

Office of Directorate General of Foreign Trade
New Delhi -0

Para 4.7 Decision(DRAFT)

MEETING NUMBER : 47/82-ALC4/2009 MEETING DATE : 16.02.2010

The Meeting No.47/82 in the year 2009-10 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2004-09 pertaining to products falling in Chapter 29 and 30 scheduled to be held on 16.02.2010 was actually held on 23.02.2010 under the Chairmanship of Addl DGFT, Shri V.K. Gupta in his chamber.

Following members were present:-

1. Shri Shaish Kumar, IA, DIPP
2. Shri D.N. Mathur, Dy. IA, Department of Pharmaceuticals
3. Shri Rajinder Pal Singh, Dy. DGFT
4. Shri Shyam Lal, FTDO

It was noted that neither the representative of DC(MSME) nor the representative of Department of Ayush are attending the Norms Committee meeting resulting pending of large number for cases for fixation of norms. It was, therefore, decided to remind both the Departments to depute the representative for attending meeting through D.O. letter at the level of DG.

At the outset, minutes of Norms Committee Meeting No. 44/82 dated 27.01.2010 were ratified by the Committee.

Case No. B-460	M/s Watson Pharma Pvt. Ltd.
Norms Committee Meeting No. 47/10	File No. 01/83/050/00752/AM04/DES-III
Meeting Date 16.02.2010	RAF No. 03/24/040/01025/AM04
Adv. Lic. No. 0310221706 dated 29.8.2003	
Withdrawn as the case has already been approved by NC in 46/82 meeting held on 09.02.2010.	

Case No. B-461	M/s GVS Labs Ltd.
Norms Committee Meeting No. 47/10	F.No.01/82/50/1561/AM06/DES-III F.No.01/82/50/1215/AM06/DES-III
Meeting Date 16.02.2010	RAF No.03/94/040/1305/AM06 RAF No.03/94/040/1137/AM06
Adv. Lic. No. 0310368505 dated 24.02.2006 Adv. Lic. No. 0310363042 dated 13.01.2006	
Committee considered case as per agenda and decided to seek comments from Zonal Jt. DGFT, Mumbai regarding circumstances in which the name of M/S Milan Laboratories (India) Pvt. Ltd has not been endorsed as supporting manufacturer in Advance licence No. 0310368505 dated 24.02.2006 and 0310363042 dated 13.01.2006 issued to	

M/S GVS Ltd. Since the licences are very old, it was also decided to close the case and reopen the same after receipt of reply from RA.

Case No. B-462	M/s Kopran Ltd.			
Norms Committee Meeting No. 47/10	File No. 01/82/050/01021/AM08 File No. 01/82/050/01704/AM07 File No. 01/82/050/01330/AM07 File No. 01/82/050/01372/AM07			
Meeting Date 16.02.2010	RAF No. 03/94/040/00511/AM08 RAF No. 03/94/040/01184/AM07 RAF No. 03/94/040/653/AM07 RAF No. 03/94/040/00951/AM07			
Adv. Lic. No. 0310440478 dated 22.08.2007 Adv. Lic. No. 0310420811 dated 23.02.2007 Adv. Lic. No. 0310409126 dated 22.11.2006 Adv. Lic. No. 0310410420 dated 01.12.2006				
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/205/2009-PI-(Norms) dated 20.01.2010 and in consultation with technical authority present in meeting, decided to revise norms under para 4.7 of HBP against Advance licence mentioned above as per details below or as applied by firm whichever is lower:-				
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Ceftriaxone Sodium Sterile	1 Kg.	1.	Ceftriaxone Sodium (Non Sterile)	1.04 kg
		2.	Acetone	1.72 kg
As regards Advance licence Nos. 0310408804 dated 20.11.2006 and 0310438246 dated 06.08.2007 for the export product Cefepime for Injection, it was decided to call for the content of Cefepime Hcl (Non-Sterile) and L-Arginine (Non-sterile) in the export product.				
RA concerned may take further necessary action as per above decision of NC.				

Case No. B-463	M/s Emcure Pharmaceuticals Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/050/00263/AM10
Meeting Date 16.02.2010	RAF No. 31/24/040/00058/AM10
Adv. Lic. No. 3110039081 dated 03.07.2009	
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/268/2009-PI-III dated 24.12.2009 and in consultation with technical authorities present in meeting, decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-	

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed
Efavirenz Micronized	1 kg.	1.	(S)-5-Chloro-(Cyclopropylethynyl)-2-Amino-(Trifluoromethyl)-Benzene Methanol	1.0173 kg

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

Case No. B-464	M/s Emcure Pharmaceuticals Ltd.			
Norms Committee Meeting No. 47/10	File No. 01/82/050/00596/AM10			
Meeting Date 16.02.2010	RAF No. 31/24/040/00111/AM10			
Adv. Lic. No. 3110040145 dated 05.10.2009				
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/268/2009-PI-III dated 24.12.2009 and in consultation with technical authorities present in meeting, decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product	Export Qty.	Sl.No.	Import items	Qty. allowed
Efavirenz Micronized	1 kg.	1.	(S)-5-Chloro-(Cyclopropylethynyl)-2-Amino-(Trifluoromethyl)-Benzene Methanol	1.0173 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No. B-465	M/s Metropolitan Eximchem Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/050/01144/AM09
Meeting Date 16.02.2010	RAF No. 03/95/040/00594/AM10
Adv. Lic. No. 0310489940 dated 13.10.2008	
Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.	

Case No. B-466	M/s Fermenta Biotech Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/162/00831/AM09
Meeting Date 16.02.2010	
Case under para 4.4.2 of HBP.	
Committee considered case as per agenda and decided to call for the specific import item No.1 i.e.either Cholesterol NF or Cholesteryl Acetate from firm. Accordingly, case was deferred for 16.06.2010.	

Case No. B-467	M/s Chemill Nutraceuticals Pvt.Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/050/00011/AM10
Meeting Date 16.02.2010	RAF No. 03/94/040/01119/AM09
Adv. Lic. No. 0310516126 dated 17.04.2009	
Committee decided to forward a copy of application to DC(MSME) and Department of Ayush for their comments. Accordingly, case was deferred for 16.03.2010.	

Case No. B-468	M/s Sterling Biotech Ltd.			
Norms Committee Meeting No. 47/10	File No. 01/82/050/00655/AM09			
Meeting Date 16.02.2010	RAF No. 34/24/040/00055/AM09			
Adv. Lic. No. 3410021673 dated 23.06.2008				
Committee considered case as per agenda and taking 95% yield and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
2 Chloro 4 Methyl Sulfonyl Benzoic Acid	1 Kg.	1.	Calcium Acetate	As applied
		2.	Cobalt-II-Acetate-4-Hydrate	As applied
		3.	Manganese-II-Acetate	As applied
		4.	2-Chl-4-methylsulfonyltoluene	0.92 kg
		5.	Hydrobromic Acid 62-63%	As applied
RA concerned may take further necessary action as per above decision of NC.				

Case No. B-469	M/s Alkaloids Corporation
Norms Committee Meeting No. 47/10	File No. 01/82/050/00483/AM08
Meeting Date 16.02.2010	RAF No. 02/24/040/00272/AM08
Adv. Lic. No. 0210107833 dated 04.01.2008	
Committee considered case as per agenda and observed that the technical information received from the firm has been forwarded to Department of Pharmaceuticals for their comments. Accordingly, case was deferred for 16.03.2010.	

Case No. A-212	M/s Fleming Lab Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/162/01125/AM09
Meeting Date 16.02.2010	RAF No. 09/24/040/00030/AM09
Adv. Lic. No. 0910033923 dated 15.05.2008	
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/187/2009-PI-(Norms) dated 07.01.2010 and in consultation with	

technical authorities present in meeting, decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

Export product	Export Qty.	Sl.No.	Import items	Qty. allowed
Ketofifen hydrogen Gumarate EP/Ketotifen Furarate	1 kg.	1.	10-Methoxy-4H-Benzo (4,5) Cyclohepta (1,2-b) Thiopen-4-one	1.179 kg

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

Case No. A-213	M/s Cipla Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/162/00107/AM10
Meeting Date 16.02.2010	RAF No. 03/94/040/00994/AM09
Adv. Lic. No. 0310505514 dated 04.02.2009	

Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/153/2009-PI-(Norms) dated 19.01.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Telmisartan and Amlodipine Tablets 80/5 mg	11,13,420 Nos.	1.	Telmisartan Granules	153 kg
		2.	Amlodipine Besilate	6.027 kg

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

Case No. A-214	M/s Unimark Remedies Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/162/00858/AM09
Meeting Date 16.02.2010	RAF No. 03/95/040/00095/AM08
Adv. Lic. No. 0310494004 dated 12.11.2008	

Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/186/2009-PI-(Norms) dated 19.01.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Naphtyridine Derivative	1 Kg.	1.	2-Amino-6-Methyl-Pyridine	0.81 kg
		2.	Ethoxy Methylene Malonic Ester	1.677 kg

		3.	Diphenyl Oxide	0.31 kg
		4.	Dimethyl Formamide	0.90 kg

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

Case No. A-215	M/s Srimi Pharmaceuticals Ltd.			
Norms Committee Meeting No. 47/10	File No. 01/82/162/01222/AM09			
Meeting Date 16.02.2010	RAF No. 09/24/040/00442/AM09			
Adv. Lic. No. 0910037267 dated 03.03.2009				
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/209/2009-PI-(Norms) dated 15.02.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Carvedilal	1 Kg.	1.	9-H-Carbazol-4-ol	1.06 kg
		2.	2-(-2-Methoxy-Phenoxy)-Ethylamine	1.089 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No. A-216	M/s Sandoz Pvt. Ltd.			
Norms Committee Meeting No. 47/10	File No. 01/82/162/00859/AM09			
Meeting Date 16.02.2010	RAF No. 03/95/040/00518/AM09			
Adv. Lic. No. 0310485890 dated 10.09.2008				
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/174/2009-PI-(Norms) dated 22.02.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
MDT-MB Adult	1 No.	1.	Rifampicin	612 mg
		2.	Dapsone Tablets 100 mg	28 Nos.
		3.	Hard Gelatin Empty Capsules	As per packing policy
		4.	Lamprene 100 mg Capsules	3 Nos.
		5.	Lamprene 50 mg Capsules	27 Nos.
MDT-PB Adult	1 No.	1.	Rifampicin	612 mg
		2.	Dapsone Tablets 100 mg	28 Nos.
		3.	Hard Gelatin Empty Capsules (For 2	As per packing policy

		Nos. Rifampicin	
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RA concerned may take further necessary action as per above decision of NC.

Case No. A-217	M/s Cipla Ltd.
Norms Committee Meeting No. 47/10	File No. 01/82/162/00110/AM10
Meeting Date 16.02.2010	RAF No. 03/94/040/01006/AM09
Adv. Lic. No. 0310505855 dated 05.02.2009	

Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/223/2009-PI-(Norms) dated 22.02.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Stavudine Capsules 15 mg [Stavudine =15.3 mg/capsule]	1 No..	1.	2,2'-anhydro,3'-O-Mesyl,5'-O-benzoyl,5-Methyl Uridine	2.73 kg/kg of Stavudine
Stavudine Capsules 20 mg [Stavudine =20.4 mg/capsule]	1 No.			
Stavudine Capsules 30 mg [Stavudine =30.6 mg/capsule]	1 No.			
Stavudine Capsules 40 mg [Stavudine =40.8 mg/capsule]	1 No.			
Lamivudine 150 mg Stavudine 30 mg tablet [Stavudine =30.6 mg/tablet]	1 No.			
Lamivudine 150 mg Stavudine 40 mg tablet [Stavudine =40.8 mg/tablet]	1 No.			

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

1	Case No.:18/22/82-ALC4/2008	Party Name:CADILA HEALTHCARE LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
	HQ File :01/82/050/00881/AM09/	RLA File :08/24/040/00076/AM09/	Lic.No/Date:0810073944 13.08.2008		
	Decision : Committee considered case as per agenda and in light of written comments of Department of Pharmaceuticals and in consultation with technical authority present in meeting, decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower:-				
	Export product	Export Qty.	Sl. No.	Import items	Qty. allowed

Paroxetine 10 mg Tablets	3,01,00,000 Nos	1.	Paroxetine Hcl Hemihydrate	4606.37 kg
Paroxetine 20 mg Tablets	15,06,80,000 Nos.	2.	Lactose Anhydrous NF	29978.74 kg
Paroxetine 30 mg Tablets	1,51,55,000 Nos.	3.	Dibasic Calcium Phosphate Anhydrous	10561.389 kg
Paroxetine 40 mg Tablets	1,96,75,000 Nos.	4.	Magnesium Stearate	500.276 kg
		5.	BOTTLES & CAPS (PACKING MATERIALS IN FINISHED FORM 60 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		6.	75 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		7.	100 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		8.	150 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		9.	400 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		10.	500 CC WHITE HDPE ROUND BOTTLE	As per packing policy
		11.	200 CC Straight Sided WHITE HDPE BOTTLE	As per packing policy
		12.	Cap 33 MM White PP CRC with Pulp Liner	As per packing policy
		13.	Cap 53 MM WHITE PP NCRC with Pulp Liner	As per packing policy
		14.	Cap 38 MM WHITE PP NCRC with Pulp Liner	As per packing policy

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

2	Case No.:24/23/82-ALC4/2008	Party Name:ARCH PHARMALABS LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00928/AM09/	RLA File :03/94/040/00512/AM09/	Lic.No/Date:0310483819 26.08.2008	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.			

3	Case No.:28/28/82-ALC4/2008	Party Name:METROCHEM API PVT. LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01077/AM09/	RLA File :09/24/040/00204/AM09/	Lic.No/Date:0910035464 29.09.2008	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.			

4	Case No.:51/29/82-ALC4/2008	Party Name:ARCH PHARMALABS LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved
	HQ File :01/82/050/01133/AM09/	RLA File :03/94/040/00529/AM09/	Lic.No/Date:0310489370 07.10.2008	
	Decision : Withdrawn as the case has already been closed by NC in 36/82 meeting held on 01.12.2010.			

5	Case No.:4/31/82-ALC4/2008	Party Name:ALCON BIOSCIENCES PRIVATE LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01161/AM09/	RLA File :03/94/040/00851/AM08/	Lic.No/Date:0310490762 17.10.2008	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.			

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Case No.:9/31/82-ALC4/2008	Party Name:SYMED LABS LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01166/AM09/	RLA File :09/24/040/00286/AM09/	Lic.No/Date:0910035677 17.10.2008		
Decision : Committee considered case as per agenda and in light of decision of NC taken in the case of M/S Anuh Pharma Ltd and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Gemfibrozil	1 Kg.	1.	5-(2,5-Dimethylphenoxy)-2,2-Dimethylpentanoic Acid	Net to Net
		2.	Methanol	1.00 kg
RA concerned may take further necessary action as per above decision of NC.				

7	Case No.:6/32/82-ALC4/2008	Party Name:KRISHNA CHEMICAL INDUSTRIES	Meet No/Date:47/82-ALC4/2009 16.02.2010	Case Approved
	HQ File :01/82/050/01181/AM09/	RLA File :34/24/040/00136/AM09/	Lic.No/Date:3410022579 21.10.2008	
	Decision :Withdrawn as the case has already been approved by NC in 45/82 meeting held on 02.02.2010.			

8	Case No.:21/24/82-ALC4/2009	Party Name:NAVIN FLUORINE INTERNATIONAL LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00518/AM10/	RLA File :03/95/040/00331/AM10/	Lic.No/Date:0310535917 31.08.2009	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

9	Case No.:9/47/82-ALC4/2009	Party Name:STAR ORECHEM INTERNATIONAL PVT. LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01052/AM10/	RLA File :50/24/040/00006/AM10/	Lic.No/Date:5010000150 25.09.2009	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

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Case No.:11/47/82-ALC4/2009	Party Name:KUDOS CHEMIE LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01054/AM10/	RLA File :22/24/040/00031/AM10/	Lic.No/Date:2210009319 01.10.2009		
Decision : Committee considered case as per agenda for ratification of norms and in light of its earlier decision taken in its 52/09 meeting held on 31.12.2008 and in consultation with technical authority 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	Export Qty.	Sl.No.	Import items	Qty. allowed
Caffeine (Synthetic Caffeine Anhydrous)	1kg.	1.	Crude Theophylline 80% w/w (wet) Loss on Drying NLT 15%	1.15 kg
		2.	Caustic Soda (flakes of Lye)	0.24 kg
		3.	Dimethyl sulphate	0.68 kg
		4.	Activated Carbon	0.100 kg
RA concerned may take further necessary action as per above decision of NC.				

11	Case No.:10/47/82-ALC4/2009	Party Name:SURYA PHARMACEUTICAL LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
	HQ File :01/82/050/01053/AM10/	RLA File :22/24/040/00032/AM10/	Lic.No/Date:2210009349 14.10.2009		
	Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/206/2009-PI-(Norms) dated 19.01.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed

Fexofenadine Hcl	1 Kg.	1.	4-Chloro Butyryl Chloride	1.216 kg
		2.	Isonicotinic Acid	0.725 kg
		3.	Chlorobenzene	1.60 kg
		4.	Magnesium	0.879 kg
		5.	Tetrahydrofuran	1.00 kg
		6.	Toluene	1.09 kg
		7.	Potassium Iodide	0.009 kg
		8.	Potassium Bicarbonate	0.300 kg
		9.	Dimethyl Sulfoxide	1.12 kg
		10.	Toluene	Already covered
		11.	Monoethylene Glycol	1.24 kg
		12.	Methanol	4.00 kg
		13.	1,2 Dimethoxy Ethane	1.12 kg
		14.	Sodium Borohydride	0.332 kg
		15.	Hexane	1.00 kg
		16.	Methylene Dichloride	3.00 kg
		17.	Acetone	2.20 kg
		18.	Methyl Iso Butylketone	3.00 kg
		19.	Isopropyl Alcohol	1.90 kg
		20.	Ethyl Acetate	2.50 kg

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

12	Case No.:1/37/82-ALC4/2009	Party Name:LAFFANS PETROCHEMICALS LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00744/AM10/	RLA File :03/95/040/00472/AM10/	Lic.No/Date:0310546350 18.11.2009	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

13	Case No.:1/47/82-ALC4/2009	Party Name:ALEMBIC LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved										
	HQ File :01/82/050/01044/AM10/	RLA File :34/24/040/00150/AM10/	Lic.No/Date:3410025800 04.12.2009											
	Decision : Committee considered case as per agenda and in light of written comments earlier forwarded by Department of Pharmaceuticals vide their U.O.. No.35011/11/2005-PI-III dated 02.02.2010 and in consultation with technical authority 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:-													
<table><tr><td>Export product</td><td>Exp. Qty.</td><td>Sl.No.</td><td>Import items</td><td>Qty. allowed</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table>					Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed					
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed										

Fenofibrate	1 Kg.	1.	4-Chloro,4 Hydroxybenzophenone	1.316 kg
		2.	Acetone	2.71 kg
		3.	Ethyl Acetate	4.47 kg
		4.	Iso Propyl Alcohol	5.43 kg
		5.	Methylene Chloride	4.92 kg
		6.	Activated Charcoal	0.100 kg

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

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Case No.:2/47/82-ALC4/2009	Party Name:ALEMBIC LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01045/AM10/	RLA File :34/24/040/00146/AM10/	Lic.No/Date:3410025799 04.12.2009	Defer Date:	
Decision : Committee considered case as per agenda and in light of earlier decision taken in 32/82 meeting held on 03.11.2009 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Azithromycin Step 3 (AZA) Azithromycin	1 KGA.	1.	Erythromycin Base	1.86 kg
		2.	Acetone	1.27 kg
		3.	Ethyl Alcohol	3.00 ltr.
		4.	Hydroxylamine Hcl	0.97 kg
		5.	Methane Sulfonyl Chloride	0.69 kg
		6.	Methanol	1.09 kg
		7.	Platinum Catalyst with base of activated carbon (5% Platinum on carbon)	1.00 gm
RA concerned may take further necessary action as per above decision of NC.				

15	Case No.:5/47/82-ALC4/2009	Party Name:ALEMBIC LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved																
	HQ File :01/82/050/01048/AM10/	RLA File :34/24/040/00149/AM10/	Lic.No/Date:3410025806 07.12.2009																	
Decision : Committee considered case as per agenda and in light of written comments earlier forwarded by Department of Pharmaceuticals vide their U.O. No.35011/55/2005-PI-III dated 08.11.2005 and in consultation with technical authority 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:-																				
<table><tr><td>Export product</td><td>Exp. Qty.</td><td>Sl.No.</td><td>Import items</td><td>Qty. allowed</td></tr><tr><td rowspan="3">Nitazoxanide</td><td rowspan="3">1 Kg.</td><td>1.</td><td>2-Amino-5-Nitrothiazole</td><td>0.59 kg</td></tr><tr><td>2.</td><td>Methylene Chloride</td><td>2.48 kg</td></tr><tr><td></td><td></td><td></td></tr></table>					Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed	Nitazoxanide	1 Kg.	1.	2-Amino-5-Nitrothiazole	0.59 kg	2.	Methylene Chloride	2.48 kg			
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed																
Nitazoxanide	1 Kg.	1.	2-Amino-5-Nitrothiazole	0.59 kg																
		2.	Methylene Chloride	2.48 kg																

		3.	Acetone	2.75 kg
		4.	Activated Carbon	0.100 kg
RA concerned may take further necessary action as per above decision of NC.				

16

Case No.:6/47/82-ALC4/2009	Party Name:ALEMBIC LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01049/AM10/	RLA File :34/24/040/00160/AM10/	Lic.No/Date:3410025856 11.12.2009		
Decision : Committee considered case as per agenda and in light of earlier decision taken in 17/82 meeting held on 21.07.2009 and in consultation with technical authority 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	Export Qty.	Sl.No.	Import items	Qty. allowed
Azithromycin Crude purity Not less than 94.5%	1 KGA.	1.	Erythromycin Thiocyanate	1.99 KGA
		2.	Acetone	4.45 kg
		3.	Hydroxylamine Hcl	0.91 kg
		4.	Methanol	2.72 kg
		5.	Plathinum Catalyst with base of activated carbon (5% platinum on carbon)	1.00 gm
		6.	Methylene Chloride	2.18 kg
		7.	Activated Carbon	0.01 kg
RA concerned may take further necessary action as per above decision of NC.				

17

Case No.:4/47/82-ALC4/2009	Party Name:ONEIRO CHEMICALS LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved
HQ File :01/82/050/01047/AM10/	RLA File :34/24/040/00155/AM10/	Lic.No/Date:3410025872 15.12.2009	

Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/229/2009-PI-(Norms) dated 05.01.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
4,5,6,7-Tetrahydro (3,2,C) Thiono Pyridine Hcl	1 Kg.	1.	Thephen-2-Ethylamine	1.13 kg
		2.	Methanol	1.956 kg
		3.	Methylene Chloride	1.03 kg

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

18	Case No.:6/43/82-ALC4/2009	Party Name:PI INDUSTRIES LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00880/AM10/	RLA File :13/24/040/00026/AM10/	Lic.No/Date:1310031040 06.01.2010	Defer Date:16.03.2009
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC			

19	Case No.:3/43/82-ALC4/2009	Party Name:ARCH PHARMALABS LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00877/AM10/	RLA File :03/94/040/00784/AM10/	Lic.No/Date:0310554371 08.01.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.			

20	Case No.:4/43/82-ALC4/2009	Party Name:ARCH PHARMALABS LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00878/AM10/	RLA File :03/94/040/00773/AM10/	Lic.No/Date:0310554372 08.01.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.			

21

Case No.:10/43/82-ALC4/2009	Party Name:RA CHEM PHARMA LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/00884/AM10/	RLA File :09/24/040/00411/AM10/	Lic.No/Date:0910040593 12.01.2010		
Decision : Committee considered case as per agenda and in light of written comments earlier forwarded by Department of Pharmaceuticals vide their U.O.. No.35011/98/2007-PI-III dated 31.03.2008 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Mebeverine Hcl	1 Kg.	1.	Methyl-2-Chloromethyl Propionate	0.66 kg
		2.	Veratic Acid	0.56 kg
		3.	Methanol	0.45 kg
		4.	Toluene	0.57 kg
		5.	1,4-Dibromobutane	0.84 kg
RA concerned may take further necessary action as per above decision of NC.				

22	Case No.:11/43/82-ALC4/2009	Party Name:CADILA HEALTHCARE LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Defered
	HQ File :01/82/050/00885/AM10/	RLA File :08/24/040/00277/AM10/	Lic.No/Date:0810085697 12.01.2010	Defer Date:16.03.2010
Decision : Committee decided to defer case for 16.03.2010 for comments of Department of Pharmaceuticals.				

23	Case No.:9/43/82-ALC4/2009	Party Name:RA CHEM PHARMA LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/00883/AM10/	RLA File :09/24/040/00354/AM10/	Lic.No/Date:0910040592 12.01.2010	Defer Date:16.03.2010
Decision : Committee decided to call for a copy of Drug Manufacturing Licence from firm. Accordingly, case was deferred for 16.03.2010.				

24	Case No.:12/47/82-ALC4/2009	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved																																
	HQ File :01/82/050/01055/AM10/	RLA File :05/24/040/00452/AM10/	Lic.No/Date:0510257143 29.01.2010																																	
Decision : Committee considered case as per agenda for ratification of norms and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/150/2009-PI (Norms) dated 01.02.2010 and in consultation with technical authority 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:-																																				
<table border="1"> <thead> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed</th></tr> </thead> <tbody> <tr> <td rowspan="3">Amoxycillin Trihydrate 500 mg & Clavulanate Potassium + Microcrystalline Cellulose (1:1) (250 + 125 mg Tablet</td><td rowspan="3">1No..</td><td>1.</td><td>Amoxycillin Trihydrate (OR)</td><td>255 mg/tablet</td></tr> <tr> <td></td><td>Its raw materials as per revised SION A-57</td><td></td></tr> <tr> <td>2.</td><td>Potassium Lavulanate + Microcrystalline Cellulose (1:1)</td><td>303.45 mg/tablet</td></tr> <tr> <td rowspan="3">Amoxycillin Trihydrate 500 mg + Potassium Calavulanate 125 mg + Microcrystalline Cellulose (1:1) Tablet</td><td rowspan="3">1 No.</td><td>1.</td><td>Amoxycillin Trihydrate (OR)</td><td>510 mg/tablet</td></tr> <tr> <td></td><td>Its raw materials as per revised SION A-57</td><td></td></tr> <tr> <td>2.</td><td>Potassium Lavulanate + Microcrystalline Cellulose (1:1)</td><td>303.45 mg/tablet</td></tr> <tr> <td>Amoxycillin Trihydrate 750 mg + Potassium Calavulanate 125 mg + Microcrystalline Cellulose (1:1) Tablet</td><td>1 No.</td><td>1.</td><td>Amoxycillin Trihydrate (OR)</td><td>765 mg/tablet</td></tr> </tbody> </table>					Export product	Export Qty.	Sl.No.	Import items	Qty. allowed	Amoxycillin Trihydrate 500 mg & Clavulanate Potassium + Microcrystalline Cellulose (1:1) (250 + 125 mg Tablet	1No..	1.	Amoxycillin Trihydrate (OR)	255 mg/tablet		Its raw materials as per revised SION A-57		2.	Potassium Lavulanate + Microcrystalline Cellulose (1:1)	303.45 mg/tablet	Amoxycillin Trihydrate 500 mg + Potassium Calavulanate 125 mg + Microcrystalline Cellulose (1:1) Tablet	1 No.	1.	Amoxycillin Trihydrate (OR)	510 mg/tablet		Its raw materials as per revised SION A-57		2.	Potassium Lavulanate + Microcrystalline Cellulose (1:1)	303.45 mg/tablet	Amoxycillin Trihydrate 750 mg + Potassium Calavulanate 125 mg + Microcrystalline Cellulose (1:1) Tablet	1 No.	1.	Amoxycillin Trihydrate (OR)	765 mg/tablet
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			Its raw materials as per revised SION A-57	
		2.	Potassium Lavulanate + Microcrystalline Cellulose (1:1)	303.45 mg/tablet

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

25

Case No.:13/47/82-ALC4/2009	Party Name:DHANUKA LABORATORIES LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01056/AM10/	RLA File :05/23/040/00160/AM10/	Lic.No/Date:0510257148 29.01.2010		
Decision : Committee considered case as per agenda and in light of earlier decision taken in 44/82 meeting held on 27.01.2010 and in consultation with technical authority 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	Export Qty.	Sl.No.	Import item	Qty. allowed
Mica Ester	1 Kg.	1.	CMOBA	0.793 kg
		2.	Thiourea	0.360 kg
		3.	Triphenyl Phosphene	0.911 kg
		4.	Mercaptobenso Thiazol Disulphide	1.157 kg
		5.	Acetone	1.94 kg
		6.	Triethylamine	0.322 kg
RA concerned may take further necessary action as per above decision of NC.				

26

Case No.:3/47/82-ALC4/2009	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved
HQ File :01/82/050/01046/AM10/	RLA File :09/24/040/00432/AM10/	Lic.No/Date:0910040753 29.01.2010	

Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/332/2009-PI-(Norms) dated 09.01.2010 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Methyl Chloromethylphenyl-3-Methoxy-2-Acrylate	2-2-1 Kg.	1.	3-Isochromanone	0.957 kg
		2.	O-Xylene	1.04 kg
		3.	Sodium Methoxide Powder	0.416 kg
		4.	N-Methylformaniolde	0.083 kg
		5.	Methanol	2.31 kg

		6.	Methyl Formate	0.543 kg
RA concerned may take further necessary action as per above decision of NC.				

27

Case No.:7/47/82-ALC4/2009	Party Name:ATUL LIMITED,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01050/AM10/	RLA File :08/24/040/00294/AM10/	Lic.No/Date:0810086114 29.01.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their U.O. No.35011/192/2009-PI-III dated 26.10.2009 and in consultation with technical authority 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	Exp. Qty.	Sl.No.	Import items	Qty. allowed
N-Carbenzyloxy Carbonyl (CBZ-L-Valine)	1 Kg.	1.	L-Valine	0.667 kg
RA concerned may take further necessary action as per above decision of NC.				

28	Case No.:8/47/82-ALC4/2009	Party Name:H.J.AROCHEM PVT. LTD.,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved
	HQ File :01/82/050/01051/AM10/	RLA File :08/24/040/00295/AM10/	Lic.No/Date:0810086115 29.01.2010	
	Decision :Committee decided to close the case as Advance Authorisation has been issued under para 4.7.1 of HBP.			

29	Case No.:14/47/82-ALC4/2009	Party Name:YASHO INDUSTRIES PVT.LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01057/AM10/	RLA File :03/95/040/00711/AM10/	Lic.No/Date:0310557940 01.02.2010	Defer Date:16.03.2010
	Decision :Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

30	Case No.:15/47/82-ALC4/2009	Party Name:HALDIA PETROCHEMICALS LTD.		Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved
	HQ File :01/82/050/01058/AM10/	RLA File :02/24/040/00213/AM10/		Lic.No/Date:0210137253 02.02.2010	
	Decision : Committee considered case as per agenda for ratification of norms and in light of written comments forwarded by Petrochemicals Division vide their O.M. No.46011/54/2008-PC.II dated 23.06.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product		Export Qty.	Sl.No.	Import items	Qty. allowed

	Benzene (from Olefin Complex)	1 MT	1.	Naphtha	1.194 MT
RA concerned may take further necessary action as per above decision of NC.					

31	Case No.:16/47/82-ALC4/2009	Party Name:YASHO INDUSTRIES PVT.LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01059/AM10/	RLA File :03/95/040/00709/AM10/	Lic.No/Date:0310558091 02.02.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

32

Case No.:17/47/82-ALC4/2009	Party Name:IPCA LABORATORIES LIMITED	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Approved	
HQ File :01/82/050/01060/AM10/	RLA File :03/94/040/00949/AM10/	Lic.No/Date:0310558204 02.02.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their U.O.. No.35011/169/2008-PI-III dated 09.04.2009 and in consultation with technical authority 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	Export Qty.	Sl.No.	Import items	Qty. allowed
Triamcinolone Acetonide	1 kg.	1.	9 Beta-11 Beta-Epoxy-16 Alpha, 17 Alpha, 21-Trihydroxy-Pregna-1,4-Diene-3,20-Dione (5TR)	1.05 kg
RA concerned may take further necessary action as per above decision of NC.				

33	Case No.:18/47/82-ALC4/2009	Party Name:AKZO NOBEL CHEMICALS (INDIA) LIMITED.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01061/AM10/	RLA File :31/24/040/00226/AM10/	Lic.No/Date:3110041784 02.02.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

34	Case No.:19/47/82-ALC4/2009	Party Name:SHIVA PHARMACHEM PVT. LTD,	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01062/AM10/	RLA File :34/24/040/00184/AM10/	Lic.No/Date:3410026242 02.02.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			

35	Case No.:20/47/82-ALC4/2009	Party Name:STERLING BIOTECH LTD.	Meet No/Date:47/82-ALC4/2009 16.02.2010	Status:Case Deferred
	HQ File :01/82/050/01063/AM10/	RLA File :34/24/040/00188/AM10/	Lic.No/Date:3410026245 02.02.2010	Defer Date:16.03.2010
	Decision : Committee decided to defer case for 16.03.2010 for comments of Department of C&PC.			