

Office of Directorate General of Foreign Trade
New Delhi -0

Para 4.7 Decision

MEETING NUMBER : 38/82-ALC4/2010 MEETING DATE : 21.12.2010

The Meeting No.38/82 in the year 2010-11 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2009-14 pertaining to products falling in Chapter 29 and 30 was held on 21.12.2010 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.I.A, Department of Pharmaceuticals
3. Shri Krishan Kumar, Dy. DGFT
4. Shri Shyam Lal, FTDO

At the outset, minutes of Norms Committee Meeting No. 36/82 dated 07.12.2010 and 37/82 dated 14.12.2010 were ratified by the Committee.

Case No. B-326	M/s Scitech Specialities Pvt. Ltd.
Norms Committee Meeting No. 38/11	F.No.01/82/050/00956/AM09/DES-III
Meeting Date 21.12.2010	RLA F. No. 03/95/040/00324/AM09
Adv. Lic. No.0310484762 dated 01.09.2008	
Committee considered case as per agenda and observed that the firm has obtained advance authorization for export of Cevamune Tablets Chlorine Nutralizer and now request of the firm for deletion of Chlorine Nutralizer is not justified. It was, therefore, decided to reject the request of the firm.	

Case No. B-327	M/s Shilpa Medicare Ltd.
Norms Committee Meeting No. 38/11	F.No.01/83/050/00095/AM07/DES-III
Meeting Date 21.12.2010	RLA F. No. 07/24/040/00046/AM07
Adv. Lic. No.0710044550 dated 26.04.2006	
Committee decided to call from the firm production and consumption data certified by Central Excise Authority. Accordingly, case was deferred for 15.02.2011.	

Case No. B-328	M/s Yasho Industries Pvt. Ltd.
Norms Committee Meeting No. 38/11	F.No.01/83/050/01040/AM08/DES-III F.No.01/83/050/01730/AM08/DES-III F.No.01/83/050/00335/AM07/DES-III
Meeting Date 21.12.2010	RLA F. No. 03/95/040/00476/AM08 RLA F. No. 03/95/040/00903/AM08 RLA F. No. 03/95/040/00371/AM07

Adv. Lic. No.0310439729 dated 16.08.2007 Adv. Lic. No.0310453620 dated 11.12.2007 Adv. Lic. No.0310386989 dated 27.06.2006	
Committee considered case as per agenda and in consultation with technical authority present in meeting, decided to amend the description of export product to read as “Dipentamethylene Thiuram Tetrasulfide (Qureacc DPTT)” without any other change in the earlier decision of NC.	
RA concerned may take further necessary action as per above decision of NC.	

Case No. B-329	M/s Star Orchem International Pvt. Ltd.
Norms Committee Meeting No. 38/11	F.No.01/82/050/01052/AM10/DES-III F.No.01/82/050/00651/AM10/DES-III
Meeting Date 21.12.2010	RLA F. No. 50/24/040/00004/AM10 RLA F. No. 50/24/040/00006/AM10
Adv. Lic. No.5010000149 dated 25.09.2009 Adv. Lic. No.5010000150 dated 25.09.2009	
Committee decided to defer case for 04.01.2011 for comments of Department of C&PC.	

Case No. B-330	M/s Vivimed Labs Ltd
Norms Committee Meeting No. 38/11	F.No.01/85/050/00236/AM10/DES-III
Meeting Date 21.12.2010	RLA F. No. 09/24/040/00504/AM10
Adv. Lic. No.0910041262 dated 11.03.2010	
Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.	

Case No. B-331	M/s Aurobindo Pharma Ltd.
Norms Committee Meeting No. 38/11	F.No.01/82/050/00585/AM10/DES-III
Meeting Date 21.12.2010	RLA F. No. 09/24/040/00006/AM10
Adv. Lic. No.0910038659 dated 23.07.2009	
Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/88/2010-PI Norms dated 05.10.2010 and in consultation with technical authority present in meeting, decided to allow import of Methylene Chloride to the extent of 14.12 kg/kg of export product without any other change in the decision taken in 27/82 meeting held on 05.10.2010.	
RA concerned may take further necessary action as per above decision of NC.	

Case No. B-332	M/s Pab Organic Pvt. Ltd.
Norms Committee Meeting No. 38/11	F.No.01/82/050/01042/AM10/DES-III

	F.No.01/82/050/01119/AM10/DES-III
Meeting Date 21.12.2010	RA F.No. 34/24/040/00154/AM10 RA F.No. 34/24/040/00153/AM10
Adv. Lic. No.3410025955 dt. 22.12.09 Adv. Lic. No.3410025954 dt. 22.12.09	
Committee considered case as per agenda and decided to call for the firm for personal hearing on any Tuesday after confirmation with the P.S. of the Chairman, NC-3 at Phone No.23063419 or from Shri Krishan Kumar, Dy. DGFT & Conveynor NC-3 at Tel. No.23061562, Ext. 380 or from Shyam Lal, FTDO at Tel.No.23061562 Ext. 269. Accordingly, the case was deferred for confirmation of the firm.	

1

Case No.:17/2/82-ALC4/2010	Party Name:DORF-KETAL CHEMICALS INDIA PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved	
HQ File :01/82/050/01251/AM10/	RLA File :03/94/040/01001/AM10/	Lic.No/Date:0310560279 15.02.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of C&PC vide their U.O. No.14010/50/2006-Ch.II dated 16.12.2010 and in consultation with technical authorities present in meeting, decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-				
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed
Organic Mixture Trade Name – SR 8114 containing 10% of (2-Hydroxy Ethyl)2-(Hepta Decenyl) Imadazoline) (10% of Amino Ethyl Ethanol Amine, 80% of Glyoxylic Acid 50%, 10% of Acumer 3100)	1 Kg.	1.	Amino Ethyl Ethanol Amine	0.0675 kg
		2.	Glyoxylic Acid 50%	0.800 kg
		3.	Acumer3100 (Nonionic Functional Terpolymer)	0.10 kg
RA concerned may take further necessary action as per above decision of NC.				

2	Case No.:5/52/82-ALC4/2009	Party Name:VIVIMED LABS LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/01198/AM10/	RLA File :09/24/040/00496/AM10/	Lic.No/Date:0910041237 09.03.2010	Defer Date:18.01.2011
	Decision :Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.			

3	Case No.:14/52/82-ALC4/2009	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved
	HQ File :01/82/050/01207/AM10/	RLA File :05/24/040/00507/AM10/	Lic.No/Date:0510260189	

10.03.2010

Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/140/2010-PI-(Norms) dated 25.11.2010 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
Cefprozil	1 Kg.	1.	7-Amino-3-[(Z)-propen-1-yl]-3-cepham-4 carboxylic acid (7 APCA)	0.708 kg
		2.	Methylene Chloride	2.348 kg
		3.	Hexamethyl Disilizane	0.392 kg
		4.	Trimethyl Chloro Silane (TMCS)	0.273 kg
		5.	Imidazole	0.008 kg
		6.	D(-)Para Hydroxy Phenyl Glycine Methyl Potassium Danesalt	1.05 kg
		7.	N-Methyl Morpholine	0.007 kg
		8.	Ethyl Chloro Formate	0.406 kg
		9.	Dimethyl Formamide	3.324 kg
		10.	Activated Carbon	0.078 kg
		11.	Acetone	2.268 kg
		12.	Methane Sulfonic Acid	0.016 kg

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

Case No.:29/52/82-ALC4/2009

Party Name:AARTI INDUSTRIES LIMITED

Meet No/Date:38/82-ALC4/2010
21.12.2010Status:Case
Approved

HQ File :01/82/050/01222/AM10/

RLA File :03/94/040/01071/AM10/

Lic.No/Date:0310564649
12.03.2010

Defer Date:

Decision : Committee considered case as per agenda and light of technical details furnished by the firm 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
Budesonide	1 Kg.	1.	1,4,9,(11)16-Pregnatetraene-3,20,Dione-21 Acetate(3TR)	2.756 kg

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

5

Case No.:12/14/82-ALC4/2010

Party Name:VDH INTERNATIONAL

Meet No/Date:38/82-ALC4/2010
21.12.2010Status:Case
Deferred

HQ File :01/82/050/00374/AM11/

RLA File :05/24/040/00514/AM10/

Lic.No/Date:0510261659

Defer

			01.04.2010	Date:18.01.2011															
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.																		
6	Case No.:2/3/82-ALC4/2010	Party Name:VIVIMED LABS LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred															
	HQ File :01/82/050/00013/AM11/	RLA File :09/24/040/00549/AM10/	Lic.No/Date:0910041571 07.04.2010	Defer Date:18.01.2011															
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.																		
7	Case No.:29/18/82-ALC4/2010	Party Name:CLEAN SCIENCE AND TECHNOLOGY PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved															
	HQ File :01/82/050/00572/AM11/	RLA File :31/24/040/00001/AM11/	Lic.No/Date:3110042802 08.04.2010																
	Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of C&PC vide their U.O. No.14010/6/2009-Ch.II dated 16.12.2010 and in consultation with technical authorities present in meeting, decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-																		
	<table border="1"> <thead> <tr> <th>Export product</th><th>Exp. Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed</th></tr> </thead> <tbody> <tr> <td rowspan="3">Monomethyl Ether of Hydroquinone (99% purity)</td><td rowspan="3">1 Kg.</td><td>1.</td><td>Anisole</td><td>1.17 kg</td></tr> <tr> <td>2.</td><td>Hydrogen Peroxide (50%)</td><td>0.90 kg</td></tr> <tr> <td>3.</td><td>Acetone</td><td>0.30 kg</td></tr> </tbody> </table>				Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed	Monomethyl Ether of Hydroquinone (99% purity)	1 Kg.	1.	Anisole	1.17 kg	2.	Hydrogen Peroxide (50%)	0.90 kg	3.	Acetone
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed															
Monomethyl Ether of Hydroquinone (99% purity)	1 Kg.	1.	Anisole	1.17 kg															
		2.	Hydrogen Peroxide (50%)	0.90 kg															
		3.	Acetone	0.30 kg															
	RA concerned may take further necessary action as per above decision of NC.																		
8	Case No.:5/3/82-ALC4/2010	Party Name:CAMPBOR & ALLIED PRODUCTS LIMITED,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved															
	HQ File :01/82/050/00016/AM11/	RLA File :03/94/040/01138/AM10/	Lic.No/Date:0310568958 09.04.2010																
	Decision :Withdrawn as the case has already been approved by NC in 12/82 meeting held on 22.06.2010.																		
9	Case No.:36/6/82-ALC4/2010	Party Name:VIVIMED LABS LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred															
	HQ File :01/82/050/00183/AM11/	RLA File :09/24/040/00033/AM11/	Lic.No/Date:0910041861 03.05.2010	Defer Date:18.01.2011															
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.																		
10	Case No.:60/14/82-ALC4/2010	Party Name:CAMPBOR & ALLIED PRODUCTS	Meet No/Date:38/82-ALC4/2010	Status:Case															

	LIMITED,	21.12.2010	Approved	
HQ File :01/82/050/00422/AM11/	RLA File :03/94/040/00108/AM11/	Lic.No/Date:0310573861 12.05.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of C&PC vide their U.O.No.14010/9/2005-Ch.II dated 26.11.2010 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 items	Qty. allowed
Astrolide in Dipropylene Glycol Main Total Astrolide content 62.5% minimum	1 kg	1.	Isoamylene	0.380 kg
		2.	Propylene Oxide	0.280 kg
		3.	Paraformaldehyde	0.088 kg
		4.	Dipropylene Glycol	0.350 kg
RA concerned may take further necessary action as per above decision of NC.				

11

Case No.:57/22/82-ALC4/2010	Party Name:CAMPHOR & ALLIED PRODUCTS LIMITED,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved	
HQ File :01/82/050/00710/AM11/	RLA File :03/94/040/00118/AM11/	Lic.No/Date:0310574865 18.05.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of C&PC vide their U.O.No.14010/9/2005-Ch.II dated 26.11.2010 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 items	Qty. allowed
Astrolide in Isopropyl Myristate Main Total Astrolide content 62.5% minimum	1 kg	1.	Isoamylene	0.380 kg
		2.	Propylene Oxide	0.280 kg
		3.	Isopropyl Myristate	0.350 kg
RA concerned may take further necessary action as per above decision of NC.				

12	Case No.:135/9/82-ALC4/2010	Party Name:SAINOR LABORATORIES PVT LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00350/AM11/	RLA File :09/24/040/00040/AM11/	Lic.No/Date:0910042075 19.05.2010	Defer Date:18.01.2011
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.			

13	Case No.:59/14/82-ALC4/2010	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2010	Status:Case
----	-----------------------------	--------------------------	------------------------------	-------------

		21.12.2010	Approved
HQ File :01/82/050/00421/AM11/	RLA File :03/94/040/00186/AM11/	Lic.No/Date:0310575233 20.05.2010	

Decision : Committee considered case as per agenda and observed that the NOC for import of “HFA-227 Propellant (1,1,1,2,3,3,3-Heptafluoropropane gas)” has been received from Ministry of Environment & Forests vide their O.M. No.11/12/2010-OC dated 26.11.2010.

Committee after detailed deliberations and in light of written comments forwarded by Department of Pharmaceuticals vide their U.O. No.35011/265/2008-PI-III dated 17.03.2009 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
Ipratropium Bromide 20 mcg inhaler (200MD) with 63 mcl Aerosol Valves	1 No.	1.	Ipratropium Bromide	4.00 mg
		2.	63 mcl Aerosol valve	As per packing policy
		3.	19 ml Aluminium Can	
		4.	Activators with dust covers/caps fitting to 19ml Aluminium can	
		5.	HFA-227 Propellant (1,1,1,2,3,3,3-Heptafluoropropane gas)	21.12 mg
Salbutamol 100 mcg and Ipratropium Bromide 20 mcg inhaler (200MD) with 63 mcl Aerosol valves	1 No.	1.	Sulbutamol	20.00 mg
		2.	Ipratropium Bromide	4.00 mg
		3.	19 ml Aluminium Can	As per packing policy
		4.	63 mcl Aerosol valve	
		5.	Activators with dust covers/caps fitting to 19ml Aluminium can	
		6.	HFA-227 Propellant (1,1,1,2,3,3,3-Heptafluoropropane gas)	21.12 mg
Budesonide 100 mcg inhaler (200MD) with 63 mcl Aerosol valves	1 No.	1.	Budesonide	20.00 mg
		2.	63 mcl Aerosol valve	As per packing policy
		3.	19 ml Aluminium Can	
		4.	Activators with dust covers/caps fitting to 19ml Aluminium can	
		5.	HFA-227 Propellant (1,1,1,2,3,3,3-Heptafluoropropane gas)	21.12 mg
Budesonide 200 mcg inhaler (200MD) with 63 mcl Aerosol valves	1 No.	1.	Budesonide	40.00 mg
		2.	63 mcl Aerosol valve	As per packing policy
		3.	19 ml Aluminium Can	
		4.	Activators with dust covers/caps fitting to 19ml Aluminium can	

		5.	HFA-227 Propellant (1,1,1,2,3,3,3-Heptafluoropropane gas)	21.12 mg
RA concerned may take further necessary action as per above decision of NC subject to the condition that firm shall maintain proper record for actual consumption of Gas against this licence and pay duty on any un-utilized gas since they have shown 20% overfilling of HFA-227 Propellant Gas				

14

Case No.:10/22/82-ALC4/2010	Party Name:FDC LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved	
HQ File :01/82/050/00663/AM11/	RLA File :03/94/040/00954/AM10/	Lic.No/Date:0310576214 26.05.2010		
Decision :Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/145/2010-PI Norms dated 25.11.2010 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
Paracetamol, Pheirnamine Maleate, Phenylephrine & Ascorbic Acid Powder (Milistan Hot Tea)	6 gm Sachet	1.	Paracetamol	505.0 mg/6 gm Sachet
		2.	Pheirnamine Maleate	25.25 mg/6 gm Sachet
		3.	Phenylephrine Hcl	10.1 mg/6 gm Sachet
		4.	Ascorbic Acid	202.0 mg/6 gm Sachet
Note: The firm has not furnished approved composition of export product Milistan HotTea Anticough and therefore, norms could not be fixed.				
RA concerned may take further necessary action as per above decision of NC.				

15	Case No.:20/22/82-ALC4/2010	Party Name:ARCH PHARMALABS LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved									
	HQ File :01/82/050/00673/AM11/	RLA File :03/94/040/00211/AM11/	Lic.No/Date:0310577127 03.06.2010										
	Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/151/2010-PI Norms dated 09.12.2010 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>Exp. Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed</th></tr> </thead> <tbody> <tr> <td>1-(4-Azido-5-Trityloxymethyl-Tetrahydro-Furan-2-YL)-5-Methyl-1H-Pyrimidine-2,4-Dione (Azido Compound)</td><td>1 kg</td><td>1.</td><td>4-Methyl-10-Trityloxymethyl-8,11-Dioxa-2,6-Diaza-Tricyclo[7.2.1.0*2,7*] Dodec-6-EN-5-one (Anhydro Compound)</td><td>1.067 kg</td></tr> </tbody> </table>				Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed	1-(4-Azido-5-Trityloxymethyl-Tetrahydro-Furan-2-YL)-5-Methyl-1H-Pyrimidine-2,4-Dione (Azido Compound)	1 kg	1.	4-Methyl-10-Trityloxymethyl-8,11-Dioxa-2,6-Diaza-Tricyclo[7.2.1.0*2,7*] Dodec-6-EN-5-one (Anhydro Compound)
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed									
1-(4-Azido-5-Trityloxymethyl-Tetrahydro-Furan-2-YL)-5-Methyl-1H-Pyrimidine-2,4-Dione (Azido Compound)	1 kg	1.	4-Methyl-10-Trityloxymethyl-8,11-Dioxa-2,6-Diaza-Tricyclo[7.2.1.0*2,7*] Dodec-6-EN-5-one (Anhydro Compound)	1.067 kg									

		2.	Dimethyl Sulfoxide	2.55 kg
		3.	Sodium Azide	0.15 kg
		4.	Methanol	1.067 kg

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

16	Case No.:34/22/82-ALC4/2010	Party Name:WEXFORD LABORATORIES P LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00687/AM11/	RLA File :07/24/040/00074/AM11/	Lic.No/Date:0710072310 17.06.2010	Defer Date:15.02.2011
	Decision :Committee decided to defer case for 18.02.2011 for comments of Department of Pharmaceuticals.			

17

Case No.:36/22/82-ALC4/2010	Party Name:EMCURE PHARMACEUTICALS LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved										
HQ File :01/82/050/00689/AM11/	RLA File :31/24/040/00052/AM11/	Lic.No/Date:3110043681 21.06.2010											
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/139/2010-PI (Norms) dated 25.11.2010 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>Mycophenolate Mofetil</td><td>1 Kg.</td><td>1.</td><td>Mycophenolic Acid</td><td>0.941 kg</td></tr></table>				Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed	Mycophenolate Mofetil	1 Kg.	1.	Mycophenolic Acid	0.941 kg
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed									
Mycophenolate Mofetil	1 Kg.	1.	Mycophenolic Acid	0.941 kg									
RA concerned may take further necessary action as per above decision of NC.													

18	Case No.:108/22/82-ALC4/2010	Party Name:MEDCHL CHEMICALS AND PHARMACEUTICALS PVT LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00761/AM11/	RLA File :09/24/040/00028/AM11/	Lic.No/Date:0910042684 14.07.2010	Defer Date:15.02.2011
	Decision :Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

19	Case No.:97/22/82-ALC4/2010	Party Name:TONIRA PHARMA LTD,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00750/AM11/	RLA File :34/24/040/00073/AM11/	Lic.No/Date:3410027520 16.07.2010	Defer Date:15.02.2011

Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.

20	Case No.:31/26/82-ALC4/2010	Party Name:LAFFANS PETROCHEMICALS LTD.,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00849/AM11/	RLA File :03/95/040/00085/AM11/	Lic.No/Date:0310583874 16.07.2010	Defer Date:18.01.2011
	Decision :Committee decided to forward a copy of application to Petrochemicals Division of Department of C&PC for their comments. Accordingly, case was deferred for 18.01.2011.			

21	Case No.:85/22/82-ALC4/2010	Party Name:CIPLA LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00738/AM11/	RLA File :03/94/040/00350/AM11/	Lic.No/Date:0310584093 19.07.2010	Defer Date:15.02.2011
	Decision :Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

22	Case No.:34/18/82-ALC4/2010	Party Name:MAHIMA LIFE SCIENCES PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00577/AM11/	RLA File :05/24/040/00147/AM11/	Lic.No/Date:0510268636 21.07.2010	Defer Date:18.01.2011
	Decision :Committee considered case as per agenda. The representatives of the firm appeared before the Committee for personal hearing and explained the case. They informed the Committee that the import item Dexamethasone Base IP/BP/USP (Crystalline) contains 40 Mesh. The Committee pointed out that the firm had not indicated the same in their application. Further, that they have also not included the particle size of the export product in the application. After detailed deliberations and in consultation with technical authorities present in meeting, Committee decided to call for Certificate of Analysis in respect of export item and import item, copy of shipping bills and copy of Bills of Entry from the firm. Accordingly, case was deferred for 18.01.2011.			

23	Case No.:35/18/82-ALC4/2010	Party Name:MAHIMA LIFE SCIENCES PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00578/AM11/	RLA File :05/24/040/00151/AM11/	Lic.No/Date:0510268639 21.07.2010	Defer Date:18.01.2011
	Decision : Committee considered case as per agenda. The representatives of the firm appeared before the Committee for personal hearing and explained the case. They informed the Committee that the assays of the export product is not less than 90% and they will not be importing second import item namely Triethyl Ortho Formate. After detailed deliberations and in consultation with technical authorities present in meeting, Committee decided to call for Certificate of Analysis in respect of import item and Declaration that the purity of export product shall not be less than 90% from the firm. Accordingly, case was deferred for 18.01.2011.			

24	Case No.:36/18/82-ALC4/2010	Party Name:MAHIMA LIFE SCIENCES PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved										
	HQ File :01/82/050/00579/AM11/	RLA File :05/24/040/00152/AM11/	Lic.No/Date:0510268642 21.07.2010											
Decision : Committee considered case as per agenda. The representatives of the firm appeared before the Committee for personal hearing and explained the case. They informed the Committee that the export product contain BP/USP. After detailed deliberations and in consultation with technical authorities present in meeting, Committee decided to ratify norms under para 4.7 of HBP as per details below or as applied by the firm whichever is lower:- <table border="1"> <thead> <tr> <th>Export product</th><th>Exp. Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed</th></tr> </thead> <tbody> <tr> <td>Dexamethasone Sodium Phosphate BP/USP</td><td>1 Kg.</td><td>1.</td><td>Dexamethasone Base</td><td>0.8 kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed	Dexamethasone Sodium Phosphate BP/USP	1 Kg.	1.	Dexamethasone Base	0.8 kg
Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed										
Dexamethasone Sodium Phosphate BP/USP	1 Kg.	1.	Dexamethasone Base	0.8 kg										

25	Case No.:29/26/82-ALC4/2010	Party Name:SARACA LABORATORIES LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00847/AM11/	RLA File :09/24/040/00163/AM11/	Lic.No/Date:0910042998 06.08.2010	Defer Date:15.02.2011
Decision :Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.				

26	Case No.:34/26/82-ALC4/2010	Party Name:DALAS BIOTECH LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00852/AM11/	RLA File :05/23/040/00122/AM11/	Lic.No/Date:0510270364 11.08.2010	Defer Date:15.02.2011
Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.				

27	Case No.:4/22/82-ALC4/2010	Party Name:MEHTA (API) PVT.LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00657/AM11/	RLA File :03/95/040/00358/AM11/	Lic.No/Date:0310587875 16.08.2010	Defer Date:15.02.2011
Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.				

28	Case No.:23/26/82-ALC4/2010	Party Name:PUNJAB CHEMICALS AND CROP PROTECTION LTD.,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00841/AM11/	RLA File :03/95/040/00350/AM11/	Lic.No/Date:0310588666	Defer

		20.08.2010	Date:18.01.2011
Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.			

29	Case No.:35/26/82-ALC4/2010	Party Name:DHANUKA LABORATORIES LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00853/AM11/	RLA File :05/23/040/00085/AM11/	Lic.No/Date:0510271131 20.08.2010	Defer Date:15.02.2011
	Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

30	Case No.:26/26/82-ALC4/2010	Party Name:NECTAR LIFESCIENCES LIMITED,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00844/AM11/	RLA File :22/24/040/00035/AM11/	Lic.No/Date:2210010327 24.08.2010	Defer Date:15.02.2010
	Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

31	Case No.:2/26/82-ALC4/2010	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00820/AM11/	RLA File :09/24/040/00226/AM11/	Lic.No/Date:0910043503 14.09.2010	Defer Date:15.02.2011
	Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

32	Case No.:3/26/82-ALC4/2010	Party Name:MAHIMA LIFE SCIENCES PVT.LTD.	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00821/AM11/	RLA File :05/24/040/00222/AM11/	Lic.No/Date:0510272765 14.09.2010	Defer Date:18.01.2011
	Decision : Committee considered case as per agenda. The representatives of the firm appeared before the Committee for personal hearing and explained the case. They informed the Committee that the import item Dexamethasone Base IP/BP/USP (Crystalline) contains 40 Mesh. The Committee pointed out that the firm had not indicated the same in their application. Further, that they have also not included the particle size of the export product in the application. After detailed deliberations and in consultation with technical authorities present in meeting, Committee decided to call for Certificate of Analysis in respect of export item and import item, copy of shipping bills and copy of Bills of Entry from the firm. Accordingly, case was deferred for 18.01.2011.			

33	Case No.:49/26/82-ALC4/2010	Party Name:SUVEN LIFE SCIENCES LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00867/AM11/	RLA File :09/24/040/00245/AM11/	Lic.No/Date:0910043540 17.09.2010	Defer Date:15.02.2011

Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.

34	Case No.:4/30/82-ALC4/2010	Party Name:PRACHI PHARMACEUTICALS PVT LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00923/AM11/	RLA File :03/95/040/00095/AM11/	Lic.No/Date:0310595471 06.10.2010	Defer Date:18.01.2011
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.			

35	Case No.:6/30/82-ALC4/2010	Party Name:ALCON BIOSCIENCES PRIVATE LIMITED	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00925/AM11/	RLA File :03/94/040/00472/AM11/	Lic.No/Date:0310595543 06.10.2010	Defer Date:15.02.2011
	Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

36	Case No.:2/30/82-ALC4/2010	Party Name:JUBILANT LIFE SCIENCES LIMITED (FORMERLY JUBILANT	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/00921/AM11/	RLA File :05/23/040/00168/AM11/	Lic.No/Date:0510274506 08.10.2010	Defer Date:18.01.2011
	Decision : Committee decided to defer case for 18.01.2011 for comments of Department of C&PC.			

37

Case No.:3/30/82-ALC4/2010	Party Name:RANBAXY LABORATORIES LTD	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Approved	
HQ File :01/82/050/00922/AM11/	RLA File :05/24/040/00233/AM11/	Lic.No/Date:0510274511 08.10.2010		
Decision : Committee considered case as per agenda and in light of written comments forwarded by Department of Pharmaceuticals vide their O.M. No.35011/140/2010-PI-(Norms) dated 25.11.2010 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
Esomeprazole Magnesium Trihydrate	1 Kg.	1.	(D-Det) D-Diethyl Tartrate	0.164 kg
		2.	5-Methoxy-2-Mercaptobenzimidazole (Metmercazole)	0.702 kg
		3.	Cumene Hydroperoxide	0.669 kg
		4.	Diisopropyl Ethylamine	0.098 kg
		5.	Magnesium Sulfate Dried	0.284 kg
		6.	Methanol	6.00 kg
		7.	Potassium Methoxide (32% Sol)	0.989 kg

		8.	Pyramethyl Alcohol	0.633 kg
		9.	Thionyl Chloride	0.585 kg
		10.	Titanium-Isopropoxide	0.109 kg
		11.	Toluene	8.40 kg
RA concerned may take further necessary action as per above decision of NC.				

38	Case No.:3/34/82-ALC4/2010	Party Name:GALPHA LABORATORIES LIMITED,	Meet No/Date:38/82-ALC4/2010 21.12.2010	Status:Case Deferred
	HQ File :01/82/050/01009/AM11/	RLA File :03/94/040/00638/AM11/	Lic.No/Date:0310600646 09.11.2010	Defer Date:15.02.2011
	Decision : Committee decided to defer case for 15.02.2011 for comments of Department of Pharmaceuticals.			

Outside Agenda

The Committee looked into the papers available in Policy-VI Section's file No.01/92/180/120/AM-11/PC-VI. This file relates to PE-1(A)/2007-GNR to PE-4(A)/2007-GNR dated 31.01.2007 registered by CBI, Gandhinagar.

The Committee considered the case with the limited purpose to give its opinion as to whether these licences were correctly issued under SION A-1945 and whether use of word 'compacted granules' instead of 'granules' resulted in undue advantage to the firm.

The Committee noted following facts:-

1. SION A-1945 is as under:-

“

SION No.	Export Item	Qty.	Import item	Qty. allowed
A-1945	Drug Formulation- Dispersible/Soluble Powder & Granules	1 kg.	Relevant bulk drug	1.01 kg/kg content in the export product

Note:- The content of bulk drug shall be worked out as per Drug Manufacturing Licence for the formulation in the dosage form.”

2. Drug Manufacturing Licence issued by Food & Drug Administration shows the name of the product as under:-

1. Paracetamol compacted granules 99.0% w/w.
2. Analgin compacted granules 99.0% w/w.
3. Trimethoprin compacted granules 99.0% w/w.

4. Norfloxacin compacted granules 99.0% w/w.

5. Diclofenac Sodium compacted granules 99.0% w/w.

The Committee observed that compacting process is a manufacturing process in itself which is intermediate stage before making tablet. As per SION A-412, a wastage of 2% is allowed for making tablets from relevant bulk drug. SION A-1945 prescribes 1% wastage for the product 'Drug Formulation-Dispersible/Soluble Powder & Granules' from relevant bulk drug as per their Drug Manufacturing Licence. Thus, by adding the word compacted before the granules in the advance licence, no extra wastage has become available to the firm. Addition of word compacted before granules was as per DML, issued by Food & Drug Administration, Gujrat. Therefore, the Committee opines that addition of word 'compacted' before granules has not resulted in any undue benefit to the firm & as a matter of fact while compacting granules, a little extra wastage is involved.

XXXXXXXXXXXXXXXXXX