

## **AGENDA FOR 1<sup>ST</sup> UAC MEETING FOR EOUs (2015 SERIES)**

### Agenda for the Unit Approval Committee for EOUs to be held on 18.03.2015.

Sub: Request for broadbanding of LoP - M/s. Apothecon Pharmaceuticals Pvt. Ltd., Dabhasa, Vadodara.

M/s. Apothecon Pharmaceuticals Pvt. Ltd., was approved for setting up a new unit at Padra-Jambusar Highway, P.O. Dabhasa, Tal. Padra, Dist. Vadodara for manufacturing of various Drugs and Formulation vide LoP dated 15.10.2008. The unit has started its commercial production on 07.07.2011.

The unit vide letter dated 09.07.2014 have requested for broad-banding of following Bulk Drugs in their LOP:

Sr. No.	Description of Items	Annual Production Capacity
1.	Colestipol Hydrochloride	20,000 Kgs.
2.	Sodium Hyaluronate	1,000 Kgs.

The UAC in its meeting held on 11.11.2014 has considered the above request of the unit for broad-banding and the Asstt. Commissioner of Central Excise, Division-II informed that the firm's earlier export performance is not good and they do not have positive NFE rather they are negative NFE. They also did not have FDA approvals for the export products sought to be incorporated in the LOP from Indian Authorities nor from any foreign countries. Asstt. Commissioner also informed that dues of Rs. 1.4 crores are to be recovered from the unit as they have not achieved positive NFE norms for EOUs. With regard to services being provided by the unit, they have not included the same in the Bond executed under Section 58 and 65 of the Customs Act. The Committee therefore decided to reject the request of broad-banding.

The unit was accordingly communicated the decision of the UAC vide this office letter dated 14.11.2014.

Also, the unit's following request for broad-banding and attestation of raw materials was pending with this office which was submitted vide letter dated 21.08.2014, 22.09.2014 and 07.10.2014:

Sr. No.	Description of Items	Annual Production Capacity
1.	Taurolidine	1,000 Kgs.
2.	Sodium Ferric Gluconate Complex	100 Kgs.
3.	Aprepitant	25 Kgs.
4.	Ropivacaine Hydrochloride	80 Kgs.

	Monohydrate	
--	-------------	--

The unit's above request was processed in file wherein DC has directed that their request for broad-banding can be considered/placed before the UAC subject to compliance of the shortcomings pointed out by the Asstt. Commissioner, Central Excise, Division-II in the UAC meeting dated 11.11.2014 Accordingly, letter dated 16.12.2014 was issued to the unit and in reply, the unit vide letter dated 22.12.2014 has intimated that they have included the Services in their Bonding Licence. However, as other shortcomings are not complied, this office vide letter dated 22.01.2015 has requested the unit to first comply with the observations pointed out by the Asstt. Commissioner, Division-II.

Now, the unit vide letter dated 21.02.2015 have stated that they are positive NFE and further stated that the allegations made in the UAC meeting held on 11.11.2014 by the Asstt. Commissioner regarding dues of Rs. 1.40 crores pending are baseless as they have not received any letter of recovery of such a huge amount pending against them. Now, the unit vide above referred letter have again requested for reconsideration of their applications for broad-banding in their LOP.

The unit's export performance from date of commencement of production i.e. 07.07.2011 to 31.03.2014 as per APR received in this office is furnished below:

-

(Rs. in lakhs)

Year	Exports			Total Exports	Total Imports
	Physical	Deemed	Service Export		
2011-12	12.523	0.000	100.626	113.149	44.571
2012-13	182.985	0.000	614.957	797.942	55.840
2013-14	212.700	119.841	1893.226	2225.767	134.151

The proposal of the unit for broad-banding of following items in their LOP are placed before UAC for consideration: -

Sr. No.	Description of Items	Annual Production Capacity
1.	Colestipol Hydrochloride	20,000 Kgs.
2.	Sodium Hyaluronate	1,000 Kgs.
3.	Taurolidine	1,000 Kgs.
4.	Sodium Ferric Gluconate Complex	100 Kgs.
5.	Aprepitant	25 Kgs.
6.	Ropivacaine Hydrochloride Monohydrate	80 Kgs.

\*\*\*\*\*