

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

Para 4.7 Officewise Statement

MEETING NUMBER : 8/82-ALC4/2007 **MEETING DATE** : 28.06.2007

1	Case No.: 5/37/82-ALC1/2005	Party Name:FDC LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/82/050/00946/AM06/	RLA File :03/94/040/00798/AM06/	Lic.No/Date:0310356218 22.11.2005	Defer Date:24.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Econazole Nitrate BP/JP/USP under para 4.7 of HBP. The Committee noted that the RLA had sent the complete three sets of the application in February, 2007, but the same were lying in the DES-IV Section. The Committee, therefore, decided to refer the copy of application to the Technical Authority. It was, therefore, decided to defer the case for four weeks.			

2	Case No.: 9/7/82-ALC1/2006	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Deferred and Re-indexed
	HQ File :01/82/050/01467/AM06/	RLA File :22/24/040/00105/AM06/	Lic.No/Date:2210005323 13.03.2006	Defer Date:10.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Anhydrous under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for two weeks. Accordingly, the Committee decided to defer the case for two weeks.			

3	Case No.: 19/6/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
	HQ File :01/83/050/00037/AM07/	RLA File :05/24/040/01018/AM06/	Lic.No/Date:0510180636 12.04.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Nesmox Capsules (Amoxycillin Capsules BP) under para 4.7 of HBP.

The Committee decided to ratify the norms of the licence as per revised SION at Sl.No.A-58 published vide Public Notice No.58 dated 26.09.2006 and SION A-54 or as applied by the firm whichever is lower..

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

4	Case No.: 7/8/87-ALC1/2006	Party Name:AGIO PHARMACEUTICALS LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Rejected
	HQ File :01/87/050/00063/AM07/	RLA File :03/94/040/00002/AM07/	Lic.No/Date:0310376482 19.04.2006	Defer Date:
	Decision : The Committee considered the case as per agenda for fixation of I/O Norms for the export product Prednisol Solution for Injection 30mg/1ml under para 4.7 of HBP. The representative of the PI Division present in the meeting informed that the firm has not given the specification of the export product as per their Drug Manufacturing Licence. The Committee noted that the firm was called for personal hearing, but they did not appear for PH. The Committee, therefore, decided to close the case.			

5	Case No.: 6/11/83-ALC1/2006	Party Name:PARABOLIC DRUGS LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
	HQ File :01/83/050/00148/AM07/	RLA File :22/24/040/00019/AM07/	Lic.No/Date:2210005522 09.05.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower.

Export product

Cloxacillin Sodium from Pen G route----1kg

Import items

1. Penicillin G Potassium first crystal-----1.43 BOU
 2. Penicillin G Amidase (Enzyme)-----0.732gm
 3. Methylene chloride----0.407kg
 4. Acetone-----0.1254kg
 5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
 - b) Hydroxy Amine Sulphate-----0.3192kg
 - c) Methyl Acetoacetate-----0.410kg
 - d) Chloroform-----0.270kg
 - e) Methylene chloride-----0.0542kg
 6. Methylene Chloride/Ethyl Acetate-----0.620kg
 7. 2-Ethyl Hexanoic acid-----0.150kg

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

6	Case No.:49/22/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00518/AM07/	RLA File :05/24/040/00391/AM07/	Lic.No/Date:0510188258 04.08.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Nesmox Capsules (Amoxycillin Capsules BP) and Nesmox (Amoxycillin Oral Suspension BP) under para 4.7 of HBP.

The Committee decided to ratify the norms for the export product Nesmox Capsules (Amoxycillin Capsules BP) as per revised SIONs at Sl.No.A-58 published vide Public Notice No.58 dated 26.09.2006 and SION A-54 or as applied by the firm whichever is lower.

As regards second export item viz. Nesmox (Amoxycillin Oral Suspension BP), the Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the norms as per details below or as applied for whichever is less.

Export Product:

Amoxycillin Oral Suspension BP/USP, each
5ml containing Amoxycillin Trihydrate
equivalent to Amoxycillin 125mg. 100 ml bottle

Import items:

1. Amoxycillin Trihydrate-----3012.83 mg.bottle of 100ml.

OR

Its relevant raw material as per revised SION Sl.No.A-58 on pro-rata basis.

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

7	Case No.: 12/28/87-ALC1/2006	Party Name:ALCHYMARS ICM SM PRIVATE LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/87/050/00482/AM07/	RLA File :04/24/040/00047/AM07/	Lic.No/Date:0410083795 25.08.2006	Defer Date:24.07.2007
	Decision : The Committee considered the case as per agenda for ratification of Norms for the export product 2-Methyl Mercapto Phenothiazine under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			
8	Case No.: 46/28/82-ALC1/2006	Party Name:BELCO PHARMA	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/82/050/00920/AM07/	RLA File :05/24/040/00343/AM07/	Lic.No/Date:0510190748 13.09.2006	Defer Date:19.07.2007

Decision : Withdrawn as this case has already been considered in the 7/08 meeting held on 20.06.2007 and the Committee had decided to call for the Drug Manufacturing Licence with the list of approved items from the firm.

9	Case No.: 11/34/87-ALC1/2006	Party Name:ALKALOIDS CORP	Meet No/Date:8/82-ALC4/2007 28.06.2007	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:24.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Senega Soft Extract under para 4.7 of HBP. The Committee noted that this case is pending for a long period for want of comments of Department of Ayush. The Committee, therefore, decided to remind Department of Ayush through D.O. letter to the Jt. Secretary, Department of Ayush. The Committee accordingly decided to defer the case for four weeks.			

10	Case No.: 9/34/82-ALC1/2006	Party Name:MAITHRI LABORATORIES (P) LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/82/050/00999/AM07/	RLA File :09/24/040/00177/AM07/	Lic.No/Date:0910027659 25.09.2006	Defer Date:24.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Moxifloxacin Hydrochloride under para 4.7 of HBP. The representative of PI Division present in the meeting informed that the case is under examination in their Department and he sought deferment of the case for four weeks. Accordingly, the Committee decided to defer the case for four weeks.			

11	Case No.: 15/34/87-ALC1/2006	Party Name:ALKEM LABORATORIES LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
	HQ File :01/87/050/00577/AM07/	RLA File :03/94/040/00658/AM07/	Lic.No/Date:0310401342 27.09.2006	Defer Date:
	Decision : Withdrawn as the case has already been approved by the Norms Committee in its 6/08 meeting held on 13.06.2007.			

12	Case No.: 24/32/82-ALC1/2006	Party Name:EMMELLEN BIOTECH PHARMACEUTICALS LIMITED,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Rejected
	HQ File :01/82/050/01101/AM07/	RLA File :03/94/040/00703/AM07/	Lic.No/Date:0310402830 06.10.2006	Defer Date:
	Decision :The Committee considered the case as per agenda and observed that the firm has not furnished technical details in the absence of which it is not possible to compute the requirement of inputs. The Committee decided to reject the case. The RLA concerned may take consequential action accordingly.			

13	Case No.:9/34/83-ALC1/2006	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00779/AM07/	RLA File :09/24/040/00256/AM07/	Lic.No/Date:0910027846 10.10.2006	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product 2,4-Dichloro Pyrimidine under para 4.7 of HBP. The Committee in the light of written comments forwarded by the PI Division vide their U.O. No.35011/14/2007 PI-III dated 10.04.2007 decided to ratify the Norms under para 4.7 of HBP as per details below or as applied for whichever is less. Export Product: 2,4-dichloro pyrimidine-----1Kg. Import items: 1. Uracil (2,4-Dihydroxy Pyrimidine)-----1.12Kg/Kg. 2. Dichloro methane (Methylene chloride)-----1.00Kg/Kg. 3. Diethyl aniline-----1.24Kg/Kg. 4. Triethylamine-----1.09Kg/Kg. 5. IPA-----0.50Kg/Kg. The RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

14	Case No.:19/32/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00804/AM07/	RLA File :05/24/040/00559/AM07/	Lic.No/Date:0510192990 18.10.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Amoxycillin Oral Suspension BP/USP/Nesmox under para 4.7 of HBP.

The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less.

Export Product:

Amoxycillin Oral Suspension BP/USP, each
5ml containing Amoxycillin Trihydrate
equivalent to Amoxycillin 125mg. 100 ml bottle

Import items:

2. Amoxycillin Trihydrate-----3012.83 mg.bottle of 100ml.

OR

Its relevant raw material as per revised SION Sl.No.A-58 on pro-rata basis.

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

Case No.:20/32/83-ALC1/2006

Party Name:NESTOR PHARMACEUTICALS
LTD.

Meet No/Date:8/82-ALC4/2007
28.06.2007

**Status:Case
Approved**

HQ File :01/83/050/00805/AM07/

RLA File :05/24/040/00561/AM07/

Lic.No/Date:0510192992
18.10.2006

Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Metronidazole Granules under para 4.7 of HBP.

The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less.

Export product:

Metronidazole Granules-----1Kg.

Import item:

1. Metronidazole-----0.3333Kg/Kg.
2. Povidone/PVPK-----Not shown in DML
3. Collidal Silicon Dioxide----- -do-

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

16	Case No.:21/32/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00806/AM07/	RLA File :05/24/040/00560/AM07/	Lic.No/Date:0510193028 19.10.2006	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Co-Trimoxazole Granules under para 4.7 of HBP. The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less. Export product: Cotrimoxazole Granules-----1Kg. Import item: 1. Trimethoprim-----0.1414Kg/Kg. 2. Sulphamethoxazole-----0.707Kg/Kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			
17	Case No.:22/32/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00807/AM07/	RLA File :05/24/040/00562/AM07/	Lic.No/Date:0510193029 19.10.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Paracetamol Granules under para 4.7 of HBP.

The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less.

Export product:

Paracetamol Granules-----1Kg.

Import item:

1. Paracetamol-----0.8686Kg/Kg.

2. Povidone/PVPK-----Not shown in DML

3. Collidal Silicon Dioxide----- -do-

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

18	Case No.:14/36/87-ALC1/2006	Party Name:ALEMBIC LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/87/050/00696/AM07/	RLA File :34/24/040/00183/AM07/	Lic.No/Date:3410017311 06.11.2006	Defer Date:24.07.2007
	Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Aza Erythromycin under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.			

19	Case No.:24/37/87-ALC1/2006	Party Name:ADVY CHEMICAL	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/87/050/00704/AM07/	RLA File :03/94/040/00836/AM07/	Lic.No/Date:0310406891 07.11.2006	Defer Date:10.07.2007
	Decision : The case has been wrongly added due to software problem.			

20	Case No.:52/36/83-ALC1/2006	Party Name:NESTOR PHARMACEUTICALS LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/83/050/00925/AM07/	RLA File :05/24/040/00585/AM07/	Lic.No/Date:0510194529 16.11.2006	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Capsules 250mg (each capsule containing Ampicillin Trihydrate equivalent to Ampicillin 250mg.) under para 4.7 of HBP.

The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less.

Export product:

Ampicillin Capsules 250mg (each capsule containing Ampicillin Trihydrate equivalent to Ampicillin 250mg.)-----1 Capsule

Import item:

1. Ampicillin Trihydrate-----285.32mg/capsule

OR

Its relevant raw material as per revised SION at Sl.No.A-69 on pro-rata basis.

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

21	Case No.: 8/44/82-ALC1/2006	Party Name:M/S.ENAL DRUGS PVT LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/82/050/01307/AM07/	RLA File :09/24/040/00237/AM07/	Lic.No/Date:0910028243 17.11.2006	Defer Date:24.07.2007
	Decision : The Committee considered the case as per agenda for ratification of Norms for the export product 2-Chloro Methyl-3, Methyl-4(2,2,2 Trifluoro Ethoxy) Pyridine HCL(Lansoprazole Chloro Compound) under para 4.7 of HBP. The Committee decided to forward the copy of application to the Technical Authority. Accordingly the case was deferred for four weeks.			

22	Case No.: 2/39/80-ALC2/2006	Party Name:BUILD MET FIBRES PVT LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Transferred to Different Section
	HQ File :01/80/050/00932/AM07/	RLA File :07/24/040/00545/AM07/	Lic.No/Date:0710048531 20.11.2006	Defer Date:
	Decision : The Committee decided to transfer the case to DES-VIII Section as the export product pertains to Plastic items.			

23	Case No.:12/41/80-ALC2/2006	Party Name:BRAWN LABORATORIES LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/80/050/01003/AM07/	RLA File :05/24/040/00737/AM07/	Lic.No/Date:0510195559 04.12.2006	Defer Date:24.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Cefadroxil Capsule 500mg (each capsule contains Cefadroxil Hemihydrate equivalent to Anhydrous Cefadroxil 500mg) under para 4.7 of HBP. The Committee decided to forward the copy of application alongwith the copy of DML to the Technical Authority. Accordingly the case was deferred for four weeks.			

24	Case No.:3/47/80-ALC2/2006	Party Name:MANTENA LABORATORIES LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/80/050/01016/AM07/	RLA File :09/24/040/00324/AM07/	Lic.No/Date:0910028524 06.12.2006	Defer Date:24.07.2007
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Benzyl (S)-(-)-1,2,3,4-Tetrahydro-3-Isoquinoline Carboxylate-Para-Toluene Sulfonic Acid Salt under para 4.7 of HBP. The Committee decided to forward the copy of complete set of application to the Technical Authority. Accordingly the case was deferred for four weeks.			

25	Case No.:7/47/87-ALC1/2006	Party Name:ALKEM LABORATORIES LTD.,	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/87/050/00855/AM07/	RLA File :03/94/040/01056/AM07/	Lic.No/Date:0310413839 28.12.2006	Defer Date:
	Decision : Withdrawn as the case has already been approved in the Norms Committee meeting No.6/08 dated 13.06.2007.			

26	Case No.:7/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01513/AM07/	RLA File :22/21/040/00108/AM06/	Lic.No/Date:2210006337 02.01.2007	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate (6APA 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-68 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

27	Case No.:8/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01526/AM07/	RLA File :22/21/040/00099/AM06/	Lic.No/Date:2210006344 03.01.2007	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

28	Case No.:10/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01529/AM07/	RLA File :22/21/040/00052/AM06/	Lic.No/Date:2210006351 04.01.2007	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

29	Case No.:9/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01528/AM07/	RLA File :22/21/040/00096/AM06/	Lic.No/Date:2210006350 04.01.2007	Defer Date:
	Decision :The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate (6APA 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-68 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

30	Case No.:11/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
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HQ File :01/82/050/01537/AM07/	RLA File :22/21/040/00104/AM06/	Lic.No/Date:2210006355 08.01.2007	Defer Date:
Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

31	Case No.:15/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01538/AM07/	RLA File :22/21/040/00100/AM06/	Lic.No/Date:2210006356 08.01.2007	Defer Date:
	Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

32	Case No.:20/46/87-ALC1/2006	Party Name:AARTI DRUGS LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/87/050/00921/AM07/	RLA File :03/94/040/01049/AM07/	Lic.No/Date:0310415184 09.01.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

33	Case No.:12/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01550/AM07/	RLA File :22/21/040/00117/AM06/	Lic.No/Date:2210006366 10.01.2007	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate (6APA 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-68 published vide Public Notice No.2 dated 19.04.2007.

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

34	Case No.: 2/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
	HQ File :01/82/050/01540/AM07/	RLA File :22/24/040/00287/AM07/	Lic.No/Date:2210006358 10.01.2007	Defer Date:
	Decision : The Committee considered the case as per agenda for ratification of Norms for the export product 6-Amino Penicillanic Acid (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-33 published vide Public Notice No.58 dated 26.09.2006. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.			

35	Case No.: 15/46/82-ALC1/2006	Party Name:BALMER LAWRIE & CO LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Transferred to Different Section
	HQ File :01/82/050/01561/AM07/	RLA File :04/24/040/00387/AM07/	Lic.No/Date:0410086890 12.01.2007	Defer Date:
	Decision : The Committee decided to transfer the case to DES-IV Section as the export product is a Chemical item.			

36	Case No.: 13/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
	HQ File :01/82/050/01588/AM07/	RLA File :22/21/040/00055/AM06/	Lic.No/Date:2210006406 18.01.2007	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower.

Export product

Cloxacillin Sodium from Pen G route----1kg

Import items

1. Penicillin G Potassium first crystal-----1.43 BOU
2. Penicillin G Amidase (Enzyme)-----0.732gm
3. Methylene chloride----0.407kg
4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg

OR

- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

37	Case No.:14/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01589/AM07/	RLA File :22/21/040/00073/AM06/	Lic.No/Date:2210006408 19.01.2007	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium (6APA Route) under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower.

Export product

Cloxacillin Sodium from 6 APA Stage----1kg

Import items

6. 6-APA-----0.490kg

7. Acetone-----0.0034kg

8. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CKIC Chloride)-----0.62kg

OR

3.a) O-chloro Benzaldehyde-----0.5034kg

3.b) Hydroxyl Amine Sulphate-----0.3192kg

3.c) Methyl Acetoacetate-----0.410kg

3.d) Chloroform-----0.270kg

3.e) Methylene chloride-----0.0542kg

9. Methylene chloride/Ethyl Acetate----0.620kg

10. 2-Ethyl Hexanoic Acid-----0.150kg

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

38	Case No.:3/8/82-ALC4/2007	Party Name:DSM ANTI-INFECTIVES INDIA LTD	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Approved
	HQ File :01/82/050/01590/AM07/	RLA File :22/21/040/00105/AM06/	Lic.No/Date:2210006409 19.01.2007	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium (6APA Route) under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower.

Export product

Cloxacillin Sodium from 6 APA Stage----1kg

Import items

1. 6-APA-----0.490kg
2. Acetone-----0.0034kg
3. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CKIC Chloride)-----0.62kg

OR

- 3.a) O-chloro Benzaldehyde-----0.5034kg
- 3.b) Hydroxyl Amine Sulphate-----0.3192kg
- 3.c) Methyl Acetoacetate-----0.410kg
- 3.d) Chloroform-----0.270kg
- 3.e) Methylene chloride-----0.0542kg
4. Methylene chloride/Ethyl Acetate----0.620kg
5. 2-Ethyl Hexanoic Acid-----0.150kg

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

39	Case No.:20/48/87-ALC1/2006	Party Name:ALCHEM INTERNATIONAL LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/87/050/00927/AM07/	RLA File :05/24/040/00765/AM07/	Lic.No/Date:0510198359 24.01.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

40	Case No.:23/48/82-ALC1/2006	Party Name:HINDUSTAN POLYAMIDES & FIBRES LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/01661/AM07/	RLA File :03/94/040/01141/AM07/	Lic.No/Date:0310417197 24.01.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

41	Case No.:4/8/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/01794/AM07/	RLA File :03/94/040/01221/AM07/	Lic.No/Date:0310418218 02.02.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

42	Case No.:5/4/82-ALC4/2007	Party Name:KDL BIOTECH LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/00035/AM08/	RLA File :03/94/040/00664/AM07/	Lic.No/Date:0310418079 02.02.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

43	Case No.:1/4/82-ALC4/2007	Party Name:HI-TECH ARAI LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/01664/AM07/	RLA File :35/24/040/00060/AM07/	Lic.No/Date:3510020470 20.02.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

44	Case No.:2/4/82-ALC4/2007	Party Name:HERBERT BROWN PHARMACEUTICAL & RESEARCH LABS	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/01906/AM07/	RLA File :03/94/040/01515/AM07/	Lic.No/Date:0310424944 29.03.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

45	Case No.:4/4/82-ALC4/2007	Party Name:SANJAY SALES CORPORATION	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/00021/AM08/	RLA File :03/95/040/01619/AM07/	Lic.No/Date:0310427817 25.04.2007	Defer Date:28.06.2007
	Decision : The case has been wrongly added due to software problem.			

46	Case No.:6/4/82-ALC4/2007	Party Name:SHALINA LABORATORIES PVT. LTD.	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/00031/AM08/	RLA File :03/95/040/00095/AM08/	Lic.No/Date:0310428999 10.05.2007	Defer Date:24.07.2007

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Diprosone Lotion 30ml under para 4.7 of HBP.

The Committee decided to call for the copy of Drug Manufacturing Licence from the firm. Accordingly the case was deferred for four weeks.

Case No.: 1/8/82-ALC4/2007	Party Name:KDL BIOTECH LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Approved
HQ File :01/82/050/00041/AM08/	RLA File :03/94/040/01418/AM07/	Lic.No/Date:0310429937 21.05.2007	Defer Date:

Decision : The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower.

Export product

Cloxacillin Sodium from Pen G route----1kg

Import items

1. Penicillin G Potassium first crystal-----1.43 BOU
2. Penicillin G Amidase (Enzyme)-----0.732gm
3. Methylene chloride----0.407kg
4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

48	Case No.: 5/8/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status: Case Deferred
	HQ File :01/82/050/00071/AM08/	RLA File :03/94/040/00254/AM08/	Lic.No/Date:0310432426 12.06.2007	Defer Date:17.07.2007

Decision :The case has been wrongly added due to software problem.

49	Case No.:6/8/82-ALC4/2007	Party Name:CIPLA LIMITED	Meet No/Date:8/82-ALC4/2007 28.06.2007	Status:Case Deferred
	HQ File :01/82/050/00072/AM08/	RLA File :03/94/040/00256/AM08/	Lic.No/Date:0310432429 12.06.2007	Defer Date:17.07.2007
	Decision : The case has been wrongly added due to software problem.			

Minutes of the Norms Committee Meeting No. 08/08 held on 28.6.07 under the Chairmanship of Shri Sanjay Rastogi, Export Commissioner.

The Committee first considered the minutes of the NC Meeting No. 07/08 held on 20.06.07 for confirmation and confirmed and adopted the same.

Case No.A-107	M/S KDL Biotech Ltd
Meeting No.08/08	File No.01/83/50/54/AM'08/DES-III
Date: 28.06.2007	RLA F.No.03/94/40/1377/AM'07
Advance licence No.0310429952 Dated 21.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg	

4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

Case No.A-108	M/S KDL Biotech Ltd
Meeting No.08/08	File No.01/83/50/53/AM'08/DES-III
Date: 28.06.2007	RLA F.No.03/94/40/1419/AM'07
Advance licence No.0310429942 Dated 21.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg	

4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

Case No.A-109	M/S Nestor Pharmaceuticals Ltd
Meeting No.08/08	File No.01/83/50/1277/AM'07/DES-III
Date: 28.06.2007	RLA F.No.05/24/40/960/AM'07
Advance licence No.0510200106 Dated 27.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Co-Trimoxazole Granules under para 4.7 of HBP. The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less. Export product: Cotrimoxazole Granules-----1Kg. Import item: 1. Trimethoprim-----0.1414Kg/Kg. 1. Sulphamethoxazole-----0.707Kg/Kg	

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

Case No.A-110	M/S Nestor Pharmaceuticals Ltd
Meeting No.08/08	File No.01/83/50/1278/AM'07/DES-III
Date: 28.06.2007	RLA F.No.05/24/40/961/AM'07
Advance licence No.0510200107 Dated 27.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Metronidazole Granules under para 4.7 of HBP. The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/29/2007-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less. Export product: Metronidazole Granules-----1Kg. Import item: 1 Metronidazole-----0.3333Kg/Kg. 2 Povidone/PVPPK-----Not shown in DML 3 Collidal Silicon Dioxide----- -do- RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-111	M/S Mission Pharmaceuticals Ltd.
Meeting No.08/08	File No.01/82/50/1614/AM'07/DES-III
Date: 28.06.2007	RLA F.No.03/95/40/1249/AM'07
Advance licence No.0310415874 Dated 15.01.2007	
The Committee considered the case as per agenda for ratification	

of Norms for the export product Erythromycin Ethyl Succinate Caps BP 250mg. under para 4.7 of HBP.

The Committee noted that the firm has already been called for personal hearing before the Norms Committee on 17.07.2007 in other two cases of the firm which were considered by the Norms Committee in its 7/08 meeting held on 20.06.2007. It was, therefore, decided to link this case with the cases for personal hearing. Accordingly, this case may be re-listed in the Norms Committee meeting to be held on 17.07.2007.

Case No.A-112	M/S Merck Ltd.
Meeting No.08/08	File No.01/82/50/1618/AM'07/DES-III
Date: 28.06.2007	RLA F.No.03/95/40/1258/AM'07
Advance licence No.0310415514 Dated 11.01.2007	

The Committee considered the case as per agenda for ratification of Norms for the export product Thiamine Disulfide under para 4.7 of HBP.

The Committee in the light of written comments forwarded by PI Division vide their U.No.35011/274/2006-PI-III dated 26.06.2007, decided to ratify the the norms as per details below or as applied for whichever is less.

Export product:

Thiamine Disulfide-----1Kg.

Import items:

1. Thiamine Hcl IP/BP/USP (Vitamin B1 Hcl)---1.4199Kg/Kg.
2. Sodium Hydroxide Pellets-----0.4634Kg/Kg.
3. Potassium Hexacyanoferate (III) GR-----0.0022Kg/Kg.
4. Hydrochloric Acid Fuming 37%-----0.3356Kg/Kg.
5. Hydrogen Peroxide Solution 35% extra Pure-0.2157Kg/Kg.
6. Acetone-----0.8702 ltrs/Kg.

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

Case No.A-113	M/S KDL Biotech Ltd
Meeting No.08/08	File No.01/82/50/367/AM'08/DES-III
Date: 28.06.2007	RLA F.No.03/94/40/1408/AM'07
Advance licence No.0310429935 Dated 21.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate IP/BP 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-114	M/S Parabolic Drugs Ltd
Meeting No.08/08	File No.01/83/50/1121/AM'07/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/283/AM'07
Advance licence No.2210006369 Dated 10.01.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-115	M/S Parabolic Drugs Ltd

Meeting No.08/08	File No.01/83/50/1133/AM'07/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/290/AM'07
Advance licence No.2210006385 Dated 16.01.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-116	M/S Parabolic Drugs Ltd
Meeting No.08/08	File No.01/83/50/1130/AM'07/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/285/AM'07
Advance licence No.2210006378 Dated 11.01.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-117	M/S Lupin Ltd
Meeting No.08/08	File No.01/82/50/1851/AM'07/DES-III
Date: 28.06.2007	RLA F.No.03/95/40/1581/AM'07
Advance licence No.0310424036 Dated 22.03.2007	

The Committee considered the case as per agenda for ratification of Norms for the export product 7-ADCA 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-35 published vide Public Notice No.2 dated 19.04.2007.

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

Case No.A-118	M/S Aurobindo Pharma Ltd
Meeting No.08/08	File No.01/87/50/953/AM'07/DES-III
Date: 28.06.2007	RLA F.No.09/24/40/429/AM'07
Advance licence No.0910029197 Dated 05.02.2007	

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

The Committee in the light of written comments forwarded by PI Division vide their U.O. No.35011/22/2007-PI-III dated 27.02.2007 decided to ratify the norms of the export product as per details below or as applied for whichever is less.

Export Product:

Simvastatin-----1Kg.

Import Items:

1. Lavastatin-----1.736Kg/Kg.
2. Acetic Acid-----1.116Kg/Kg.
3. Carbon DC Enoaniticromos (activated carbon)-0.035Kg/Kg.
4. Cyclohexane-----5.27Kg/Kg.
5. Methanol-----13.64Kg/Kg.
6. Methyl Iodide-----0.61Kg/Kg.
7. Methylene Chloride-----3.04Kg/Kg.
8. N,N-Dimethylformamide-----1.71Kg/Kg.
9. N-Butylithium in Hexanes-----0.988Kg/Kg.

10.Pyrrolidine-----1.208Kg/Kg.
 11.Tert Butyldimethylsilyl chloride-----1.62Kg/Kg.
 12.THF-----8.09Kg/Kg.

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

Case No.A-119	M/S Aurobindo Pharma Ltd.
Meeting No.08/08	File No.01/87/50/884/AM'07/DES-III
Date: 28.06.2007	RLA F.No.09/24/40386/AM'07
Advance licence No.0910028957 Dated 10.01.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cephalexin (Cephalexin Monohydrate) (from 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-116 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-120	M/S Aurobindo Pharma Ltd.
Meeting No.08/08	File No.01/87/50/985/AM'07/DES-III
Date: 28.06.2007	RLA F.No.09/24/40/261/AM'07
Advance licence No.0910029298 Dated 12.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Nelfinavir Mesylate (From PHIQ Route) under para 4.7 of HBP. The Committee decided that the application of the firm may be forwarded to the Technical Authority. The case was, therefore, deferred for four weeks.	

Case No.A-121	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/72/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/310AM'07
Advance licence No.2210006598 Dated 19.03.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-122	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/68/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/307AM'07
Advance licence No.2210006593 Dated 19.03.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-123	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/58/AM'08/DES-III

Date: 28.06.2007	RLA F.No.22/21/42/71/AM'05
Advance licence No.2210006475 Dated 07.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg 4. Acetone-----0.1254kg 5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg OR 5.a) O-chloro Benzaldehyde-----0.5034kg b) Hydroxy Amine Sulphate-----0.3192kg c) Methyl Acetoacetate-----0.410kg d) Chloroform-----0.270kg e) Methylene chloride-----0.0542kg 6. Methylene Chloride/Ethyl Acetate-----0.620kg 7. 2-Ethyl Hexanoic acid-----0.150kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-124	M/S DSM Anti-Infectives India Ltd
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Meeting No.08/08	File No.01/82/50/253/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/7/AM'08
Advance licence No.2210006705 Dated 03.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg 4. Acetone-----0.1254kg 5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg OR 5.a) O-chloro Benzaldehyde-----0.5034kg b) Hydroxy Amine Sulphate-----0.3192kg c) Methyl Acetoacetate-----0.410kg d) Chloroform-----0.270kg e) Methylene chloride-----0.0542kg 6. Methylene Chloride/Ethyl Acetate-----0.620kg 7. 2-Ethyl Hexanoic acid-----0.150kg RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

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Case No.A-125	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/96/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/2AM'08
Advance licence No.2210006653 Dated 10.04.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product 6-Amino Penicillanic Acid (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-33 published vide Public Notice No.58 dated 26.09.2006. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-126	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/70/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/308/AM'07
Advance licence No.2210006595 Dated 19.03.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower. Export product Cloxacillin Sodium from Pen G route----1kg Import items 1. Penicillin G Potassium first crystal-----1.43 BOU 2. Penicillin G Amidase (Enzyme)-----0.732gm 3. Methylene chloride----0.407kg	

4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

Case No.A-127	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/67/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/306/AM'07
Advance licence No.2210006592 Dated 19.03.2007	

The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium under para 4.7 of HBP.

The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm whichever is lower.

Export product
Cloxacillin Sodium from Pen G route----1kg

Import items

1. Penicillin G Potassium first crystal-----1.43 BOU
2. Penicillin G Amidase (Enzyme)-----0.732gm
3. Methylene chloride----0.407kg

4. Acetone-----0.1254kg
5. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CMIC Chloride)-----0.62kg
- OR
- 5.a) O-chloro Benzaldehyde-----0.5034kg
- b) Hydroxy Amine Sulphate-----0.3192kg
- c) Methyl Acetoacetate-----0.410kg
- d) Chloroform-----0.270kg
- e) Methylene chloride-----0.0542kg
6. Methylene Chloride/Ethyl Acetate-----0.620kg
7. 2-Ethyl Hexanoic acid-----0.150kg

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

Case No.A-128	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/410/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/10AM'08
Advance licence No.2210006746 Dated 28.05.2007	
The Committee considered the case as per agenda for ratification of Norms for the 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-58 published vide Public Notice No.58 dated 26.09.2006. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-129	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/21/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/1AM'08
Advance licence No.2210006652	

Dated 10.04.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product 6-Amino Penicillanic Acid (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-33 published vide Public Notice No.58 dated 26.09.2006. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-130	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/71/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/305AM'07
Advance licence No.2210006597 Dated 19.03.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product 6-Amino Penicillanic Acid (Pencillin 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-33 published vide Public Notice No.58 dated 26.09.2006. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-131	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/61/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/24/40/139/AM'06
Advance licence No.2210006480 Dated 08.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin 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-69 published vide Public Notice No.2 dated 19.04.2007.

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

Case No.A-132	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/59/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/21/42/64/AM'05
Advance licence No.2210006476 Dated 07.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Ampicillin Trihydrate (6APA 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-68 published vide Public Notice No.2 dated 19.04.2007. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.	

Case No.A-133	M/S DSM Anti-Infectives India Ltd
Meeting No.08/08	File No.01/82/50/54/AM'08/DES-III
Date: 28.06.2007	RLA F.No.22/21/42/69/AM'05
Advance licence No.2210006461 Dated 02.02.2007	
The Committee considered the case as per agenda for ratification of Norms for the export product Cloxacillin Sodium (6APA Route) under para 4.7 of HBP. The Committee in light of the report of the Deptt. of C&PC forwarded vide their U.O.No.35011/165/2006/PI-III(Part-IV) dated 9.3.2007 decided	

to fix I/O Norms for the export product for the purpose of para 4.7 of HBP only as under or as applied by the firm which ever is lower.

Export product

Cloxacillin Sodium from 6 APA Stage----1kg

Import items

1. 6-APA-----0.490kg
2. Acetone-----0.0034kg
3. 3-(2-Chlorophenyl)-5-Methyl Isoxazole Carbonyl Chloride (CKIC Chloride)-----0.62kg

OR

- 3.a) O-chloro Benzaldehyde-----0.5034kg
- 3.b) Hydroxyl Amine Sulphate-----0.3192kg
- 3.c) Methyl Acetoacetate-----0.410kg
- 3.d) Chloroform-----0.270kg
- 3.e) Methylene chloride-----0.0542kg
4. Methylene chloride/Ethyl Acetate----0.620kg
5. 2-Ethyl Hexanoic Acid-----0.150kg

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

Case No.B-107	M/S Medreich Ltd
Meeting No.08/08	File No.01/82/50/795/AM'06/DES-III
Date: 28.06.2007	RLA F.No.07/24/40/553/AM'06
Advance licence No.0710040930 Dated 18.10.2005	
The Committee considered the case as per agenda for ratification of Norms for the export product Iodine 20Mg+Peptone 75Mg Tablets Iodone Tablets under para 4.7 of HBP. The Committee decided that the application alongwith the reply received from the firm may be forwarded to the Technical Authority. The case was accordingly deferred for four weeks.	

Case No.B-108	M/S IPCA Laboratories Ltd	
Meeting No.08/08	File No.01/82/50/661/AM'07/DES-III	
Date: 28.06.2007	Advance licence No. 0310392753 dated 02.08.2006 0310370771 dated 09.03.2006 0310240505 dated 08.12.2003 0310366791 dated 14.02.2006	
The Committee considered the case as per agenda for correction in the specification of item of imports and exports and enhancement in the quantity of the above mentioned Advance licences. The Committee decided to allow corrections in the import and export items as per details below;		
Advance Licence No. & date	Specification of item earlier allowed	Corrected item
0310392753 dated 02.08.2006	Pro[rama;jc (export product)	Propranolol HCL
0310370771 dated 09.03.2006	Paroxetin HCL (export product)	Paroxetine HCL
0310240505 dated 08.12.2003	Nebumelone (export product) Iso Propylalcohol (import item No.4)	Nabumetone Iso Propyl alcohol
0310366791 dated 14.02.2006	Glimepride (export product)	Glimepiride
As regards enhancement in the quantity of inputs, the Committee decided to maintain status quo. RLA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.		

Case No.B-109	M/S Dr. Reddy's Laboratories Ltd
Meeting No.08/08	File No.01/82/50/43/AM'06/DES-III
Date: 28.06.2007	RLA F.No.09/24/40/548/AM'06
Advance licence No.0910025936	

Dated 13.04.2006

The Committee considered the case as per agenda for ratification of Norms for the export product Gemcitabine HCL under para 4.7 of HBP.

The Committee decided that the application alongwith the reply received from the firm may be forwarded to the Technical Authority. The case was accordingly deferred for four weeks.

Case No.B-110	M/S Alco Laboratories India Ltd
Meeting No.08/08	File No.01/87/50/663/AM'05/DES-III
Date: 28.06.2007	RLA F.No.08/80/40/261/AM'0
Advance licence No.0810041692 Dated 02.09.2004	

The Committee considered the case as per agenda for amendment in the item of import against the above mentioned advance licence.

The Committee decided to allow amendment in the item of import as per details below;

From	To
Amino Acetic Acid	Glycine T Grade (Amino Acetic Acid) Purity not more than 98.5% and Chloride content 0.50%.

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

Case No.B-111	M/S MSN Pharma Pvt. Ltd.
Meeting No.08/08	File No.01/82/50/611/AM'07/DES-III
Date: 28.06.2007	RLA F.No.09/24/40/110/AM'07
Advance licence No.0910027025 Dated 26.07.2006	

The Committee considered the case as per agenda for ratification of Norms for the export product Moxifloxacin Hydrochloride API under para 4.7 of HBP.

The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.

Case No.B-112	M/S MSN Pharma Pvt. Ltd.
Meeting No.08/08	File No.01/82/50/1233/AM'07/DES-III
Date: 28.06.2007	RLA F.No.09/24/40/215/AM'07
Advance licence No.0910028088 Dated 03.11.2006	
The Committee considered the case as per agenda for ratification of Norms for the export product Moxifloxacin Hydrochloride API under para 4.7 of HBP. The representative of PI Division present in the meeting informed the Committee that the case is under examination in their Department and he sought deferment for four weeks. The Committee accordingly decided to defer the case for four weeks.	

Case No.B-113	M/S Glenmark Pharmaceuticals Ltd
Meeting No.08/08	File No.01/82/50/2021/AM'05/DES-III
Date: 28.06.2007	RLA F.No.03/24/40/2398/AM'05
Advance licence No.0310321344 Dated 15.03.2005	
The Committee considered the case as per agenda for ratification of Norms for the export product Gilimepride under para 4.7 of HBP. The Committee on the recommendation of the representative of PI Division present in the meeting decided to ratify the Norms under para 4.7 of HBP as per written comments forwarded by PI Division vide their U.O. No.35011/127/2006-PI-III dated 14.08.2006 or as applied for whichever is less. Export Product: Tenoxicam-----1Kg.	

Import items:

1. Methyl-3-[Methoxy Carbonyl) [Amino] Sulfonyl]-2-Thiophene Carboxylate-----2.70Kg./Kg.
2. Acetone-----2.40Kg/Kg.
3. Methanol-----1.60Kg/Kg.

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

Case No.B-114	M/S Glenmark Pharmaceuticals Ltd
Meeting No.08/08	File No.01/82/50/3109/AM'05/DES-III
Date: 28.06.2007	RLA F.No.03/24/40/2516/AM'04
Advance licence No.0310256280 Dated 04.03.2004	

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

The Committee on the recommendation of the representative of PI Division present in the meeting decided to ratify the Norms under para 4.7 of HBP as per written comments forwarded by PI Division vide their U.O. No.35011/378/2003-PI-III dated 08.12.2003 or as applied for whichever is less.

Export Product:

Gilimepride-----1Kg.

Import items:

1. 4-(2-3-Ethyl-4-Methyl-2-Oxo-3-Pyrroline-1-Carboxamido Ethyl Phenyl Sulfonamide)-----0.96Kg/Kg.
2. Trans-4-Methyl Cyclohexyl Isocyanate-----0.39Kg/Kg.
3. Acetone-----2.50Kg/Kg.
4. Methanol-----2.50Kg/Kg.
5. Toluene-----Not required in the process

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

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