

**Office of Directorate General of Foreign Trade
New Delhi -0**

Para 4.7 Decision

MEETING NUMBER : 6/82-ALC4/2015 MEETING DATE : 09.07.2015

Meeting No. 06/82/2015 of 2015-16, to considered the cases/issues under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2015-20 pertaining to Chemical and Allied products and falling under Chapter 29 and 30, was scheduled for 09.07.2015 but actually held on 21.08.2015 under the Chairmanship of Dr. S.K. Bansal, Jt. DGFT in Room No.11, Udyog Bhawan, New Delhi.

Following members were present:-

Smt. Barnali Khastagir, U.S. D/o Pharmaceuticals, Shashtri Bhavan, New Delhi
Shri A.K. Tyagi, Consultant, Department of Pharmaceuticals
Shri D.N. Mathur, Consultant, Department of Pharmaceutical
Shri Nirmal Kumar, Dy. Director General of Foreign Trade.
Shri Mahendra Vikram Singh, Foreign Trade Development Officer

The following cases/issues were discussed and the committee took the decision as mentioned against each case.

	Case No.:1/13/82-ALC4/2014	Party Name:HETERO LABS LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
1	HQ File :01/82/050/01004/AM15/	RLA File :09/24/040/00417/AM15/	Lic.No/Date:0910061188 07.11.2014	Defer Date: 16.09.201509.07.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

	Case No.:7/6/82-ALC4/2015	Party Name:VIRUPAKSHA ORGANICS LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
2	HQ File :01/82/050/00603/AM16/	RLA File :09/24/040/00069/AM16/	Lic.No/Date:0910061966 01.05.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

	Case No.:8/6/82-ALC4/2015	Party Name:VIRUPAKSHA ORGANICS LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
3	HQ File :01/82/050/00604/AM16/	RLA File :09/24/040/00070/AM16/	Lic.No/Date:0910061965 01.05.2015	Defer Date: 16.09.2015

Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.

4	Case No.:2/6/82-ALC4/2015	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00598/AM16/	RLA File :09/24/040/00165/AM16/	Lic.No/Date:0910062242 23.06.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

5	Case No.:1/6/82-ALC4/2015	Party Name:HERBOCHEM	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00597/AM16/	RLA File :09/24/040/00148/AM16/	Lic.No/Date:0910062238 23.06.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

6	Case No.:6/6/82-ALC4/2015	Party Name:LAKE CHEMICALS PRIVATE LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00602/AM16/	RLA File :07/24/040/00075/AM16/	Lic.No/Date:0710108415 24.06.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

7	Case No.:3/6/82-ALC4/2015	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00599/AM16/	RLA File :09/24/040/00179/AM16/	Lic.No/Date:0910062259 30.06.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

8	Case No.:4/6/82-ALC4/2015	Party Name:HETERO LABS LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00600/AM16/	RLA File :09/24/040/00188/AM16/	Lic.No/Date:0910062261 30.06.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

9	Case No.:5/6/82-ALC4/2015	Party Name:GULBRANDSEN CHEMICALS PVT LTD	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00601/AM16/	RLA File :34/24/040/00091/AM16/	Lic.No/Date:3410041336 01.07.2015	Defer Date: 16.09.2015

Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Chemicals.

10	Case No.:9/6/82-ALC4/2015	Party Name:AUROBINDO PHARMA LIMITED	Meet No/Date:6/82-ALC4/2015 09.07.2015	Deferred
	HQ File :01/82/050/00605/AM16/	RLA File :09/24/040/00176/AM16/	Lic.No/Date:0910062314 07.07.2015	Defer Date: 16.09.2015
Decision : The Committee considered the case for ratification of norms and decided to defer the case for want of comments from D/o C&PC Pharmaceuticals.				

Manual Agenda of NC Meeting No.06/82/2015
Scheduled to be held on 09.07.2015 but actually held on 21.08.2015

Case No. B- 01 M.No.06/16 Date 09.07.2015	M/s. Unichem Laboratories Ltd. File No.01/82/50/0002/AM-16 RLA No.3/95/040/00884/AM15 Adv.Auth. No. 0310793384 dt. 29.01.2015
Decision: The Committee considered this case for correction in Unit of Measurement of export product from number to kg. norms already ratified by NC in its meeting No.01/82/2015 dated 15.4.2015 under para 4.07 of HBP Vol. as per agenda. The Committee decided to correct the unit of measurement of export product to read as 1kg instead of 1 number. RA may take necessary action as the decision of NC.	

Case No. B- 02 M.No.06/16 Date 09.07.2015	M/s. Pregna International Ltd. File No.01/82/50/347/AM-14 RLA No.3/95/040/00071/AM14 Adv.Auth.No.0310733040 dt. 01.05.2013
Decision: The Committee considered this case for correction in Unit of Measurement of export product from number to kg. and revision of norms under para 4.07 of HBP Vol. as per agenda and decided to defer the case for want of comments of D/o C&PC Chemicals & Petrochemicals.	

Case No. B-03 M.No.06/16 Date 09.07.2015	M/s. Softgel Healthcare Pvt. Ltd. File No.01/82/50/862/AM-14 RLA No.04/24/040/100/AM14 Adv.Auth.No.0410149961 dt.18.09.2013
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Decision: The Committee considered this case for revision of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to call for copy of DML and complete Technical Literature furnished with the composition given in the DML and deferred the case.

Case No. B-04
M.No.06/16
Date 09.07.2015

M/s. Otsuka chemicals (India) Pvt.Ltd.
File No.01/82/50/434/AM-14
Adv.Auth.No.0510360662 dt.24.07.2013

Decision: The Committee considered this case for amend the chemical name of GCTA where Norms already ratified by NC in its meeting No.17/2013 dt. 5.12.2013 under para 4.7 of HBP as per agenda. The Committee noted that Technical Literature provided by the firm is insufficient of deferent description of export product applied by the firm presently.

Case No. B-05
M.No.06/16
Date 09.07.2015

M/s. Yasho Industries Pvt. Ltd.
File No.01/82/50/1121/AM-13
Adv.Auth.No.0310718082 dt. 24.12.2012

Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.

Case No. B-06
M.No.06/16
Date 09.07.2015

M/s. Survival Technology Pvt. Ltd.
File No.01/82/50/1331/AM-12
Adv.Auth.No.0310678569 dt. 25.1.2012

Decision: The Committee considered this case for revision of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.

Case No. B-07
M.No.06/16
Date 09.07.2015

M/s. Charm Cosmetics Pvt. Ltd.
File No.01/82/50/451/AM-04
Adv.Auth.No0310218428 dt. 12.08.2003

Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee noted that information has already been called for from the firm and reply is awaited. The committee decided await the reply and deferred the case.

Case No. B-08
M.No.06/16
Date 09.07.2015

M/s. Ecologic Chemicals Pvt. Ltd.
File No.01/82/50/932/AM-13
Adv.Auth.No.0910053811 date 14.09.2012

Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee in light of the written comments of D/o C&PC provided vide O.M. No.35011/354/2014-PI (Norms) dated August, 2014 decided to ratify the norms as per details given below or as applied by the firm whichever is less:

Export product	Qty.	Sl.No.	Import items	Qty. in kg.
D,L-2-(6-methoxy-2-naphthyl) propionic acid	1	1	Beta naphthol	1.14
		2	Methylene Chloride	2.286

		3	Hydrobromic Acid 48%	0.278
		4	Sodium Sulfit	0.185
		5	Ethyl Lactate	1.30
		6	Palladium	0.010gm
		7	Toluene	0.61

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

Case No. B-9 M.No. 06/16 Dated 09.07.2015	M/s. Lotus Enterprise, Mumbai F.No. 01/82/50/1148/AM07/DES-III RLA F.No. 03/95/40/588/AM07 Advance Licence No. 0310403889 dated 12.10.2006
Decision: : The Committee considered this case for revision of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-10 M.No. 06/16 Dated 09.07.2015	M/s. Encube Ethicals Pvt. Ltd. F.No. 01/82/50/1176/AM15/DES-III RLA F.No. 03/94/40/627/AM15 Advance Licence No. 0310790209 dated 13.10.2014
Decision: The Committee considered the representation of the firm for ratification of norms under para 4.07 of HBP Vol. (I) as per agenda. The Committee observed that this case was earlier considered by the ALC in its meeting No. 17/82 held on 05.02.2015 for fixation of input output norms for different export products. This case was rejected by the Committee because of the large number of inputs in the application. It was also decided by the Committee to advise the firm to send separate applications for specific export item.	
2. The Committee re-considered the case for ratification of the norms. The Committee, in consultation with the representatives of Deptt. of Pharmaceuticals present in the meeting, decided to ratify as per details given below or as applied by the firm whichever is less:	
i) Bulk drug allowed with 2% wastage (for import items at Sr.No. 13,34,36,52,69,74,90,106,109,112,115,116,119,120,127,128,136,137,138,146,147,148,154, 155,156,157,163,164,165,166,172,173,174,175,178,179,180,181,184,185,186,187,190,191, 192,193,196,197,198,201,202,203,206,207,208). ii) Exceipent – net to net without wastage for reasons as detailed in Case No.29. iii) Packing material as per relevant packing policy. iv) Wherever items mentioned as any other, only the specific items mentioned will be allowed. v) Import item at Sr.No.152, 153, 161, 162, 170, 171 would be allowed only after satisfying conditions if any applicable for the import of such items.	
RA may verify from master batch formula.	

Case No. B-11 M.No. 06/16 Dated 09.07.2015	M/s. FDC Ltd. F.No. 01/82/50/740/AM13/DES-III RLA F.No. 03/94/40/374/AM13 Advance Licence No. 0310706515 dated 27.08.2012			
Decision: The Committee considered this case for revision of norms under para 4.07 of HBP Vol. as per agenda. The Committee in light of comment of D/o Pharmaceuticals in the meeting decided to revise the norms as per details given below:-				
Export product	Qty.	Sl.No.	Import items	Qty. in kg.
Oral Rehydration salt (ORS)	21.8 gm	1	Sodium Citrate	2.9gm
	Sachet	2	Glucose Anhydrous	13.50gm

		3	Printed laminate	2.017gm
		4	Citric Acid Anhydrous	0.988gm
		5	Neotame powder	0.005gm

Case No. B-12 M.No. 06/16 Dated 09.07.2015	M/s. Camphor & Allied Products Ltd. F. No. 01/82/50/1071/AM13/DES-III F.No. 01/82/50/623/AM13/DES-III F.No. 01/82/50/741/AM13/DES-III F. No. 01/82/50/950/AM14/DES-III
Decision: The Committee considered this case for correction in the export product norms already ratified under para 4.07 of HBP Vol. as per agenda.	
The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-13 M.No. 06/16 Dated 09.07.2015	M/s. Enaltec Labs Pvt.Ltd. F.No. 01/82/50/1196/AM15/DES-III RLA F.No. 03/94/40/511/AM15 Advance Licence No. 0310789281 dated 16.09.2014
Decision: The Committee considered the case for correction in the export product as per agenda. The committee decided to correct the description of import item to read as under:	
6-[(1E)-2-[4-(4-FLUOROPHENYL)-6- (1-METHYLETHYL)-2-[METHYL (METHYLSULFONYL)AMINO]-5-PYRIMIDINYL]ETHENYL] -2,2-DIMETHY L-1,3-DIOXANE-4-ACETIC ACID 1,1-DIMETHYLETHYL ESTER	
RA may take further necessary action as per decision of NC.	

Case No. B-14 M.No. 06/16 Dated 09.07.2015	M/s. KLJ Plasticizers Ltd. F.No. 01/82/50/1128/AM15/DES-III RLA F.No. 05/23/40/313/AM15 Advance Licence No. 0510391766 dated 28.10.2014
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-15 M.No. 06/16 Dated 09.07.2015	M/s. KLJ Plasticizers Ltd. F.No. 01/82/50/1036/AM15/DES-III RLA F.No. 05/23/40/256/AM15 Advance Licence No. 0510391459 dated 07.10.2014
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-16 M.No. 06/16 Dated 09.07.2015	M/s. KLJ Plasticizers Ltd. F.No. 01/82/50/831/AM15/DES-III RLA F.No. 05/23/40/214/AM15 Advance Licence No. 0510390804 dated 28.08.2014
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-17 M.No. 06/16 Dated 09.07.2015	M/s. Metropolitan Eximchem Ltd. F.No. 01/82/50/1085/AM14/DES-III RLA F.No. 03/95/40/736/AM14 Advance Licence No. 0310762602 dated 19.12.2013
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-18 M.No. 06/16 Dated 09.07.2015	M/s. Lupin Ltd. F.No. 01/82/50/1186/AM11/DES-III Adv. Auth.No.0310602565 dated 23.11.2010
Decision: The committee considered the case for amend the description of import item as per agenda. The Committee in light of written comments provided O.M.No.35011/150/2010-PI (Norms) decided to amend the description of import item to read as "T-butyl -3S-Amino-2,3,4,5-Tetrahydro-1-H-(1)-Benazepin-2-One-1-Acetate" . RA may take necessary action as per decision of NC.	

Case No. B-19 M.No. 06/16 Dated 09.07.2015	M/s. Generix Chemie (I) Pvt Ltd. F.No. 01/82/50/537/AM06/DES-III Adv. Auth.No.0310343371 dated 18.8.2005
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-20 M.No. 06/16 Dated 09.07.2015	M/s. Gopinath Che Tech Ltd. F.No. 01/82/50/562/AM14/DES-III Adv. Auth.No.0810124122
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Chemicals.	

Case No. B-21 M.No. 06/16 Dated 09.07.2015	M/s. AMI Lifesciences pvt. Ltd. F.No. 01/82/50/1186/AM11/DES-III Adv. Auth. No.: 3410038410 Date: 11.11.2013 No.3410038409 Date: 11.11.2013 No.3410038227 Date: 18.10.2013 No.: 3410037474 Date: 23.07.2013
Decision: The Committee considered this case for revision of norms under para 4.07 of HBP Vol. as per agenda. The Committee noted that no consumption data available hence it is decided to call for production consumption data dully certified by Central Excise Authorities for last 3 years and deferred the case.	

Case No. B-22
M.No.0616
Date 09.07.2015

M/s. Sohan Healthcare Pvt. Ltd.
File No.01/82/50/1172/AM12
RLA No.31/83/040/00210/AM12
Adv.Auth.No.3110052542 dt. 19.1.2012

Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda.

The Committee noted that this case has already been approved by NC in its meeting **No.15/82/2012 dated 09.08.2012 vide case No.3/43/82-ALC4/2011** in the light of written comments received from Department of Pharmaceuticals vide their OM No. 35011/164/2012-PI (Norms) dated 24.7.2012, but typographical error is seen in the export product **BP/EP?USP While Crystalline Powder**. The Committee decided to correct error in the export product to **read as BP/EP/USP White Crystalline powder without any change in the ratified norms** as per details given below or as applied by the firm, whichever is less:

Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed kg/kg
Metformin Hydrochloride BP/EP/USP White Crystalline Powder	1 kg	1.	Dicyandiamide	0.567
		2.	Di Methyl Amine HCL	0.60
		3.	Mix Xylene	0.027
		4.	Methanol	0.237

RA may take appropriate action as per the decision of Norms Committee.

Case No. B-23
M.No.0616
Date 09.07.2015

M/s. Sohan Healthcare Pvt. Ltd.
File No.01/82/50/1309/AM12
RLA No.31/83/040/00228/AM12
Adv.Auth.No.3110053067 dt. 21.2.2012

Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda.

The Committee noted that this case has already been approved by NC in its meeting **No.15/82/2012 dated 09.08.2012 vide case No.2/48/82-ALC4/2011** in the light of written comments received from Department of Pharmaceuticals vide their OM No. 35011/164/2012-PI (Norms) dated 24.7.2012, but typographical error is seen in the export product description i.e. **BP/EP?USP While Crystalline Powder**. The Committee decided to correct in the description in export product to read as **BP/EP/USP White Crystalline Powder without any change in the ratified norms** as per details given below or as applied by the firm, whichever is less:

Export product	Exp. Qty.	Sl.No.	Import items	Qty. allowed kg/kg
Metformin Hydrochloride BP/EP/USP White Crystalline Powder	1 kg	1.	Dicyandiamide	0.567
		2.	Di Methyl Amine HCL	0.60
		3.	Mix Xylene	0.027
		4.	Methanol	0.237

RA may take appropriate action as per the decision of Norms Committee.

Case No. B-24 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Divi's Laboratories Ltd. F.No. 01/82/50/491/AM15/DES-III RLA F.No. 09/24/40/150/AM15 Adv.Auth. No. 0910060536 dated 25.06.2014
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Pharmaceuticals.	

Case No. B-25 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Divi's Laboratories Ltd. F.No. 01/82/50/514/AM15/DES-III RLA F.No. 09/24/40/658/AM14 Adv. Auth. No. 0910059678 dated 28.03.2014
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee decided to defer the case for want of comment of D/o C&PC Pharmaceuticals.	

Case No. B-26 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Aarti Drug Ltd. F.No. 01/82/50/427 /AM13/DES-III Adv.Auth. No.0310714511 dt. 7.11.2012 Adv. Auth. No.0310737543 dt.13.6.2013
Decision: The Committee considered this case for ratification of norms under para 4.07 of HBP Vol. as per agenda. The Committee noted that relevant portion of British Pharmacopia to show that 2-Thiophene Ethylamine and Thiophene-2-Ethanol are one and same, had been called for from the firm and same has not been received so far. The committee decided to await the reply and defer the case.	

Case No. B-27 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Encube Ethicals Pvt.Ltd. F.No. 01/82/50/1176/AM15/DES-III Adv.Auth. No.0310790209 dt.13.10.2014
Decision: This case has listed above at Sl.No.10, therefore decided to withdraw the case.	

Case No. B-28 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Encube Ethicals Pvt.Ltd. F.No. 01/82/50/232/AM12/DES-III Adv.Auth. No.0310625603 dt.. 07.04.2011
Decision: The representations of the firm for revision of input output norms, already allowed in ALC meeting No. 03/82 dated 02.05.2013, for the export product "Sodium Fusidate Ointment" based on the revised C.A. Certificate has been considered by the Committee. The Committee was informed that the matter is being examined on file as per the written comments of Deptt. of Pharmaceuticals, vide O.M. No. 61011/01/2015-PI-Norms dated 10.06.2015 which informed that certain submissions made by the firm need to be investigated by the DGFT. It was brought to the notice of the Committee that the Zonal Office, Mumbai has been directed to investigate the matter in view of the facts brought to the notice by the Deptt. of Pharmaceuticals, and also submit a factual report. Since the matter is under investigation for what appears to be fraudulent documentation entered into by the firm and its representatives, besides other issues of investigation and the outcome/report is still awaited, no further action in the matter is to be taken by the Committee at this stage. The unit may like to cooperate with the investigation 2. Other cases of the unit had also been listed on the agenda and in which, keeping in view the principles of natural justice, an opportunity to be heard by the Committee had been offered, which was not availed.	

Case No. B-29 Meeting No. 6/AM16 Dated 09.07.2015	M/s. Encube Ethicals Pvt.Ltd. F.No. 01/82/50/708/AM12/DES-III Adv. Lic. No. 0310646711 dated 05.08.2011 Adv. Lic. No. 0310664617 dated 14.11.2011 Adv. Lic. No. 0310697620 dated 06.06.2012
Decision: The firm's request for revision of input output norms has been considered by the Committee. It was noted by the Committee that this case for revision of norms was considered by the Norms Committee in its meeting No. 03/AM15 held on 25.06.2014 for the export product "Canesten Vag Cream and Clotrimazole 10% vaginal cream 5 gm tube". It was observed by the Committee that there are no wastage norms for excipients in the SION. Excipients have been allowed on net to net basis in all cases of pharmaceuticals formulation. However, the Company may apply for amendment in SION A-1931 as per policy provisions for induction of excipients in the SION and the same may be considered by Norms Committee on the basis of all -industry data on wastage. The Committee was informed that the firm M/s. Encube Ethicals Pvt. Ltd. has not applied for amendment in SION A-1931 so far. However, they have been representing continuously for wastage of excipients against the aforesaid export product. 1. The firm had obtained an advance authorization for export of a product in which import of excipients had been applied for with a certain wastage. The wastage to be allowed was to be decided by the norms committee in consultation with the Department of Pharmaceuticals. The minutes were recorded and wastage on excipients was not allowed. 2. The matter was again referred to the Department of Pharmaceuticals and the exact	

comments of the Deptt. of Pharmaceuticals is as follows:-

"As regards admissibility of wastage of excipients in production of cream/ointments it is to inform that the major cost of any medicine is predominantly constituted by bulk drug or API used. Admissible wastage is allowed only on the API. The norms committee has not allowed any wastage on excipients to any applicant as these are not included in the SION A 1931 for ointment and creams. During the manufacture of ointment and cream, all ingredients including API and excipients are added to the blending vessel and no chemical reaction is generally involved and there is hardly any material lost.

As such while there is no justification for allowing wastage on excipients used in ointments and creams, there is a need to revisit the SION A 1931 to appropriately reducing them from 2% wastage on APIs too. Moreover in order to meet the excess requirement of APIs or excipients, the exporters can avail Duty Drawback facility as per the Foreign Trade Policy instead of entirely relying on Advance Authorizations."

3. Numerous representations against the decision of the Norms Committee were made by the applicant and the matter was again considered by the NC-3. Some of the representations are reproduced below for the sake of transparency:

*On Mon, Aug 17, 2015 at 10:04 PM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:
Dear Mr. Mahendra Vikram Singh,*

Please see the attachment. Below the letter, there is a production & consumption certificate duly authenticated by the Chartered Accountant. Please note that if the DGFT has adopted a professional certificate to be the way forward then that certificate has to be respected & cannot be discarded or trashed without any reason. If the DGFT does not believe in professional certification then any such certificate should not be called for.

The use of professional certificate such as that of CA is pervasive to many departments & the whole Income Tax department functions on the basis of that. Further, this issue was thrashed out about a year ago with Mr. Pravir Kumar, the incumbent DGFT & Mr. D. K. Singh, Addl. DGFT in the case of recognition/issuance of status certificate. The DGFT/Addl. DGFT accepted that once the CA has authenticated the FOB value of exports, the demand for any statement/document is a frivolous exercise simply giving rise to harassment & rent seeking therefore avoidable. The same principle therefore applies to the CA certificate given for the fixation of the norms.

As explained time & again, the wastage of 2% is simply governed by common sense in case of excipients & cannot be defied. Even now, if you have any valid objections, please specify the same in a transparent manner & send it to rajiv.pec@gmail.com & the same will be addressed immediately.

On Sun, Aug 16, 2015 at 9:43 AM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:

ENCUBE ETHICALS PVT LTD.

UNIT NO.24, STEEL MADE INDL. ESTATE, MAROL VILLAGE, ANDHERI (E), MUMBAI 400059

Ph: 912266783848 Fax: 912229204336 Email: kuntal.p@encubeethicals.com

RG:NC:DGFT:77

17.8.2015

The O/o DGFT,

New Delhi

Top Urgent

Attn.: Mr. M. V. Singh, FTDO

Dear Sir/Madam,

Sub: Fixation of Norms—Serious issues arising due to callous approach.

Ref:

Case No.:25/26/82-ALC4/2011	Party Name:ENCUBE ETHICALS Meet PVT LTD	No/Date:8/82- ALC4/2013 11.07.2013
HQ File :01/82/050/00708/AM12/	RLA File :03/94/040/00385/AM12/	Lic.No/Date:0310646711 05.08.2011

2. Rejoinder to our letter RG:NC:DGFT:71 dtd. 14.8.2015

With reference to the above, we have to submit as under:

1. At the very outset, we have to state that all the facts are placed on record which establish in an incontrovertible manner that 2% wastage cannot be denied in case of the excipients going into the manufacture of the exports of creams, ointments & gels. This needs to be read in conjunction with the facts placed on record. There is no query or discrepancy pointed out to be addressed from our end. The issue of norms is a scientific exercise & need not be decided in closed rooms behind the curtains but should be done in a transparent manner. Therefore, the following pertinent points need to be addressed by the norms committee &/or the experts of the norms committee.

A. Is the norms committee denying that there is SION already existing for creams & ointments at Sr. No. A-1931 permitting import of bulk drugs with 2% wastage?

B. Is the norms committee trying to say that the flow chart does not establish beyond doubt that both the bulk drugs & the excipients undergo the same manufacturing process?

C. If the bulk drugs & the excipients undergo the same manufacturing process then how can the wastage be different in case of the excipients? Please give scientific basis for this claim.

D. Is the norms committee &/or the experts of the norms committee trying to say that they are not bound by the SION A-1931 even in light of the facts mentioned at B & C above?

E. Is the norms committee &/or the experts of the norms committee trying to say that 2% wastage has not been allowed in case of excipients produced through the same manufacturing process & in the same reactors? How can there be a whimsical approach adopted in the fixation of the norms?

F. Is the norms committee &/or the experts of the norms committee trying to say that whatever goes into the reactors constitutes the final output & the wastage is finally determined by the theoretical yield of the batch size versus the number of tubes produced finally in the batch manufacturing process. Is the norms committee &/or the experts of the norms committee trying to say that there are different number of tubes produced with bulk drug as ingredients & that with excipients. Why we are not in a position to respect the common sense.

G. Is the norms committee &/or the experts of the norms committee trying to say that in the process of manufacture of medicinal creams & ointments, there will be no manufacturing wastage at all? Please give scientific basis for this claim.

H. Is the norms committee &/or the experts of the norms committee are made aware that the unit files production returns with the C. Ex. Authorities & audited from time to time & there is no discrepancy noticed then why this data is not being accepted without assigning any reasons for it.

I. Is the norms committee &/or the experts of the norms committee are not made aware that Master Batch Formula approved by the FDA authorities is sacrosanct & there cannot be any deviation of whatsoever nature. There are no discrepancies noticed by the FDA then why the data is not being accepted without assigning any reasons for it.

J. Is the norms committee &/or the experts of the norms committee are not made aware that the manufacturing facilities are approved by TGA, Australia; EMA-valid throughout the European Union & FDA, USA besides many others & subject to regular inspections therefore why the data is not being accepted without assigning any reasons for it. Data integrity is one of the import aspects in these inspections & no discrepancy is tolerated?

K. Is the norms committee &/or the experts of the norms committee are not made aware that if they do not believe anything then they can depute experts to the manufacturing plant & audit the records by themselves & not only that, they can audit the production process in itself.

We hereby declare that there is not more than 98% yield in respect of any cream, ointment or gel manufacturing batch therefore wastage of 2% in case of excipients cannot be denied.

As pointed out earlier, there is no discrepancy pointed out to be addressed. However, as per the Supreme Court, a reasoned speaking order is essential. There is no such order issued to deny the wastage in respect of the ingredients. Therefore the denial of wastage in respect of the excipients is not legally valid. Please note that without the norms committee specifying the objection by way of a reasoned speaking order, how can the exporter understand the objection & address it properly.

Please note that there can be errors because there is tremendous pressure to deliver the results but there is absolutely no cheating. Therefore, the bonafide errors need to be rectified & acknowledged & not result in denial of legitimate rights. For e.g., if the ingredient quantity is grossly wrong i.e. even lower than the theoretical quantity then that cannot be fixed as the norm of consumption instead of that discrepancy should be taken up with the exporter for rectification. No authority can abuse the official & advance the wrongs by relying on any bonafide error under any circumstances. The issues are to be sorted out in a clear & transparent manner & this cannot be avoided under any circumstances. The exporter is not into cheating & cannot be cheated.

If any further information is needed then please send e mail to rajiv.pec@gmail.com & the matter will be immediately attended.

We await your most immediate action/reply in the matter.

Thank you.

Yours Faithfully,

For Encube Ethicals P. Ltd.,

Rajiv Gupta

Adviser-Legal Compliances.

On Fri, Aug 14, 2015 at 6:23 PM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:

Encube Ethicals Pvt Ltd

Unit N.24, Steelmade Industrial Estate, Marol Village, Andheri (E), Mumbai : 400059

Tel: 022-29203838 / 29204335 / 66783848; Fax: 022-29204336

RG:NC:DGFT:71

14.8.2015

The O/o DGFT,

New Delhi

Top Urgent

Attn.: Mr. M. V. Singh, FTDO

Dear Sir/Madam,

Sub: Fixation of Norms—Serious issues arising due to callous approach.

Ref:

Case No.:25/26/82-ALC4/2011	Party Name:ENCUBE ETHICALS PVT LTD	Meet No/Date:8/82-ALC4/2013 11.07.2013
HQ :01/82/050/00708/AM12/	RLA :03/94/040/00385/AM12/	Lic.No/Date:0310646711 05.08.2011

With reference to the letter No. 01/82/50/708/AM-12/DES-III/ dtd. 14.8.15, we have to submit as under:

We would prefer to appear in the PH through the videoconferencing route. When Mr. L.N. Lakhanpal was the DGFT, at that point of time, this facility was started & availed of. Therefore, please make it convenient to arrange for the videoconferencing.

Further, please note that all the facts appear on record for arriving at logical conclusion in the matter.

Finally, we do not find any query/discrepancy in the matter being raised about the wastage in respect of the excipients to be addressed. It is essential that the authorities point out any issue to be explained so that the same can be addressed.

The issue has been discussed in a threadbare manner with Dr. V. K. Subburaj, Secretary, Department of Pharmaceuticals & he is seized of the matter & given the information that the same will be settled in 2-3 days time.

We did not receive any minutes of the meeting. Till the time of the receipt of this mail, we were not aware of any personal hearing being scheduled in the matter. We have put in the search module the file no. Of the letter on the DGFT website but there is no search item found concerning the PH was reported. Please note that owing to the very short notice, it is very difficult to visit Delhi. The company is in the process of inspections& audit on 20.8.2015 & 21.8.2015 therefore the PH at Delhi cannot be attended. Simultaneously the company is gearing up the production for M/s. Actavis order, which is of substantial value therefore, it is very difficult to change the schedules at this point of time.

If any further information then please send e mail to rajiv.pec@gmail.com & the matter will be immediately attended.

We await your most immediate action/reply in the matter.

Thank you.

Yours Faithfully,

For Encube Ethicals P. Ltd.,

Rajiv Gupta

Adviser-Legal Compliances.

Dear Mr. Mahendra Vikram Singh, FTDO, NC-III; Dr. S. K. Bansal, Chairman, NC-III; Mr. Pravir Kumar, DGFT; Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals,

The focus shifted to the rectification of the norms pending for more than 15 months now. However, this case of the fixation of the norms is equally important. We gave all the details once again in the e mail with the bookmarks, which will enable anybody to navigate just by way of the click of mouse between the documents

to be looked into to arrive at the norms. Therefore, it is simply a bogey being raised saying that it is difficult to fix the norms.

It is important for us to know, what is done in this case at the earliest because even this case is inordinately delayed. There is no any valid discrepancy pointed out therefore there is no reason to delay decision because fixation of the norms is a scientific exercise.

Would appreciate your quick reply in the matter.

Best Regards,
Rajiv Gupta

On Mon, Aug 17, 2015 at 9:02 PM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:

Dear Mr. Mahendra Vikram Singh, FTDO, NC-III; Mr. Pravir Kumar, DGFT; Dr. V.K. Subburaj,

Please see the attachment. We reiterate that the letter complains the complete master explaining in the most simplistic manner the correlation between the Export product & the corresponding imports with relation to the manufacturing process; Master Batch Formula attested by the FDA; Flow Chart & the Drug Master File. Please note that all the attachments are bookmarked therefore you can click on the bookmark & see the related

document. There can be nothing more easier than this & this format can be used by the DGFT for uploading of the data so that the exporters are really facilitated & saved from the inconvenience of filing 7 copies of the application for no reason. As pointed out, no expert can ever fail to understand what is presented for the fixation of the norm.

Mr. Mahendra Vikram Singh, we were advised to file the reply before 19.8.15 & we have done it well before time. This file can be downloaded & opened by any of the members of the norms committee or the experts of the norms committee. Further, please note that we reiterate that there is single product of export under the authorization i.e. creams & ointments covered under generic entry of DION A-1931 therefore on one should abdicate the responsibility under any circumstances & deprive the exporters of the legitimate rights. The 2% wastage cannot be denied in respect of the excipients as explained several times because both the bulk drugs as well as the excipients suffer the same wastage & this is simply governed by common sense. There is no room for any discrepancy & therefore norms should be fixed without any problems. If required, the contents of the mail can be examined by any experts located anywhere in the world & no one will have any reason to disagree with any claims. Please note that if even now, there is any problem, the same should be clearly stated & the same will be attended immediately. Please send the mail to rajiv.pec@gmail.com.

The hard copy of this mail will also be delivered by the courier to the DGFT office tomorrow morning. Mr. Mahendra Vikram Singh, I will give you a call after I get the confirmation of the courier being delivered to your office. Please ensure that this is presented in the Norms Committee meeting for perusal of the experts. However, the copy of this mail is marked to Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals also because the e mail ID of Mr. D. N. Mathur is inactive. I will speak to Dr. Subburaj, tomorrow morning in this matter.

Best Regards,
Rajiv Gupta

On Sun, Aug 16, 2015 at 9:32 AM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:

ENCUBE ETHICALS PVT LTD

Sub: Fixation of Norms

Ref:

Case No.:173/13/82-ALC4/2014

Party Name:ENCUBE ETHICALS Meet
PVT LTD

No/Date:17/82-

ALC4/2014
05.02.2015

2. Rejoinder to letter No. RG:NC:DGFT:72 dtd. 14.8.2015

With reference to the above, we have to submit as under:

A. There is a single export order against which this AA is applied. Therefore, once again it is convenient to apply a single authorization because the complete exports can be effected under a single AA without any worry for committing any error in putting the AA number in the shipping documents.

B. The authorizations are involving imports of bulk drugs from unregistered sources therefore they are covered under policy circular No. 9 & therefore cannot be clubbed & redeemed even in case of a bonafide error. As an exporter, we would like to avoid any risk.

C. Please note that even if the norms committee advise is followed & 13 AAs are applied instead of 1 then our overheads will multiply tremendously because the imports & exports documents will have to be prepared in accordance with the AAs. The fact is that in case of imports instead of debiting 1 AA, we can be forced to debit 13 AAs on repeat basis & bear those expenses unnecessarily. Similarly, in case of exports, we can be compelled to file 13 S/Bs instead of 1 on repeat basis & bear unnecessary overheads separately in respect of these unnecessary hassles created due to 13 AAs being forced upon the exporter. The DGFT officials should apply their mind before making such absurd recommendations. The Export Promotion means removal/reduction of transaction costs & not forcing the exporter to increase them.

D. Please understand that as explained earlier, there cannot be any difficulty in finding out the exports & related imports from the application & the FDA licence or the Master Batch formula or CoPP within a set of documents in any case. This is simply a one-time exercise & not very difficult to conduct. We can say so because all the documents are properly organized & put up & there is absolutely no deficiency pointed out. Please note that the fixation of the norms is a scientific exercise & in this case of formulations, the process of manufacture is common to all & therefore the exercise simply involves the multiplication of the ingredient content by a factor of 1.02. Only in very few cases, there is application of mind required because the unit of import & label content are differently dealt with. However, all this is explained in detail to arrive at correct values for sure. With these applications made available on record, there cannot be any cause for any complain in terms of the examination of the documents & fixation of the norms.

E. Though not of any consequence, please note that it is not for the first time, that the norms for so many items are required to be fixed in respect of a single application. Please refer to the following application. There were norms fixed for 21 export items.

Case No.:30/12/82-ALC4/2013	Party	Name:ENCUBE Meet	No/Date:17/82-	Status:Case
	ETHICALS PVT LTD	ALC4/2013		Approved
		05.12.2013		

HQ	File RLA	File Lic.No/Date:0310737624	Defer Date:
:01/82/050/00454/AM14/	:03/94/040/00140/AM14/	13.06.2013	

Thus you will observe that there were 21 Export Items in this case & there 139 items of imports. Therefore number of items of imports & exports cannot result into rejection of the application for the issue of AA. The AA applicant has to minimize the cost of transaction & increase the ease of doing business & the DGFT office is obligated to ensure that.

F. Please note that just because a S/B is of small value & there are more than thousand shipments made to discharge the export obligation, it does not mean that this is inconvenient to examine the documents then

the DGFT can reject the case for the discharge of the export obligation. Some of the customers work on no inventory carrying basis to reduce transaction costs & therefore the shipment has to be ensured on everyday basis then this cannot be objected to by the DGFT because of inconvenience under any circumstances because this approach is simply ridiculous. The DGFT is mandated to be a facilitator & cannot kill the exporters for the way the business is required to be conducted.

G. Finally, it is pertinent to point out that the DGFT has collected Rs. 50000 as application fees therefore it is difficult to understand that why the DGFT is not in a position to process the AA application for the fixation of the norms even after collecting such high amount of fees.

H. Please note that there is only single product involved in the applications i.e. creams & ointments. The norms committee &/or the experts of the norms committee are therefore wrong in saying that there are 13 AAs applications are required to be made. Please note that the norms committee &/or the experts of the norms committee cannot challenge the common sense because all the products are covered under SION A-1931 if the application is not made in terms of Para 4.7 as such but covered under SION. Please note that this cannot be defied/challenged in any case because this is an admitted fact. Therefore, the point of law is that the bulk drugs going into the manufacture are to be allowed @ 1.02 times the actual content in the cream/ointment. Further, as explained in great detail several times, the excipients also have to be allowed for imports with 2% wastage because both the bulk drug as well as the excipients undergo the same manufacturing process. Therefore the point to note is that the norms committee &/or the experts of the norms committee cannot abdicate or walk out of their responsibility saying that it is difficult to fix the norms because the pertinent point is that all the products are manufactured through the same process with the help of the same reactors as such. Only the ingredients & the size of the reactors may be different. It is really a matter of serious concern & the DGFT needs to deal with this seriously.

I. Further, please refer to point D of our letter No. RG:NC:DGFT:72 dtd. 14.8.2015. In addition to Sr. No. 16 A, please refer to the manual application form, particularly Form 11 A; Sr. No. 1 (a) where the per unit of consumption is given. Therefore even the consumption per unit is calculated & given. The authorities have to simply see the content & multiply the same by a factor of 1.02 as explained & even these figures are given, therefore there is simply verification of data & nothing beyond that. This is a case of third country contact manufacturing because the product & the brand belongs to the overseas customer. The foreign buyer therefore gives the complete details including the Master Batch formula for conducting manufacturing & this is sacrosanct. Therefore there is no way that there can be any violation at any point of time. Then how & why the Norms Committee & the experts of the norms committee are not able to see the facts in right perspective & indulging into denial of legitimate entitlement without assigning any reason even after the Supreme Court has ruled finally that a reasoned speaking order is essential in each & every case.

Besides this, we send another mail putting everything in an easy to understand stepwise manner, which will enable any person with reasonable understanding of examining the data & fixing the norms to arrive at a logical conclusion for fixing the norms. There cannot be any reason for anybody with a scientific mind to deny this. Therefore under any circumstances, there is absolutely no reason for any person to deny the legitimate entitlement to the exporter.

Please note that everything is explained in threadbare manner but then too if any further information/clarification is needed then please send e mail to rajiv.pec@gmail.com & the matter will be immediately attended.

Please allow 4 hours time to respond.

On Fri, Aug 14, 2015 at 7:51 PM, Rajiv Gupta <rajiv.pec@gmail.com> wrote:
ENCUBE ETHICALS PVT LTD.

UNIT NO.24, STEEL MADE INDL. ESTATE, MAROL VILLAGE, ANDHERI (E), MUMBAI 400059
Ph: 912266783848 Fax: 912229204336 Email: kuntal.p@encubeethicals.com

RG:NC:DGFT:72

14.8.2015

Ref:

Case ALC4/2014	No.:173/13/82-	Party ETHICALS PVT LTD	Name:ENCUBE	Meet ALC4/2014 05.02.2015	No/Date:17/82-
HQ :01/82/050/01176/AM15/	File	RLA :03/94/040/00627/AM15/	File	Lic.No/Date:0310790209 13.10.2014	

With reference to the above, we have to submit as under:

1.As stated in the letter, there are 13 items of exports & 209 items of imports therefore the firm is advised to send separate application for specific export item. Further, the letter states that in the norms committee, it has not been found possible to fix the norms as applied by you. There can be nothing more absurd than this.

The reasons are recorded below:

A. I have perused the FTP/HBP & there is no such provision in the law, which says that separate applications have to be filed for specific export product because there cannot be one because it is the Exporter's prerogative to file the AA application & get the legitimate entitlement. Therefore, there cannot be any rejection on this count.

B. If this application is broken down into 13 applications as advised then please answer the question that whether this is not multiplying the work for all concerned. If there are 13 applications made then there will be 13 AAs issued; the exporter will have to be careful about effecting & monitoring exports under a particular AA & there will be closure of 13 authorizations. Therefore work is simply multiplied 13 times. Further, the Norms Committee will still have to finalize the norms for all the export products in any case. Therefore increasing the number of applications does not mean that norms need not be finalized in certain cases.

C. It cannot be the case of the Norms Committee & the experts of the norms committee that they cannot understand the details of the export product & the related imports. Further, it cannot be the case of the norms committee that they cannot locate the drug manufacturing licence or the Batch Manufacturing sheet in the complete set of documents placed on record. The exporter has filed the application correctly in the prescribed format & the complete details are properly discernible. Therefore, we really fail to understand that why the norms committee & the experts of the norms committee are not willing to facilitate the exporter by fixing the norms.

D. Please see the application format. Please go to the Sr. No. 16 A of the application. The said serial number gives complete information in the easily understandable manner that what goes into the manufacture of the export product. For e.g. in case of this application, the serial number 16 A of the application clearly shows that the export item No. 1 requires 14 inputs to be imported; the export item No. 2 requires 23 inputs to be imported & so on & so forth. Therefore, it is difficult to understand that how the Norms Committee & the experts of the norms committee can find it difficult to understand the correlation between the export product & the inputs going into the manufacture & see it in combination with the FDA licence & the Master Batch formula duly certified by the FDA authorities. Even if a separate application is made then too exactly the same exercise has to be carried out. Therefore, why the Norms Committee & the experts of the norms committee are not willing to fix the norms & facilitate the exporter. As explained already, separate application will not decrease the work in any case.

E. We reiterate, it is governed by common sense that whether the norms committee considers single application or thirteen applications, in any case, the norms committee will have to examine the same documents made available & fix the norms for all the products. Therefore, the work of the norms committee is not reduced by breaking the single application application into thirteen applications in any case? Further, the number of import items in the application is on the higher side because of different stock keeping units (SKU) being exported. However, the Norms Committee has to examine the norm for a particular SKU & then norm being made applicable on pro rata basis for all other pack sizes. This is again governed by the common sense & there is a specific provision in the general rules for the norms

applicability.

F. Last but not the least important is the fact that the applicant has already effected imports under the AA therefore there is no way that the fixation of norms can be declined to inflict pecuniary losses on the exporter. More so because, Policy Circular No. 9 condition is applicable to the inputs.

G. Not only for the reasons cited already, the application fee concession was availed by the applicant through the single application. The DGFT cannot deny such advantage to us just because the number of import inputs is higher in number because there is no such provision in the law. Please note that if there is any such limitation applicable then the same should be specified clearly & the application should not be accepted by the EDI system. Please note that the DGFT is required to facilitate the exporters & not to harass them.

Lets us take an example that the exporter is exporting a missile & the exporter applies for 500 inputs to be allowed to be imported. Does that mean that the application will be rejected. The answer is emphatic No.

H., even as a layman, you will comprehend that the item of export is Ointment/cream & there exists Standard Input Output Norms for the same under Sr. No. A1931. Therefore, there is no real work to be carried out except check the Master Batch formula of the cream/ointment duly approved by the FDA & then multiply the content by the factor of 1.02 because in case of cream & ointments all ingredients (active as well as the excipients) are subject to same manufacturing process. Therefore, by way of common sense, it is absolutely established in an incontrovertible manner that wastage of 2% is applicable for all the ingredients going into the manufacture of the export product. As pointed out time & again, the exporters are compelled to file applications under para 4.7 of the HBP because norms are not fixed for the excipients. There is an authority of the GoI in the name & style National Pharmaceutical Pricing Authority (NPPA), which studies the products for fixing the prices of the pharmaceutical products therefore exhaustive data is available with the government for the fixation of the norms. Therefore, the exporters should not be unnecessarily harassed for no reason. Once again, all this is simply common sense & beyond challenge because any sane person will understand that wastage of more than 2% takes place in the manufacture of the creams & ointments as it is a highly sophisticated technology involving high speed production & packaging. The products are exported to the most developed markets of the world where zero tolerance of any error is the norm. The manufacturing is not under control of the state FDA authorities but subject to audit by the International agencies from time to time. Therefore, there is absolutely no scope for any error at any point of time.

I.If we really believe that the Norms Committee & the experts of the norms committee are not able to comprehend the complete details given in the application for the issue of AA & the related documents such as the FDA licence as well as the Master Batch Formula just because of the number of items being more in the application then it raises very serious doubts about the competence because fixation of the norms is a scientific process therefore it is essential that the Norms Committee & the experts of the norms committee need to understand the details given in the application & the related documents & arrive at a logical conclusion. It is also pertinent to point out here that the production process of the different creams, ointments & gels is same therefore the wastage is not significantly different. Please note that the wastage is in excess of 2% but because of the Standard Input output norms are fixed for these products, the exporters are constrained to claim 2% wastage only in respect of the Active ingredients.

J. Please note that under the generic norm A1931, any number of items can appear in the AA for the purpose of exports as well as imports. As pointed out in several communications, the wastage in case of excipients @2% cannot be denied because it is governed by common sense that the Active Ingredients (Bulk drug) & the excipients are subject to the same manufacturing process therefore the wastage in both the class of inputs would be the same. Therefore, it is essential that the exporters need not be compelled to approach the Norms Committee, time & again.

Because of the time constraint, I send this mail. A rejoinder will follow, if necessary. This mail may please be read in conjunction with the mail bearing reference RG:NC:DGFT:71 dtd. 14.8.2015 regarding appearing in the PH at Delhi on 21.8.15.

If any further information/clarification is needed then please send e mail to rajiv.pec@gmail.com & the

*matter will be immediately attended.
We await your most immediate action in the matter.
Thank you.
Yours Faithfully,
For Encube Ethicals P. Ltd.,*

*Rajiv Gupta
Adviser-Legal Compliances.
Unimax Chemicals P. Ltd.
Unimax House, Plot No. 32, RSC 14/18, Sector-2, Near Sulochana Hospital, Charkop, Kandivali west,
Mumbai-67
Ph.: 29676661 Fax: 29676663 E mail: exports@unimax.co.in
RG:NC:DGFT:7*

1.5.2015

The O/o DGFT,

New Delhi

Top Urgent

Dear Sir/Madam,

Sub: 1. Fixation of Norms—Why the GoI officials cheat by giving the wrong information

2. Does cheating have the sanction & acceptance of the DGFT.

Ref: F. No. 01/82/50/00165/AM15/DES-III

Preamble:

The DGFT has to act as a facilitator & not as a stumbling block. The experts cannot defy the scientific basis/rationale/common sense & turn the whole process of the fixation of norms into a joke. There has to be responsibility & accountability in the system.

With reference to the subject matter, we have to submit as under:

1. The AA No. 0310771527 was issued by the RLA, Mumbai as early as 24.2.2014. UCPL is a recognized Export House for 2nd term running. In terms of paragraph 3.10.4 of the FTP, the status holder is given the benefit of fixing the norms within a period of 60 days. However, even after completion of 14 months, the NC has failed to ratify the norms. The norms as applied by the exporter are to be accepted in case the NC fails to finalize the norms within 4 months or issue a deficiency letter. The NC did not issue any deficiency letter within 4 months, therefore the exporter cannot be denied the norms as applied for. However, the DGFT fails to show any accountability & efficiency but the exporter has to bear the brunt for no fault of theirs. Under these circumstances the moot question which arises is that what is the sanctity of the written word of the law if the law is not to be implemented! Why the officials are not held accountable for such serious lapses. Why the DGFT should cheat the exporters & deprive them of their legitimate entitlement.

2. Please see Annexure 1. This is the copy of the reply of Department of Pharmaceuticals. The department says that the information is sought from the exporter & the information is yet to be received. This is an outright lie & therefore cheating, which is a punishable offence. Therefore, it is incumbent on the DGFT to take appropriate action. The exporters cannot be subjected to unending harassment by abuse of official position & advancing wrong information.

3. Please see Annexure 2. This is the copy of the minutes of the norms committee of the DGFT held on 23.1.15. I

Other correspondence was also considered.

4. In response to various issues raised by the applicant, DGFT had earlier replied to the applicant as follows:

4.I.

F.No. 01/82/50/708/AM-12/DES-III/

Date:14.08.2015

To,

M/s. Encube Ethicals Pvt. Ltd.,
Unit No. 24, Steelmade Indl. Estates,
Moral Village, Andheri(E),
Mumbai-400 059

Subject: Meeting of NC-III, to be held on 21.08.2015.

Sir,

I am directed to refer to your representations on the issue of grant of wastage on excipients, which presently stand disallowed.

In this regard, it is to inform that a meeting of NC-III is scheduled to be held on 21.08.2015 at 2.30 p.m. in Room No. 11, in DGFT, Udyog Bhawan, New Delhi, and in this meeting, the representations received from M/s. Encube Ethicals Pvt. Ltd. in the matter of wastage on excipients shall be taken-up for consideration. It is proposed to conclusively resolve the matter in this meeting.

Keeping in view the principles of natural justice, a representative(s) of the Unit may avail an opportunity to be personally heard, and it is accordingly informed that a technical person preferably dealing with production may be deputed to attend the meeting, in case you wish to be heard in person.

4.II.

F.No. 01/82/50/708/AM-12/DES-III/

Date: 21.08.2015

To,

M/s. Encube Ethicals Pvt. Ltd.,
Unit No. 24, Steelmade Indl. Estates,
Moral Village, Andheri(E),
Mumbai-400 059

Subject: Meeting of NC-III, to be held on 21.08.2015

Sir,

I am directed to refer to your e-mail RG:NC:DGFT:81 dated 21.08.2015 on the subject mentioned above and to inform that the Norms Committee serves the function of fixing the wastage norms. For this purpose, inputs are obtained from the

concerned technical authorities. For instance, a particular input item may be allowed with the wastage of 1.03 kg./kg. content and the claimant may have applied for 1.05 kg./kg. content. There would be thousands of such items in thousands of cases. If detailed reasons for every fixation are to be provided to every applicant for every variation between the quantity applied for by him and the quantity allowed, the system evolved to facilitate exporters may hardly be able to function. Against the large number of ad-hoc norms fixed, very few representations have been received and not a single request appears to have been received for seeking reasons. This adequately shows that industry by and large accepts the decisions of the Norm Committee and also that Industry does not feel the requirement of reasons every time there is a variation between the quantity applied and the quantity allowed. Moreover, any expectation held by an applicant in this regard would appear to be unreasonable. As an applicant, you were required to submit an undertaking to abide by decisions of Norms Committee, and you would have submitted such a declaration. You had been informed earlier that wastage on excipients was not allowed by the Norms Committee. It was not the case that excipients were not allowed at all. In fact, the same were allowed on net to net basis without wastage. Dissatisfied with the decision, you have submitted representations. In your representations, you have submitted various reasons and grounds. Now that you have been given adequate opportunity of representation and the Committee is to apply its mind to the said grounds taken by you, for reaching a conclusive decision, it was only natural that an opportunity to be heard may be provided in valid compliance of the principles of natural justice, irrespective whether or not there is a particular issue which is to be understood in a personal hearing. The Committee understands its duty to act fairly and reasonably and repeated expressions of apprehension are uncalled for. A decision was taken and you were unhappy with the same. You have represented and your representation is coming up for consideration. All your issues have been seen and understood. To say that you have no idea as to why an opportunity to be heard was offered to you is not correct. Application of the principles of natural justice should not be labelled a mere formality.

You had earlier been informed that a parcel containing documents would be delivered to this office and the same should be taken into consideration. It had been informed to you that letter No. RG:NC:DGFT:77 dated 17.08.2015 and your letter No. RG:NC:DGFT:79 also dated 17.08.2015 have been received and will be taken into consideration. Another parcel of similar nature containing letters bearing the same numbers has been received and these letters shall be considered in conjunction with all the correspondence on record.

4.III.

F.No. 01/82/50/708/AM-12/DES-III/

Date:20.08.2015

To,

M/s. Encube Ethicals Pvt. Ltd.,
Unit No. 24, Steelmade Indl. Estates,

Moral Village, Andheri(E),
Mumbai-400 059

Subject: Meeting of NC-III, to be held on 21.08.2015.

Sir,

This is with reference to your e-mail sent on 20.08.2015 at 12.00 Noon and further at 4.22 pm. It is stated in the mail that you gave a call regarding two matters which are under consideration by the NC. You have already been informed that the submission made by you have been taken on record and will be duly considered. If there is anything else you would like to submit for the consideration of the NC, you may do so. The provision for reducing Oral submissions made over telephone into writing at our end and placing before the Committee is not available. There is nothing in your mails which has not been understood at this end. This aspect has already been communicated to you.

In case there is any issue which requires telephonic discussion with your good self, a call shall be placed to you on the numbers provided by you. In case, however, there is no issue which requires personal discussions with you, placing a telephone call to you would not serve any official purpose. It would be highly unlikely that there would be something you wish to explain on telephone which cannot be sent in writing from you end.

In your mails, you have given the impression that you are being forced to appear for a personal hearing. You are hereby informed that, as already stated in the letter, the opportunity for personal hearing was by way of a facility extended to you keeping in view the principle of natural justice, considering that a huge number of mails have been written by you to represent your matter before various authorities and that since the issue is to be conclusively resolved, it appeared appropriate to provide you an opportunity to be heard. Providing an opportunity to be heard is an accepted procedure, and it is a matter of choice for you as to whether you wish to be heard or not. Since you explained that no purpose would be served by the same and reiterated your earlier submissions, you were duly informed that the said submissions shall be considered.

An applicant can claim the facilities/provisions as notified by the Government from time to time in the FTP/HBP. The facility of video conferencing has not been notified in the FTP.

You had informed earlier that a parcel containing documents would be delivered to this office and the same should be taken into consideration. It is to inform that your letter No. RG:NC:DGFT:77 dated 17.08.2015 and your letter No. RG:NC:DGFT:79 also dated 17.08.2015 have been received and will be taken into consideration.

5. It was observed as follows:-

1. There is a large variety of excipients used by the industry. The exact excipient used in formulations is not fixed and can vary from case to case. The quality of excipients is also not fixed and tends to vary. The Control strategies which concern excipient functionality and/or performance related issues need to be based on excipient manufacturer's process capabilities and can be negotiated between the excipient user and excipient maker.

2. The quantity of excipients used in a formulation can alter the effectiveness of the formulation. Moreover, a significant change in excipient properties i.e., any change by the manufacturer of an excipient that alters an excipient physical or chemical property outside the limits of normal variability, or that is likely to alter the excipient performance in the dosage form, cannot be ruled out.
3. Excipients are usually non-reactive, and may not take part in the chemical reactions. Inactive ingredients are components of a drug product that do not increase or affect the therapeutic action of the active ingredient, which is usually the active drug. Inactive ingredients are added during the manufacturing process of pharmaceutical products such as tablets, capsules, suppositories, and injections. Inactive ingredients may also be referred to as inert ingredients or excipients, and generally have no pharmacological effect. Examples of inactive ingredients include binding materials (which may be excipients), dyes, preservatives, and flavoring agents. Agents that combine with active ingredients to facilitate drug transport in the body are also considered inactive.
4. Excipients do not generally constitute the major part of the cost of the formulation.
5. There has been no demand whatsoever from the industry for allowance of wastage on excipients. No representation from the industry association/representative body has been received in this regard.
6. Most applications received by the Norms Committee either do not include excipients or request for excipients on net to net basis.
7. Pharmaxcil has been recommending the fixation of SIONs in approximately 45 products. Many of these products require excipients. However, the norms proposed by Pharmaxcil and approved by Department of Pharmaceuticals make no mention of wastage for excipients.
8. The manufacturing practices adopted by industry are by and large standardized. It cannot be the case that industry all over India is able to successfully manufacture products for exports without the support of grant of wastage on excipients, if indeed such wastage was essential and carried a significant impact on the manufacturing process as claimed by just one or two odd units.
9. The issue of fixation of wastage is to be decided in consultation with technical experts, in consonance with the requirements/demands of trade and industry as supported by the concerned representing bodies/Export Promotion Councils, and in the furtherance of the objectives of the Foreign Trade Policy. The simple fact that a particular unit may incur wastage on a particular item in its manufacturing process does not entitle that unit to claim wastage norms as a matter of right by itself. The trends of that industry sector have to be kept in mind while deciding individual cases. Precedents can help, but cannot be the thumb rule.
10. None of SIONs allow any wastage as repeatedly claimed by the company. The higher amounts of APIs are allowed to take care of its efficiency deterioration over the entire shelf life of the medicine.
11. In the modern global environmental scenario, the Industry has to try to reduce wastage in any input and to contain their cost of production. The environmental load through usage of excess inputs in any product is not desirable nor need to be institutionalized by way of including "wastage" as permissible for any input.

12. As on date, neither the technical experts support the demand for wastage on excipients nor the concerned representing bodies/Export Promotion Councils make mention of the requirement of the same. Moreover, the public interest is not seen to be served by grant of wastage on excipients as claimed in the instant case.
13. No published SION(Standard Input Output Norm) is seen to exist which allows wastage on excipients. SION for pharma products have existed for decades. Pharma industry is vocal in its demands. Yet the industry has never demanded wastage on excipients in the SIONs.
14. The applicant has sought to explain the requirements of wastage on excipients by explaining that if all the ingredients are put in a vessel and mixed, then upon taking out the product from the vessel, some amount of ingredients would stick inside the vessel. However, if this seemingly crude explanation is considered, it would imply that when the next batch of ingredients is added, some amount would already be available inside the vessel, and may not really have been 'lost'.
15. Allowance of wastage on excipients was not found to have any direct correlation to improved quality of the export product.
16. Rather than seeking wastage on excipients, it would be more appropriate for the manufacturer to improve upon the manufacturing process.
17. It was noted that excipients have not been disallowed; rather, the same have been allowed on net to net wastage.
18. As an applicant, the unit was required to submit an undertaking to abide by decisions of Norms Committee, and would have submitted such a declaration in the RA. The unit was aware that in this case, wastage of excipients was disallowed by the Norms Committee and the same were allowed on net to net basis. Now the representations made by the applicant have again been duly considered by the NC-3, and with the unanimous approval of all the members it is conclusively decided that wastage on excipients as requested by the applicant in this case is not admissible. The earlier decision to allow excipients on net to net basis stands.

Case No. C-01
M.No. 06/16
Dated 09.07.2015

Reference from Pharmexcil
F.No. 01/82/162/139/AM15/DES-III

Decision: It was decided to return the written comments received from Department of Pharmaceuticals vide their O.M;No.35011/75/2015-PI Norms dated 11.08.2015 with request to re-check the recommended quantity with already fixed SION.