

**Minutes of the Approval Committee's Meeting in respect of VSEZ and Private SEZs in Andhra Pradesh held on 25.05.2023 through video conferencing under the Chairmanship of Shri MUPPAALA SRINIVAS, IRSME, Development Commissioner, VSEZ**

Present:

1. Smt Roshni Aparanji Korati, IAS, Joint Development Commissioner, VSEZ
2. Shri B. N. Ramesh, ITS, Dy. DGFT, Visakhapatnam
3. Shri SNJHK Varma, IRS, Specified Officer, VSEZ
4. Shri Suresh Babu, Jt. Commissioner, IT, Vijayawada
5. Shri Ch. Ganapathi, GM, DIC, Visakhapatnam
6. Dr. G. Raju, Asst. Development Commissioner (Labour)
7. Smt. Kalyani, Drug Inspector, Drug Control Department, Visakhapatnam

Development Commissioner, VSEZ and Chairman of the Unit Approval Committee for SEZs and EOUs in Andhra Pradesh welcomed the Members and the ADC apprised them briefly about the proposals placed before the Committee for its consideration. The items listed in the Agenda were discussed and following decisions were taken in respect of each SEZ/EOU.

**VSEZ AGENDA – ANDHRA PRADESH**

**Agenda Item No.01:- Ratification of the Minutes of the meeting held on 10.05.2023.**

The committee noted and ratified the minutes of the UAC meeting held on 10.05.2023

**Agenda Item No. 02 : Request of M/s. Aurobindo APL Health Care LTd, unit-IV, in APIIC Multi Product SEZ, Nellore for inclusion of additional products in the LoA.**

The Approval Committee after due deliberations, approved the proposal for inclusion of the following additional products in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006, subject to the condition that the unit shall submit the copy of the NDPS license issued in respect of the products mentioned at Sl.No.4 & 5.

S.No	Name of the Product	Strength(mg)	UOM	Annual Capacity	HSN Code
1	Glycopyrrolate Tablets USP	1 mg	Mil	3.9	30049099
2	Glycopyrrolate Tablets USP	2 mg	Mil	1.03	30049099
3	Clonazepam Tablets	0.5 mg	Mil	5.185	30049099
4	Clonazepam Tablets	1 mg	Mil	2.972	30049099
5	Clonazepam Tablets	2 mg	Mil	4.288	30049099
6	Methylprednisolone Tablets USP	8 mg	Mil	0.2331	30049099
7	Methylprednisolone Tablets USP	32 mg	Mil	0.0482	30049099

**Agenda Item No. 03 : Request of Dr. Reddy's Laboratories LTd, FTO SEZ Process unit-01, a unit in Dr. Reddy's Laboratories LTd SEZ, Ranasthalam, Srikakulam for inclusion of additional product in the LoA.**

The Approval Committee after due deliberations, approved the proposal for inclusion of the following additional products in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006.

S. No	Name of the Product	Category	HSN Code	Annual capacity in Nos.
1	Loratadine and Pseudoephedrine Sulfate extended-release tablets 10mg/240mg	Tablets	30049039	17,50,000

**Agenda Item No. 04 : Request of M/s. Divi's Laboratories Limited (SEZ unit) , a unit in Divi's Laboratories Limited SEZ, Chippada, Visakhapatnam for inclusion of additional products in the LoA.**

The Approval Committee after due deliberations, approved the proposal for inclusion of the following additional products in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	Annual Capacity (in MT)
1	6-Methyl-3,6,9-Triaza-1(2,6)-Pyridinacyclodecaphane/Pyramine	Intermediate	29333919	3.000
2	Canthaxanthin 10% DG/MC	Nutraceuticals	29369000	10.00
3	Astaxanthin 5% DC/BN	Nutraceuticals	29362100	05.00
4	Astaxanthin 5% DG/QN	Nutraceuticals	29362100	05.00
5	Lycopene 10% MB	Nutraceuticals	29369000	05.00
6	Zeaxanthin 14%LF/N	Nutraceuticals	29362290	05.00
7	Beta Carotene 5% Emulsion	Nutraceuticals	29362100	40.00
8	Vitamin K2 0.2% DC	Nutraceuticals	29362930	25.00

**Agenda Item No. 05 : Request of M/s. Divi's Laboratories Limited (DSN SEZ unit) , a unit in Divi's Laboratories Limited SEZ, Chippada, Visakhapatnam for inclusion of additional products in the LoA**

The Approval Committee after due deliberations, approved the proposal for inclusion of the following additional products in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	Annual Capacity (in MT)
1	Tert-butyl ((5S,6R)-6-methyl-2-oxo-5-phenylpiperidin-3-yl) carbamate/Lactam C11010409-F (Telluride)	Intermediate	2933 7990	4

**Agenda Item No. 06 : Request of M/s. Eisai Pharmaceuticals India Pvt Ltd , a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.**

The Approval Committee after due deliberations, approved the proposal for inclusion of the following additional product in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006.

S. No	Name of the Product	Intermediate/API/ Formulation	ITC HS Code	Annual Capacity
1	<b>Lemborexant</b> (Generic Name: Dayvigo)	API	2902 90 90	6,000 KG

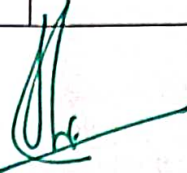
Regarding the following product, UAC has informed the unit to obtain the Drug License in the name of the product proposed to be exported and to submit the proposal to place the same in the next UAC.

2	<b>Methycobal 500 mcg Tablets</b> (Generic Name: Mecobalamin Tablets 500 mcg)	Formulation	30049099	300 Million
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**Agenda No.7 :- Request of M/s. Natco Pharma Limited a unit in M/s Ramky Pharma City, Parawada, Visakhapatnam for inclusion of (Pharmaceutical Product) Manufacturing Services ” in the LoA - Reg**

The Approval Committee after due deliberations, approved the proposal for inclusion of “Manufacturing Services” in the LoA in terms of the provisions of Rule 19(2) of SEZ Rules'2006 for the purpose of manufacturing of the following products exclusively for M/s.Sun Pharma Limited, Hyderabad and export the same from M/s.Natco Pharma Limited, SEZ Unit. The unit shall receive the manufacturing services charges in Foreign currency.

Sl.No.	Product Description	ITCHS Code	Type	Annual Capacity
1.	LenalidomideCapsues 2.5 mg	30049049	Oral Dosage	0.20 Million  Or  Two lakhs
2.	LenalidomideCapsues 5 mg	30049049	Oral Dosage	
3.	LenalidomideCapsues 5 mg	30049049	Oral Dosage	
4.	LenalidomideCapsues 5 mg	30049049	Oral Dosage	
5.	LenalidomideCapsues 5 mg	30049049	Oral Dosage	
6.	LenalidomideCapsues 5 mg	30049049	Oral Dosage	



**(SRINIVAS MUPPAALA) IRSME  
Development Commissioner &  
Chairman, Unit Approval Committee**