

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

Para 4.7 Decision(DRAFT)

MEETING NUMBER : 36/82-ALC4/2007 MEETING DATE : 08.01.2008

The Meeting No.36/08 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 08.01.2008 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

Case NoB-475	M/S Alkem Laboratories Ltd
Norms Committee Meeting No36/08	FNo01/82/50/1321/AM04
Meeting Date:08.01.2008	RLA FNo03/24/40/2052/AM04
Adv. Lic.No.0310247427 dated 14.01.2004	
Committee considered case as per agenda for revision of norms for export product Cefuroxime Sodium Injection under para .7 of HBP. Committee observed that while recording the minutes of earlier meeting held on 04.10.2007, three zeros were added in the quantity of export products. Committee, therefore, in consultation with representative of PI Division present in meeting decided to revise the norms as per details below. Export Product: Cefuroxime Sodium Injection 1.5g (each vial contains 1.5g of Sterile Cefuroxime Sodium) BP/USP-----1,38,320 Vials Import item: Sterile Cefuroxime Sodium BP/USP-----226.84kg Export product: Cefuroxime Sodium Injection 750mg (each vial contains 750mg of Sterile Cefuroxime Sodium) BP/USP-----1,61,000 Vials Import item: Sterile Cefuroxime Sodium BP/USP-----132.02kg Export product: Cefuroxime Sodium Injection 250mg (each vial contains 250mg of Sterile Cefuroxime Sodium) BP/USP-----4,250 Vials	

Import item:

Sterile Cefuroxime Sodium BP/USP-----1.162kg.

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

Case NoB-476	M/S Aurobindo Pharma Ltd.
Norms Committee Meeting No36/08	FNo01/87/50/230/AM07
Meeting Date:08.01.2008	RLA F.No.09/24/40/11/AM07
Adv. Lic.No.0910026489 dated 02.06.2006	
Committee considered case as per agenda for revision of norms for export product Indinavir Sulfate under para .7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case NoB-477	M/S Bharat Serums and Vaccines Ltd.
Norms Committee Meeting No36/08	FNo01/87/50/230/AM07
Meeting Date:08.01.2008	RLA F.No.09/2/0/11/AM07
Adv. Lic.No.091002689 dated 02.06.2006	
Committee considered case as per agenda for classification of Anti-Rabies Serum and Snake Venom Anti-Serum IP under a separate category "Biologicals" in DEPB Schedule rate as recommended by Department of Biotechnology.	
Committee decided that case may be re-listed on 29.01.2008 and representatives of Department of Revenue and Department of Bio-technology may be requested to attend the said meeting to decide the case. Accordingly, case was deferred for three weeks.	

Case NoB-478	M/S Wanbury Ltd.
Norms Committee Meeting No36/08	F.No.01/83/50/1270/AM07
Meeting Date:08.01.2008	RLA F.No.03/95/40/1095/AM07
Adv. Lic.No.0310420522 dated 22.02.2007	
Committee considered case as per agenda for ratification of norms for export product Sertraline Hcl under para 4.7 of HBP.	
Committee observed that there is no merit for re-consideration of the request	

of firm. It was, therefore, decided to maintain status quo.

Case NoB-479	M/S Alkem Laboratories Ltd.
Norms Committee Meeting No36/08	F.No.01/87/50/967/AM07
Meeting Date:08.01.2008	RLA F.No.03/94/40/1200/AM07
Adv. Lic.No.0310418737 dated 07.02.2007	
Committee considered case as per agenda for revision of norms for export product Amoxycillin and Cavulanate Potassium Tablets 375mg, 625mg and 100mg para 4.7 of HBP.	
Committee decided to defer case for two weeks for comments of PI Division.	

Case NoB-480	M/S Cipla Ltd.
Norms Committee Meeting No36/08	F.No.01/82/50/588/AM04
Meeting Date:08.01.2008	RLA F.No.03/94/40/1099/AM04
Adv. Lic.No.0310224465 dated 12.09.2003	
Committee considered case as per agenda for ratification of norms for export product Clavet Dops (Palatable Drops)(Amoxicillin & Clavulanate Potassium for Oral Suspension) under para 4.7 of HBP.	
Committee decided to call for a copy of application from firm. Accordingly, case was deferred for four weeks.	

Case NoB-481	M/S Penam Laboratories Ltd.
Norms Committee Meeting No36/08	F.No.01/82/162/450/AM08
Meeting Date:08.01.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 6-APA, SION at Sl.No.A-33.	
Committee decided to defer case for three weeks for Department of Revenue representative was not present in the meeting and DOR comments were not available.	

Case NoB-482	M/S Lupin Ltd.
Norms Committee Meeting No36/08	F.No.01/82/162/285/AM05
Meeting Date:08.01.2008	
Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 3C7ACCA, SION at Sl.No.A-2119. Committee decided to defer case for three weeks for Department of Revenue representative was not present in the meeting and DOR comments were not available.	

Case NoB-483	M/S Shalina Laboratories Pvt. Ltd.
Norms Committee Meeting No36/08	F.No.01/83/50/1084/AM07
Meeting Date:08.01.2008	RLA F.No.03/95/40/1163/AM07
Adv. Lic.No.0310414239 dated 02.01.2007	
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 of PI Division and in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- Export product: Betasol Lotion 30ml Import item: Betamethasone Base BP-----16.816mg/30ml Bottle RA concerned may take further necessary action as per above decision of Norms Committee.	

Case NoB-484	M/S Shalina Laboratories Pvt. Ltd.
Norms Committee Meeting No36/08	F.No.01/83/50/1083/AM07
Meeting Date:08.01.2008	RLA F.No.03/95/40/1164/AM07
Adv. Lic.No.0310414237 dated 02.01.2007	
Committee considered case as per agenda for ratification of norms for export product Epiderm Lotion 30ml under para 4.7 of HBP. Committee in light of written comments of PI Division and in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-	

Export product:
Epiderm Lotion 30ml

Import item:
Betamethasone Base BP-----15.15mg/30ml Bottle

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

Case No.C-29	M/S Amsal Chem Pvt. Ltd.
Norms Committee Meeting No36/08	F.No.01/87/50/456/AM08
Meeting Date:08.01.2008	
Committee considered case as per agenda for amendment in the description of export product in respect of export product at Sl.No.55 in DEPB Schedule.	
Committee decided to call for All Industry Data/Central Excise Data from Pharmexcil/firm. Accordingly, case was deferred for six weeks.	

Case No.A-960	M/S Gland Pharma Ltd.
Norms Committee Meeting No36/08	F.No.01/82/50/257/AM08
Meeting Date:08.01.2008	RLA F.No.09/24/40/356/AM08
Adv. Lic.No.0910032089 dated 14.11.2007	
Committee considered case as per agenda for ratification of norms for export product Adenosine Injections USP under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-961	M/S Cadila Healthcare Ltd.
Norms Committee Meeting No36/08	F.No.01/82/50/189/AM08
Meeting Date:08.01.2008	RLA F.No.08/24/40/159/AM08
Adv. Lic.No.0810067316 dated 24.09.2007	
Committee considered case as per agenda for ratification of norms for export product Paroxetine Hcl under para 4.7 of HBP.	
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/73/2007-PI-III dated 31.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.	

Export product:

Paroxetine Hcl-----1kg.

Import items:

1. Racemic alcohol-----2.069kg/kg.
2. D(-)Tartaric Acid-----1.517kg/kg
3. Toulene-----5.25kg/kg
4. Methanol-----6.50kg/kg
5. Sesamol-----0.550kg/kg
6. Dimethyl sulfoxide-----2.00kg/kg
7. Phenyl chloro formate-----0.778kg/kg
8. Isopropyl alcohol-----2.27kg/kg
9. Acetone-----5.19kg/kg

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

Case No.A-962	M/S Codexis Laboratories India Pvt. Ltd.
Norms Committee Meeting No36/08	F.No.01/82/50/290/AM08
Meeting Date:08.01.2008	RLA F.No.05/24/40/660/AM08
Adv. Lic.No.0510212818 dated 30.11.2007	
Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1,1-Dimethylethyl-6-Cyanomethyl-1,2-Dimethyl-1-3-Dioxane-4-Acetate(ATS-8) NLT 99% under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-963	M/S Bal Pharma Ltd.
Norms Committee Meeting No36/08	F.No.01/82/50/289/AM08
Meeting Date:08.01.2008	RLA F.No.07/24/40/652/AM08
Adv. Lic.No.0710055002 dated 14.12.2007	
Committee considered case as per agenda for ratification of norms for export product Amiloride Hcl under para 4.7 of HBP.	
Committee decided to defer case for four weeks for comments of PI Division.	

Case No.A-964	M/S Sandoz Pvt. Ltd.
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Norms Committee Meeting No36/08	F.No.01/82/50/209/AM08
Meeting Date:08.01.2008	RLA F.No.03/95/40/488/AM08
Adv. Lic.No.0310441155 dated 29.08.2007	
Committee considered case as per agenda for ratification of norms for export product Blistersheet (Pauci-Bacillary) Child, MB-Blistersheet (Multi-Bacillary) Child and MB-Blistersheet (Multi-Bacillary) Adult under para 4.7 of HBP. Committee decided to hand over file to representative of PI Division for their comments. Accordingly, case was deferred for six weeks.	

1	Case No.:135/24/87-ALC1/2007	Party Name:SUDEEP PHARMA LTD.,	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Transferred
	HQ File : 01/87/050/00174/AM06/	RLA File : 34/24/040/00021/AM06/	Lic.No/Date:3410013421 18.05.2005	
	Decision :Committee considered case as per agenda for ratification of norms for export product Di Calcium Phosphate Anhydrous USP or Di Calcium Phosphate Anhydrous (D.C.) and Dicalcium Phosphata Anhydrous USP or Di Cascium Phosphate Anhydrous (Powder) under para 47 of HBP. Committee decided to transfer case to DES-IV as export product pertains to Chemical Sector.			

2	Case No.:11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/87/050/00566/AM07/	RLA File : 02/24/040/00189/AM07/	Lic.No/Date:0210094006 25.09.2006	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Senega Soft Extract under para 47 of HBP. Committee decided to defer case for four weeks for comments of Department of MSME.			

3	Case No.:445/24/83-ALC1/2007	Party Name:SMILAX LABORATORIES LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01268/AM07/	RLA File : 09/24/040/00478/AM07/	Lic.No/Date:0910029428 22.02.2007	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product {3-5[room-1-(fluorophenyl)(1,3-dihydro isobenzo			

furanyl)]propyl] dimehylamine oxalate under para 47 of HBP.

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

Case No.:12/7/83- ALC1/2007	Party Name:RANTUS PHARMA PVT LTD	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Case Approved
HQ File : 01/83/050/00083/AM08/	RLA File : 09/24/040/00433/AM07/	Lic.No/Date:09100299 34 10.04.2007	

Decision : Committee considered case as per agenda for ratification of norms for export product Tramadol Base under para 47 of HBP.

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

Export product:
Tramadol Base-----1kg.

Import items:

1. Cyclohexanone-----1.74kg/kg
2. Dimethylamine Hcl-----1.16kg/kg
3. Metabromo Anisole-----2.03kg/kg
4. IPA-----1.65kg/kg
5. THF-----1.8926kg/kg
6. Paraformaldehyde-----0.35kg/kg

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

Case No.:530/24/83- ALC1/2007	Party Name:ENVEE DRUGS PVT LTD	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Case Deferred
HQ File : 01/83/050/00143/AM08/	RLA File : 34/24/040/00296/AM07/	Lic.No/Date:34100186 01 18.04.2007	Defer Date: 19.02.2008

Decision : Committee considered case as per agenda for ratification of norms for export product Betamethasone Valerate BP/USP under para 47 of HBP.

Committee decided to call for technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.

6	Case No.:550/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/00188/AM08/	RLA File : 09/24/040/00526/AM07/	Lic.No/Date:0910030104 25.04.2007	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Propafenone Hydrochloride under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

7	Case No.:6/4/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
	HQ File : 01/82/050/00031/AM08/	RLA File : 03/95/040/00095/AM08/	Lic.No/Date:0310428999 10.05.2007	
	Decision : Committee considered case as per agenda for ratification of norms for export product Diprosone Lotion 30ml under para 47 of HBP. Committee in light of written comments of PI Division and in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Diprosone Lotion 30ml Import item: Betamethasone Base BP-----15.15mg/30ml Bottle RA concerned may take further necessary action as per above decision of Norms Committee.			

8	Case No.:636/24/83-ALC1/2007	Party Name:MATRIX LABORATORIES LTD	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/00412/AM08/	RLA File : 09/24/040/00531/AM07/	Lic.No/Date:0910030365 28.05.2007	Defer Date: 05.02.2008
	Decision : Committee considered case as per agenda for ratification of norms for export product Cylohexyl Ester under para 47 of HBP.			

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

9	Case No.:655/24/83-ALC1/2007	Party Name:CADILA PHARMACEUTICALS LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/00530/AM08/	RLA File : 08/24/040/00066/AM08/	Lic.No/Date:08100654 23 15.06.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Methscopolamine Tannate under para 47 of HBP. Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.				

10	Case No.:3/20/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
	HQ File : 01/82/050/00146/AM08/	RLA File : 03/95/040/00277/AM08/	Lic.No/Date:03104375 31 26.07.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Epiderm Lotion 30ml under para 47 of HBP. Committee in light of written comments of PI Division and in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Epiderm Lotion 30ml Import item: Betamethasone Base BP-----15.15mg/30ml Bottle RA concerned may take further necessary action as per above decision of Norms Committee.				

11	Case No.:999/24/83-ALC1/2007	Party Name:VIVIN LABORATORIES PRIVATE LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01017/AM08/	RLA File : 09/24/040/00154/AM08/	Lic.No/Date:09100312 00 24.08.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product [1S,4R]-4-[(2-Amino-6-Chloro-5-Formamido-4-				

Pyrimidinyl)Amino]-2-cyclopentene-1-Methanol under para 47 of HBP.

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

Case No.:1000/24/83-ALC1/2007	Party Name:VASUDHA PHARMA CHEM LTD	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
HQ File : 01/83/050/01018/AM08/	RLA File : 09/24/040/00185/AM08/	Lic.No/Date:09100312 01 24.08.2007	Defer Date: 05.02.2008

12 Decision : Committee considered case as per agenda for ratification of norms for export product 8-Chloro-5,6-Dihydro-11h-benzo(5,6)cyclohepta(,2-b)Pyridene-11-one under para 47 of HBP.

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

Case No.:42/25/83-ALC1/2007	Party Name:AARTI DRUGS LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Withdrawn
HQ File : 01/83/050/01067/AM08/	RLA File : 03/94/040/00299/AM08/	Lic.No/Date:03104414 32 30.08.2007	

13 Decision : Committee considered case as per agenda for ratification of norms for export product Nitazoxanide under para 47 of HBP.

Committee decided to withdraw case as same has been considered in its 35/08 meeting.

Case No.:5/27/83-ALC1/2007	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Withdrawn
HQ File : 01/83/050/01079/AM08/	RLA File : 09/24/040/00234/AM08/	Lic.No/Date:09100313 29 31.08.2007	

14 Decision : Committee considered case as per agenda for ratification of norms for export product Florfenicol under para 47 of HBP.

Committee decided to withdraw case as same has been considered in its 35/08 meeting.

15 Case No.:29/27/83-ALC1/2007	Party Name:AVENTIS PHARMA LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Withdrawn
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HQ File : 01/83/050/01103/AM08/	RLA File : 03/94/040/00521/AM08/	Lic.No/Date:03104417 08 03.09.2007	
Decision : Withdrawn.			

Case No.:38/27/83-ALC1/2007	Party Name:DALAS BIOTECH LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Added
HQ File : 01/83/050/01112/AM08/	RLA File : 05/24/040/00451/AM08/	Lic.No/Date:05102085 44 05.09.2007	Defer Date:

Decision : Committee considered case as per agenda for ratification of norms for export product 7 AVCA under para 47 of HBP.

The Committee in light of its earlier decision taken in its 34/82 meeting held on 26.12.2007 vide Case No.1/29/83-ALC1/2007 decided to ratify the norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.

16 Export Product:
7AVCA (7Amino-3-vinyl-cephalosporanic acid-----1Kg.

Import items:

Sl.No.	Description of import item	Quantity allowed
1.	7-Phenylacetamido-3-chloromethyl cephalosporanic Acid Para Methoxybenzyl Ester (GCLE)	2.672kg/kg
2.	Triphenyl Phosphine	1.26kg/kg
3.	Methylene Chloride	10.31kg/kg

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

Case No.:34/27/83- ALC1/2007	Party Name:ANUS LABORATORIES LTD.,	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Case withdrawn
17 HQ File : 01/83/050/01108/AM08/	RLA File : 09/21/040/00119/AM08/	Lic.No/Date:09100314 04 05.09.2007	
Decision :Withdrawn.			

18 Case No.:54/27/83- ALC1/2007	Party Name:GLENMARK PHARMACEUTICALS LTD.,	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Case Deferred
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HQ File : 01/83/050/01128/AM08/	RLA File : 03/94/040/00525/AM08/	Lic.No/Date:03104419 78 06.09.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

Case No.:61/27/83- ALC1/2007	Party Name:APITHECARY PHARMA PVT LTD.	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Cas e Deferred
HQ File : 01/83/050/01135/AM08/	RLA File : 09/24/040/00147/AM08/	Lic.No/Date:09100314 43 07.09.2007	Defer Date: 05.02.2008
19	Decision : Committee considered case as per agenda for ratification of norms for export product Omeprazole Sulphide or 5-Methoxy-2-[(4-Mehoxy-3,5-Dimehyl-2-Pyridine-2-Methyl]hio]-1H-Benzimidazole under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.		

Case No.:94/27/83- ALC1/2007	Party Name:ENVEE DRUGS PVT LTD	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Cas e Deferred
HQ File : 01/83/050/01168/AM08/	RLA File : 34/24/040/00082/AM08/	Lic.No/Date:34100196 47 14.09.2007	Defer Date: 19.02.2008
20	Decision : Committee considered case as per agenda for ratification of norms for export product Betamethasone Valerae BP/USP under para 47 of HBP. Committee decided to call for technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.		

Case No.:12/22/82- ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:36/82- ALC4/2007 08.01.2008	Status:Cas e Deferred
HQ File : 01/82/050/00182/AM08/	RLA File : 03/94/040/00638/AM08/	Lic.No/Date:03104436 98 19.09.2007	Defer Date: 05.02.2008
21	Decision : Committee considered case as per agenda for ratification of norms for export product Carvedilol under para 47 of HBP.		

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

22	Case No.:13/22/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00183/AM08/	RLA File : 13/24/040/00018/AM08/	Lic.No/Date:13100250 51 21.09.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Biotin Granules under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

23	Case No.:14/22/82-ALC4/2007	Party Name:AMOL PHARMACEUTICALS PVT. LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00184/AM08/	RLA File : 13/24/040/00017/AM08/	Lic.No/Date:13100250 52 21.09.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Vitamin B12 Granules under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.				

24	Case No.:16/22/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
	HQ File : 01/82/050/00186/AM08/	RLA File : 03/95/040/00574/AM08/	Lic.No/Date:03104440 49 24.09.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Diprosone Lotion 30ml under para 47 of HBP. Committee in light of written comments of PI Division and in consultation with technical authorities present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Diprosone Lotion 30ml Import item:				

Betamethsone Base BP-----15.15mg/30ml Bottle

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

25	Case No.:154/27/83-ALC1/2007	Party Name:ALEMBIC LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Withdrawn
	HQ File : 01/83/050/01228/AM08/	RLA File : 34/24/040/00140/AM08/	Lic.No/Date:3410019698 25.09.2007	
Decision :Withdrawn.				

26	Case No.:26/29/83-ALC1/2007	Party Name:INDO GERMAN ALKALOIDS	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
	HQ File : 01/83/050/01291/AM08/	RLA File : 03/94/040/00663/AM08/	Lic.No/Date:0310445049 03.10.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Ipecacuanha Tincture under para 47 of HBP. Committee in light of written comments forwarded by Department of MSME vide their U.O. No.5(9)/2005-Chem. dated 09.01.2008 and in consultation with representative of Department of MSME present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Ipecacuanha Tincture BP/EP (containing emetine 0.2% +/- 0.02%)-----850 ltrs. Import item: Ipecacuanha roots-----348.5kg RA concerned may take further necessary action as per above decision of Norms Committee.				

27	Case No.:25/29/83-ALC1/2007	Party Name:CIPLA LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01290/AM08/	RLA File : 03/94/040/00684/AM08/	Lic.No/Date:0310445036 03.10.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of				

norms for export product Lamivudine under para 47 of HBP.

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

Case No.:9/29/83-ALC1/2007	Party Name:HETERO LABS LTD.	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
HQ File : 01/83/050/01274/AM08/	RLA File : 09/24/040/00278/AM08/	Lic.No/Date:09100317 04 04.10.2007	Defer Date: 05.02.2008

28 Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate under para 47 of HBP.

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

Case No.:33/29/83-ALC1/2007	Party Name:AUCTUS PHARMA PRIVATE LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
HQ File : 01/83/050/01298/AM08/	RLA File : 09/24/040/00244/AM08/	Lic.No/Date:09100317 13 05.10.2007	Defer Date: 05.02.2008

29 Decision : Committee considered case as per agenda for ratification of norms for export product {1R.2S.5R)-Methyl-5S-Methyl-5S-(ytosine-1-YL)-1,3-Oxathiolane-2R-Carboxylate/CME-Compound under para 47 of HBP.

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

Case No.:71/29/83-ALC1/2007	Party Name:HONEST BIO-VET PVT. LTD	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
HQ File : 01/83/050/01336/AM08/	RLA File : 08/24/040/00174/AM08/	Lic.No/Date:08100677 47 11.10.2007	

30 Decision : Committee considered case as per agenda for ratification of norms for export product Menadione Sodium Bisulphite Complex (MSB65%) under para 47 of HBP.

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

Export product:
Menadione Sodium Bisulphite Complex (MSB 65%)-----1Kg.

Import items:

1. Beta Methyl Naphthalene-----0.88kg/kg
2. Sodium Dichromate-----1.62kg/kg
3. N-Butanol-----0.28kg/kg

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

31	Case No.:10/30/83-ALC1/2007	Party Name:SALVI CHEMICAL INDUSTRIES LIMITED	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Transferred
	HQ File : 01/83/050/01379/AM08/	RLA File : 03/95/040/00721/AM08/	Lic.No/Date:03104466 66 17.10.2007	
Decision : Committee considered case as per agenda for ratification of norms for export product Electrolytic Iron Powder (325Mesh) under para 47 of HBP.				
Representative of PI Division present in meeting informed Committee that export product is not a pharma item. Committee, therefore, decided to transfer case to DES-IV.				

32	Case No.:2/26/82-ALC4/2007	Party Name:CIRON DRUGS & PHARMACEUTICALS P. LTD.,	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/82/050/00220/AM08/	RLA File : 03/94/040/00755/AM08/	Lic.No/Date:03104473 19 22.10.2007	Defer Date: 05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product Drugs Formulations Drops Namely Fecistil Drops under para 47 of HBP.				
Committee observed that firm has been requested to furnish a copy of DML vide letter dated 02.01.2008. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for two weeks.				

33	Case No.:50/30/83-ALC1/2007	Party Name:JUPITER BIOSCIENCE LIMITED,	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Deferred
	HQ File : 01/83/050/01419/AM08/	RLA File : 09/24/040/00336/AM08/	Lic.No/Date:09100318 78	Defer Date:

		24.10.2007	05.02.2008
Decision : Committee considered case as per agenda for ratification of norms for export product N-T-Boc-L-Phyenylalanine 99% Purity under para 47 of HBP. Committee decided to defer case for four weeks for comments of PI Division.			

Case No.:2/28/82-ALC4/2007	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:36/82-ALC4/2007 08.01.2008	Status:Case Approved
HQ File : 01/82/050/00236/AM08/	RLA File : 05/24/040/00592/AM08/	Lic.No/Date:0510211195 26.10.2007	
34	Decision : Committee considered case as per agenda for ratification of norms for export product Cefuroxime Axetil Amorphous under para 47 of HBP. Committee decided to withdraw case as same has already been approved in its 35/82 meeting.		

Outside Agenda:

Outside Agenda-1	M/S Shasun Chemicals & Drugs Ltd.
Norms Committee meeting No.36/08	F.No.01/82/50/204/AM08
Meeting Date: 08.01.2008	RLA F.No.04/24/40/255/AM08
Adv.Lic.No.0410091462 dated 10.10.2007	
Committee considered case as per agenda for ratification of norms for export product Spironolactone tablets 100mg under para 4.7 of HBP. The file handed over to representative of PI was received back. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 31.12.2007 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Spironolactone tablets 100mg Import items: 1. Spironolactone EP-----102.50mg/tablet 2. Lactose Monohydrate-----300.00mg/tablet 3. Povidone EP-----7.00mg/tablet 4. Hydroxy Propyl methyl Cellulose 6000EP-----10.00mg/tablet	

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

Outside Agenda-2	M/S Shasun Chemicals & Drugs Ltd.
Norms Committee meeting No.36/08	F.No.01/82/50/203/AM08
Meeting Date: 08.01.2008	RLA F.No.04/24/40/254/AM08
Adv.Lic.No.0410091460 dated 10.10.2007	
Committee considered case as per agenda for ratification of norms for export product Spironolactone tablets 50mg under para 4.7 of HBP. The file handed over to representative of PI was received back. Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 31.12.2007 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower. Export product: Spironolactone tablets 100mg Import items: 1. Spironolactone EP-----51.00mg/tablet 2. Lactose Monohydrate-----200.00mg/tablet 3. Povidone EP-----5.00mg/tablet 4. Hydroxy Propyl methyl Cellulose 6000EP-----7.00mg/tablet RA concerned may take further necessary action as per above decision of Norms Committee.	

Outside Agenda-3	M/S Devats (India) Pvt. Ltd.
Norms Committee meeting No.36/08	F.No.01/83/50/422/AM08
Meeting Date: 08.01.2008	RLA F.No.05/24/40/921/AM07
Adv.Lic.No.0510204173 dated 29.05.2007	
Committee considered case as per agenda for ratification of norms for export product Nystatin oral suspension USP, 210000 bottles each 30ml under para 4.7 of HBP.	

The file handed over to representative of PI was received back.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 01.01.2008 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Nystatin oral suspension USP, 210000 bottles, each 30ml

Import items:

1. Nystatin-----113.778kgs.

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

Outside Agenda-4	M/S Ponalab
Norms Committee meeting No.36/08	F.No.01/83/50/640/AM08
Meeting Date: 08.01.2008	RLA F.No.04/24/40/255/AM08
Adv.Lic.No.0410091462 dated 10.10.2007	
Committee considered case as per agenda for ratification of norms for export product 8-Hydroxy Quinoline under para 4.7 of HBP.	
The file handed over to representative of PI was received back.	
Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 17.12.2007 and in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.	
Export product:	
8-Hydroxy Quinoline-----1kg.	
Import items:	
1. 2-Nitro phenol-----1.53kg/kg	
2. Acrolein-----0.51kg/kg	
3. Methanol-----1.04kg/kg	
4. Raney's Nickel-----0.100kg/kg	
RA concerned may take further necessary action as per above decision of Norms Committee.	

