AGENDA FOR THE 125th UAC MEETING (VSEZ UNITS) SCHEDULED AT 1100 A.M ON 22.02.2021 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 22.01.2021

Agenda item No.2

Request of M/s.Reddy's Laboratories Ltd., Formulation unit IX, Plot No. Q1 toQ5 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 products in their LoA under broad banding in terms of Rule 19(2) of SEZ Rules, 2006:

Sl.No.	Item of manufacture	App.Annual Capacity in Nos.	ITCHS
1	Carboprost Tromethamine Injection USP 250 mcg/ml in pre-filled syringe	200000	30041090
2	Plerixafor 20mg/ml solution for injection	250000	30041090

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.HMF07-14051/1165/2020—DD-DDCA dt.22.01.2021 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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Agenda item No.3

Request of M/s.Reddy's Laboratories Ltd., Formulation unit IX, Plot No. Q1 toQ5 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 products in their LoA under broad banding in terms of Rule 19(2) of SEZ Rules, 2006:

Sl.No.	Item of manufacture	ITCHS	unit	App.Annual Capacity in Nos.
1	Triamcinolone acetonide injectable suspension, USP 40mg/mil	30049090	Nos.	15,39,999

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.HMF07-14051/132/2021—DD-DDCA dt.11.02.2021 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 proposal of the unit for inclusion of the above mentioned product in their existing LoA is placed before UAC in terms of Rule 19(2)of SEZ Rules, 2006, for consideration.

Agenda item No.4

Request of M/s.Reddy's Laboratories Ltd., Formulation unit VII, Plot No. P1 to P9 for inclusion of New products in their LoA under broad banding – reg.

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The unit was issued LOA dt.23.03.2005 for manufacture of injectables /injections(pre-filled Syringes, vials & cartridges as amended from time to time and had commenced production on 22.4.2010 as per records.

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The unit vide their letter dt.09.02.2021 requested for inclusion of New product for manufacture of 'Nelarabine Injection 250 mg/50ml (5 mg/ml) under ITCHS 30049049 at an annual capacity of 19000 kg under broad banding in their LoA.

The unit submitted flow chart for manufacture of the above product, and declared that the item is not a restricted/prohibited item under ITC HS.

The unit submitted copy of approval given by Drug Control Administration, Guntur vide HMMF07-14051/41/2021-DD-DDCA dt.26.1.2021 under License in Form 29 for the purpose of Examination, test for chemical and instrumental analysis. This product manufactured against this Test Licence are not for any commercial use and shall be used for Bio/clinical studies subject to the grant of BE/CT permission from the DCG(I) Office.

The proposal of the unit for inclusion of the above mentioned product in their existing LoA is placed before UAC in terms of Rule 19(2)of SEZ Rules, 2006, for consideration.

Agenda item No5

Request of M/s.Reddy's Laboratories Ltd., Formulation unit VII, Plot No. P1 to P9 for inclusion of New products in their LoA under broad banding – reg.

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The unit was issued LOA dt.23.03.2005 for manufacture of injectables /injections(pre-filled Syringes, vials & cartridges as amended from time to time and had commenced production on 22.4.2010 as per records.

The unit vide their letter dt.16.02.2021 requested for inclusion of the following New product for manufacture under broad banding, in their LoA.

Sl.No.	Item of manufacture	unit	ITCHS	Annual capacity
1	Lenvatinib Capsules 4 mg 4 milligram (mg)	Nos.	30041090	2240000
2	Lenvatinib Capsules 10 mg 10 milligram (mg)	Nos.	30041090	2240000

The unit submitted flow chart for manufacture of the above product, and declared that the item is not a restricted/prohibited item under ITC HS.

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The unit submitted copy of approval given by Central Drugs Standard Control Organization, Hyderabad vide licence No.CT14/HZ/20/000473 dt.10.11.2020 under the provision of New Drugs and Clinical Trials Rules, 2019 for examination, test and analysis and Form CT 14 mentions that the license is valid for 3 years from the date of its issuance.

The proposal of the unit for inclusion of the above mentioned product in their existing LoA is placed before UAC in terms of Rule 19(2)of SEZ Rules, 2006, for consideration.

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