00537/AM07/	Lic.No/Date:09100309 51 20.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 4-Piperidone Monohydro Hydrochloride (4-Piperidone H2O Hcl) under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: 4-Piperidone Monohydro Hcl-----1kg. Import items: 1. Methyl Acrylate-----3.195kg/kg 2. Ethyl chloroformate-----1.53kg/kg 3. Tetrahydrofuran-----2.00kg/kg 4. Tri methyl ortho formate-----0.97kg/kg 5. Di Iso Propyl ether-----5.19kg/kg 6. Methanol-----4.73kg/kg 7. Carbon-----100gm/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

13 0	Case No.:829/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	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: 04.12.200 7
	Decision : Committee considered case as per agenda for ratification of norms for export product Cis-4-amino-3-methoxy-Piperidine-1-carboxylic acid ethyl ester monohydrochloride under para 4.7 of HBP.			

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 18.10.2007 observed that while the firm has applied the norms from Methyl acrylic Stage, the chemistry given by them is based on Ethyl Acrylate. Since the chemistry furnished by the firm does not match with the norms applied by firm. Committee, therefore, decided to seek clarification from firm. Accordingly, case was deferred for six weeks.

13 1	Case No.:830/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00822/AM08/	RLA File : 09/24/040/00068/AM08/	Lic.No/Date:0910030973 23.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 2-Butyl-4-Chloro-5-Formyl Imidazole (OR) 2(n-Butyl)-4-Chloro-5-Formyl Imidazole under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/94/2007-PI-III dated 18.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: 2(n butyl)-4-chloro-5-formyl Imidazole-----1kg. Import items: 1. Valeronitrile-----1.38kg/kg 2. Phosphorous-----0.58kg/kg 3. Dimethyl formamide-----1.16kg/kg 4. Methanol-----0.41kg/kg 5. Toluene-----1.50kg/kg 6. Glycine-----0.80kg/kg 7. Carbon-----0.100kg/kg RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

13 2	Case No.:832/24/83-ALC1/2007	Party Name:MANGALAM DRUGS & ORGANICS LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/00825/AM08/	RLA File : 03/95/040/00362/AM08/	Lic.No/Date:0310437194 23.07.2007	
	Decision : Committee considered case as per agenda for ratification of			

norms for export product Amodiaquine Base under para 4.7 of HBP.

Committee observed that SION for this export product were deleted and All Industry Data was called for from Pharmexcil, but they have not furnished the same. In view of data not forthcoming from Pharmexcil, Committee, therefore, decided to close case.

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

13 3	Case No.:82/21/82-ALC4/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00132/AM08/	RLA File : 05/24/040/00311/AM08/	Lic.No/Date:0510206654 24.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Simvastatin under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

13 4	Case No.:840/24/83-ALC1/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00837/AM08/	RLA File : 09/24/040/00155/AM08/	Lic.No/Date:0910030999 25.07.2007	Defer Date: 04.12.2007
	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. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/97/2007 PI-III dated 18.10.2007 decided to call for following information from firm. 1. Complete and balanced chemical reactions for each step of manufacturing process alongwith molecular weight and % yield of molar basis. 2. Material balance for the entire process. 3. Requirement and recovery of solvents at each step of manufacturing process.			

	4. Copy of technical literature in support of the yields envisaged in each step. Accordingly, case was deferred for six weeks.
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135	Case No.:4/19/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/82/050/00145/AM08/	RLA File : 03/95/040/00204/AM08/	Lic.No/Date:0310437530 26.07.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Betasol Lotion 30ml under para 4.7 of HBP. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/86/2006-PI-III dated 26.09.2007 observed that firm has applied for import of Betamethasone base whereas DML specifies use of Clobetasol Propionate and firm has not given any technical justification for above. Committee, therefore, decided to close the case. RA concerned may take further necessary action as per above decision of Norms Committee.			

136	Case No.:845/24/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/00842/AM08/	RLA File : 09/24/040/00423/AM07/	Lic.No/Date:0910031011 27.07.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Nevirapine Hemihydrate 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.			

137	Case No.:869/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/00871/AM08/	RLA File : 09/24/040/00138/AM08/	Lic.No/Date:0910031028 01.08.2007	
	Decision : Committee considered case as per agenda for ratification of			

norms for export product 5-O Benzoyl02,3-Didehydro-5-Methyl Uridine (An Intermediate of Stavudine) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/108/2007 PI-III dated 30.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

5-O-Benzoyl-3-Mesyl-2,2 Anhydro-5-methyl uridine-----1Kg.

Import items:

1. 5-Methyl uridine-----1.327kg/kg
2. N-Methyl Morpholine-----Not allowed as specific use and recovery not

Indicated by firm.

3. Methane sulfonyl chloride-----1.21kg/kg
4. Dimethyl formamide-----1.325kg/kg

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

138	Case No.:895/24/83-ALC1/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/83/050/00903/AM08/	RLA File : 05/24/040/00360/AM08/	Lic.No/Date:0510207216 06.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Imipenem/Imipenem Crude under para 4.7 of HBP. Committee decided to withdraw this case as same has already been approved in Meeting No.24/82 held on 16.10.2007.			

139	Case No.:898/24/83-ALC1/2007	Party Name:DALAS BIOTECH LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Withdrawn
	HQ File : 01/83/050/00906/AM08/	RLA File : 05/24/040/00375/AM08/	Lic.No/Date:0510207303 07.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product 7AVCA under para 4.7 of HBP.			

Committee decided to withdraw this case as same has already been approved in Meeting No.24/82 dated 16.10.2007.

14 0	Case No.:962/24/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Ca se Deferred
	HQ File : 01/83/050/00978/AM08/	RLA File : 03/94/040/00493/AM08/	Lic.No/Date:03104393 77 14.08.2007	Defer Date: 04.12.200 7
	Decision : Committee considered case as per agenda for ratification of norms for export product Phenyl Thio Proline 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.			

14 1	Case No.:960/24/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Ca se Approved
	HQ File : 01/83/050/00976/AM08/	RLA File : 09/24/040/00200/AM08/	Lic.No/Date:09100311 60 16.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Ampicillin Anhydrous under para 4.7 of HBP. Committee decided to ratify norms as per revised SION at SI.No.A-60 published vide Public Notice No.70 dated 15.10.2007. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

14 2	Case No.:111/21/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82- ALC4/2007 06.11.2007	Status:Ca se Withdraw n
	HQ File : 01/82/050/00156/AM08/	RLA File : 03/94/040/00517/AM08/	Lic.No/Date:03104401 08 20.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 4.7 of HBP. Committee was informed that Advance Authorisation was issued under			

para 4.7.1 of HBP under Adhoc Norms Fixed Category and hence there is no need for ratification of norms. Committee, therefore, decided to withdraw case.

14 3	Case No.:113/21/82-ALC4/2007	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00157/AM08/	RLA File : 22/24/040/00030/AM08/	Lic.No/Date:22100069 84 20.08.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil 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.			

14 4	Case No.:989/24/83-ALC1/2007	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01007/AM08/	RLA File : 22/24/040/00034/AM08/	Lic.No/Date:22100069 91 21.08.2007	Defer Date: 18.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Cefprozil 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.			

14 5	Case No.:49/25/83-ALC1/2007	Party Name:ELPPE CHEMICALS PRIVATE LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/01074/AM08/	RLA File : 03/94/040/00548/AM08/	Lic.No/Date:03104410 39 28.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Niclosamide Piperazine Salt under para 4.7 of HBP.			

Committee in consultation with technical authorities and in light of its earlier decision taken in its 46/82 meeting held on 22.02.2006 vide Case No.47/38/82 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:

Niclosamide Piperazine Salt Paste-----1Kg.

Import items:

1. Salicylic Acid-----0.650kg/kg
2. Triethylamine-----0.260kg/kg
3. Piperazine Anhydrous-----0.130kg/kg
4. Isopropyl Alcohol-----1.940kg/kg

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

14 6	Case No.:12/25/83-ALC1/2007	Party Name:ALLIANCE LABORATORIES PVT.LTD.	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Rejected
	HQ File : 01/83/050/01037/AM08/	RLA File : 03/94/040/00556/AM08/	Lic.No/Date:0310441279 30.08.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP. Committee perused reply of firm and observed that reply is incomplete. Committee, therefore, decided to close the case. RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

14 7	Case No.:12/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	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: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Saquinavir 200mg Capsules/Saquinavir 200mg Capsules under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

148	Case No.:54/27/83-ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	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: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

149	Case No.:72/27/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	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: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium- Non Infringing under para 4.7 of HBP. Committee decided to call for Central Excise certified consumption and production Data from firm. Accordingly, case was deferred for six weeks.			

150	Case No.:111/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01185/AM08/	RLA File : 03/94/040/00622/AM08/	Lic.No/Date:0310443342 17.09.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

151	Case No.:129/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01203/AM08/	RLA File : 03/94/040/00632/AM08/	Lic.No/Date:0310443548	Defer Date:

			18.09.2007	04.12.2007
Decision : Committee considered case as per agenda for ratification of norms for export product Sibutramine Hydrochloride under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.				

152	Case No.:160/27/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01234/AM08/	RLA File : 03/94/040/00658/AM08/	Lic.No/Date:0310444208 25.09.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP. Committee decided to defer case for four weeks for want of comments of PI Division.			

153	Case No.:170/27/83-ALC1/2007	Party Name:IND-SWIFT LABORATORIES LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Approved
	HQ File : 01/83/050/01244/AM08/	RLA File : 22/24/040/00042/AM08/	Lic.No/Date:2210007091 26.09.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Atorvastatin Calcium 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.24/40/82 decided to ratify Norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm which ever is lower. Export product: Atorvastatin Calcium-----1kg Import items: 1. Methyl Isobutyl Acetate-----1.76kg/kg 2. Betaalanine-----0.100kg/kg 3. 3-Ethyl-5-O(2-hydroxyethyl)-4-Methyl Thiozolium Bromide-----0.30kg 4. (4R-cis)-1,1-dimethyl ethyl-6-cyanomethyl 2,2-dimethyl-1,3-dioxane-4-acetate (ATS-8)-----1.08kg 5. Sodium Metabisulphide-----0.037kg			

6. Parafluoro Benzaldehyde-----0.85kg
 7. IPA-----8.375kg
 8. Tertiary Butyl Methyl Ether-----4.37kg

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

15 4	Case No.:67/29/83-ALC1/2007	Party Name:LUPIN LIMITED	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/83/050/01332/AM08/	RLA File : 03/95/040/00677/AM08/	Lic.No/Date:0310445931 10.10.2007	Defer Date: 04.12.2007
	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 call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

15 5	Case No.:1/27/82-ALC4/2007	Party Name:MISSION PHARMACEUTICALS LTD.,	Meet No/Date:27/82-ALC4/2007 06.11.2007	Status:Case Deferred
	HQ File : 01/82/050/00222/AM08/	RLA File : 03/95/040/00545/AM08/	Lic.No/Date:0310447430 23.10.2007	Defer Date: 04.12.2007
	Decision : Committee considered case as per agenda for ratification of norms for export product Ciprofloxacin Tabs BP 500mg under para 4.7 of HBP. Committee decided to call for a copy of application alongwith a copy of Advance Authorisation from concerned RA. Accordingly, case was deferred for four weeks.			

Date:06.11.2007
 Place:New Delhi

Shyam Lal
 Foreign Trade Development Officer