

**AGENDA FOR THE 123<sup>rd</sup> UAC MEETING (VSEZ UNITS) SCHEDULED AT 1100 A.M ON 21.12.2020 ON VIDEO CONFERENCE UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER,VSEZ, SHRI A.RAMA MOHAN REDDY, IFS, FROM HIS CHAMBERS IN THE ADMINISTRATIVE BUILDING, DUVVADA, VSEZ**

**Agenda item No.1.**

Ratification of the minutes of the UAC meeting for VSEZ units held on 24.11. 2020 .

**Agenda item No.2**

**Request of M/s.Reddy's Laboratories Ltd., Formulation unit IX, Plot No. Q1 to Q5 for inclusion of New products in their LoA – reg.**

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The unit was issued LoA dt.08.06.2012 for manufacture of pharmaceutical tablets, capsules, injections and commenced production w.e.f.1.11.2017 . The unit intends to add the following new product in their LoA under broad banding in terms of Rule 19(2) of SEZ Rules, 2006:

Sl.No.	Item of manufacture	Dosage	ITCHS	Exhibit quantity (approx.)	Batches in Nos.
1	Phytonadione Injectable Emulsion USP 10mg/ml	Injection	30049099	5,00,000	

The unit declared that the above products are not in restricted/prohibited list of goods in terms of ITC(HS).

The unit has submitted process chart of manufacture of the above drug.

The unit submitted photo-copy of Test Licence No.HMF07-14051/256/2020-TECH-DCA dt.16.07.2020 from Drug Control Administration, Govt.of A.P. for the purpose of Examination, Test for chemical and instrumental analysis and not for any commercial use and shall be used for Bio/clinical studies subject to grant of BE/CT permission from the DGG(I) office.

The unit also submitted Form-29 in respect of both the products wherein it is mentioned that the Licence is valid for 3 years from the date of its issue.

The request of the unit is placed before UAC in terms of Rule 19(2) of SEZ Rules, 2006, for consideration.

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