AGENDA FOR THE UNIT APPROVAL COMMITTEEs MEETING FOR THE VSEZ & PRIVATE SEZs OF ANDHRA PRADESH UNDER THE CHAIRMANSHIP OF SHRI SRINIVAS MUPPAALA, IRSME, ZONAL DEVELOPMENT COMMISSIONER TO BE HELD ON 25.05.2023 AT 12.00 NOON THROUGH WEBEX

VSEZ AGENDA – ANDHRA PRADESH

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

The minutes of the UAC meeting held on 10.05.2023 has been circulated to all the members of the UAC and also placed on the VSEZ website. No comments have been received from the members of UAC. The minutes are placed before UAC for ratification.

PVT SEZ AGENDA – ANDHRA PRADESH

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

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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.

M/s. Aurobindo APL Health Care Ltd. a unit in in APIIC Multi Product SEZ, Nellore has requested for inclusion of following additional products in the existing LoA. The unit has been advised to submit the copies of CFE/CMP issued by the APPCB in respect of the proposed products The unit has informed that their unit is a Formulation unit and the requirement of CFE/CMP is not applicable in the case of unit set up for formulations.

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

The unit has submitted Drug License Copies issued by DCA, GOAP dated:11.03.23, 15.3.23, 09.04.2021 and 24.01.2023 which are valid upto 31.03.2026. The unit has furnished flow charts and NFE for each category of the proposed product. The unit has projected Exportsof Rs. 874 Lakhs, Import of Rs.122.28 Lakhs and NFE ofRs. 752.49 in respect of the above products.

The above products with ITC HS code 30049099are free for export as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval Committee may approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity.

Accordingly, the proposal is placed before UAC for consideration.

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.

Dr.Reddy's Laboratories LTd, FTO SEZ Process unit-01 a unit in Dr. Reddy's Laboratories Ltd SEZ, Ranasthalam, Srikakulam has requested for inclusion of the following additional products in the existing LoA :

S. No	Name of the Product	Category	HSN Code	Annual capacity in Nos.	Apprx value of the goods(Rs)
1	Loratadine and Pseudoephedrine Sulfate extended-release tablets 10mg/240mg	Tablets	30049039	1750,000	0.10 Cr

The unit has submitted Test License in Form-29 issued by Drug Control Authority of the above product for a quantity of 17,50,000 Tablets exclusively for the purpose of R & D formulation development/manufacturing of Exhibit batches.

The unit has informed that the Drug license is for Testing and Analysis purpose and hence there will be no commercial sale of the product until the same is commercialised. The unit has informed that there will be no change in Annual capacity and NFE.

The unit has furnished product details, process flow chart and submitted declaration that the product is free for export and not a prohibited one. The unit has furnished CFO issued by APPCB for the combined site including all plants of Dr. Reddy's Lab and informed that their unit is a Formulation unit for manufacture of Tablets and Capsules (Formulation unit) falling under Orange category of Industries.

The above product with ITC HS code 30049039 is free for export subject to conditions as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval Committee approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity.

The request is placed before UAC for consideration.

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.

M/s. Divi's Laboratories Limited (SEZ unit) a unit in M/s. Divi's Laboratories Limited SEZ vide letter dated 15.5.2023 has requested for inclusion of the following additional product in the existing LoA.

The unit has informed that they proposed to manufacture below given R&D product in their SEZ unit during the FY 2023-24 and obtained the approval from the APPCB to manufacture 100 MT of R & D products in a year through their CFO APPC/VSP/VSP12368/HO/CFO/2021 dated 19.3.2021 which is valid upto 30.11.2026. They have obtained permission to manufacture 13.8 MT of R& D products out of 100 MT permission. The total quantity proposed to be manufactured alongwith below product is about 16.800 MT. The unithas been informed to submitthe List of the products which were already approved and the unit has submitted the list of products and the same is attached to the agenda.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	Annual Capacity (in MT)	NFE details for 5 years (in Cr)
1	6-Methyl-3,6,9-Triaza-1(2,6)-Pyridinacyclodecaphane/Pyramine	Intermediate	29333919	3.000	7.5
2	Canthaxanthin 10% DG/MC	Nutraceuticals	29369000	10.00	30.00
3	Astaxanthin 5% DC/BN	Nutraceuticals	29362100	05.00	125.00
4	Astaxanthin 5% DG/QN	Nutraceuticals	29362100	05.00	125.00
5	Lycopene 10% MB	Nutraceuticals	29369000	05.00	22.00
6	Zeaxanthin 14%LF/N	Nutraceuticals	29362290	05.00	78.00
7	Beta Carotene 5% Emulsion	Nutraceuticals	29362100	40.00	56.00
8	Vitamin K2 0.2% DC	Nutraceuticals	29362930	25.00	100.00

The unit has informed that the above product at Sl.No. 1 does not fall under prohibited item and submitted process details, raw materials and their consumption coefficients.

For Sl. 2 to 7, the unit has informed that they have obtained the approval from APPCB through CFE for the APIs, which are included in their LOA. The products for which they have applied are for inclusion in the LOA are only derivatives of these APIs which will be used as food and dietary supplements which do not require separate approval from APPCB. Further , it is informed that these products are not falling under drugs and they are only food supplements and submitted Food license (FSSAI License) obtained for the above products.

The Net Foreign Exchange from the export of the above product in the next five years is estimated around Rs.543 Cr with existing facility and manpower hence no additional employment envisaged.

The above product with above ITC HS code are free for export as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval Committee may approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity.

Accordingly, the proposal is placed before UAC for consideration.

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.

M/s. Divi's Laboratories Limited (DSN SEZ unit) a unit in M/s. Divi's Laboratories Limited SEZ vide letter dated 14.03.2023 has requested for inclusion of the following additional product in the existing LoA. The unit has been advised to submit CFE/CMP from APPCB vide this office letter dated 31.03.2023.

In response, the unit vide letter dated 24.04.2023 has informed that the proposed product is an 'Intermediate product' which is to be manufacture at R & D trail /validation batches for qualification of the product. They have obtained permission from APPCB for the manufacture of 100 MT of R & D products vide consent order dated 19.3.2021 which is valid upto 30.11.2026. Once the validation of the product is complete, based on Customer's requirement, they will apply for inclusion of the products in LOA after obtaining necessary approval form APPCB. It is informed that they manufacture R&D productof 0.0216 MT during the year 2023-24.

The unit propose to manufacture R&D products about 10.450 MT out of 100 MT permitted by APPCB during the FY 2023-24. The manufacture of R &D products are within 'permissible limits of APPCB approval. The unit has informed that they have obtained LoA for R & D products for 35.60 MT during the FY 2023-24, out of the total approved 100 MT by APPCB and balance quantity is about 64.40 MT as per LOA. The details break up enclosed.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	Annual Capacity (in MT)	NFE details for 5 years (in Cr)
1	Tert-butyl ((5S,6R)-6-methyl-2-oxo-5-phenylpiperidin-3-yl) carbamate/Lactam C11010409-F (Telluride)	**Intermediate**	2933 7990	4	20

The unit has informed that the above product at Sl.No. 1 does not fall under prohibited item and submitted process details, raw materials and their consumption coefficients.

The Net Foreign Exchange from the export of the above product in the next five years is estimated around Rs.20 Cr with existing facility and manpower hence no additional employment envisaged.

The above product with above ITC HS code **2933 7990** is free for export as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval Committee may approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity.

Accordingly, the proposal is placed before UAC for consideration.

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.

M/s. Eisai Pharmaceuticals India Pvt Ltd,a unit in Ramky Pharma SEZ, Parawada, vide letters dated. 17.05.2023 has requested for inclusion of the following additional products in the existing LoA:

S. No	Name of the Product	Intermediate/API/ Forumulation	ITC HS Code	Annual Capacity
1	**Lemborexant** (Generic Name: Dayvigo)	API	2902 90 90	6,000 KG
2	**Methycobal 500 mcg Tablets** (Generic Name: Mecobalamin Tablets 500 mcg)	Formulation	30049099	300 Million

For. Sl.1: the unit informed that they propose to **manufacture and export the product Lemborexant** for which the **Generic name is Dayvigo.** The manufacturing license was obtained in the name of Lemborexant and initially the pollution control certificate was issued based on the generic name which is **Dayvigo.** The unit has submitted the Manufacturing License issued by Drug Control Authority, product details, process flow chart and description of HSN code and also submitted APPCB copy for manufacturing the product **which was issued as per the Generic name** Dayvigo as mentioned in Point No. 34 under Bulk Drugs (API) segment.

For Sl. No.2 the unit has informed that they proposed to manufacture and export the product Methycobal 500 mcg Tablets for which the Generic name is Mecobalamin Tablets 500 mcg. The manufacturing license was obtained as per Generic name Mecobalamin Tablets 500 mcg and initially the pollution control certificate was issued in the name of Methycobal 500 mcg Tablets. Manufacturing license was issued as per the generic name of the product which is Mecobalamin Tablets 500 mcg as mentioned in the Point No. 32 of the manufacturing license certificate. Also submitted consent granted by APPCB for manufacturing the product **Methycobal 500 mcg Tablets** as mentioned in Point No. 7 under Formulation segment (Qty of 400 Million per Annum).

The unit submitted Manufacturing License issued by Drug Control Authority, product details, process flow chart and description of HSN code.

The above product with ITC HS code 2902 90 90 and 30049099 are free for export as per Schedule 2-Export Policy, ITC(HS)2018.

In terms of Rule 19(2), approval Committee may approve proposal for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity.

Accordingly, the proposal is placed before UAC for consideration.

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.

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M/s. Natco Pharma Limited a unit in M/s Ramky Pharma City SEZ has informed that M/s.Sun Pharma Ltd. has approached them for the manufacture of their product at the SEZ unit. M/s.Sun Pharma will provide all the required Raw-material, Packing materials and any other consumables required for manufacturing their product and M/s.Natco Pharma will manufacture the same into finished dosages as per their licence(s) as per the agreement reached between both of them. M/s.Natco Pharma will export the finished product from the SEZ Unit premises by filing the bills jointly with the authorities.

As per the agreement reached, M/s. Natco Pharma intend to manufacture the following products for M/s.Sun Pharma Limited and in that context requested for inclusion of additional activity i.e., "Manufacturing Services" for rendering manufacturing services exclusively for M/s.Sun Pharma Limited" specifically for manufacture of the following products.

Sl.No.	Product Description	ITCHS Code	Type	Annual Capacity	Expected Revenue per annum
1.	LenalidomideCapsues 2.5 mg	30049049	Oral Dosage	0.20 Million Or Two lakhs	Rs.5.00 Cr.
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		

M/s.Natco Pharma was granted approval vide LoA dated: 19.11.2014 for manufacture of Lenalidomide Capsules as per the provisions of SEZ Rules'2006.

M/s.Sun Pharma Limited was also in possession of the Drug License No.NH/138/N/NH/139 dated: 22.11.2021 issued for manufacture and export of Lenalidomide Capsules issued by DNHDD, Silvassa and valid upto 29.07.2024.

As per the agreement reached between both of them, it is observed that M/s.Sun Pharma Limited will supply the required raw-materials, consumables, Packing materials for manufacture of the above free of cost and will not avail/claim and duty exemptions.

M/s.Natco Pharma informed that they will manufacture the above products out of the raw-materials, consumables received free of cost and export them directly from the SEZ premises by jointly filing the bills in the name of M/s.Natco Pharma and M/s.Sun Pharma Limited as per the provisions of the SEZ Rules'2006.

Kind reference is invited to Rule-19(2) of SEZ Rules'2006 – wherein the Unit Approval Committee may also approve proposals for **broad-banding**, diversification, enhancement of

capacity of production change in the items of manufacture or service activity, if it meets the requirements of rule 18.

The Specified Officer, VSEZ vide letter dated: 26.04.2023(04.05.2023) has informed that – As per the definition of “Service” given in Section 2(z) of the SEZ Act, 2005, a service shall earn foreign exchange.

M/s.Natco Pharma Limited has informed that as per the amended agreement reached between both the parties, they will receive the service charges in foreign currency.

In terms of Rule-19(2) of SEZ Rules’2006, the request of M/s.Natco Pharma Limited is placed for before the UAC for consideration please.

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