<u>AGENDA FOR THE APPROVAL COMMITTEES MEETING FOR THE VSEZ</u> <u>& PRIVATE SEZS OF ANDHRA PRADESH UNDER THE CHAIRMANSHIP OF</u> <u>SHRI SRINIVAS MUPPAALA, IRSME, ZONAL DEVELOPMENT COMMISSIONER</u> TO BE HELD ON 25.07.2023 THROUGH HYBRID MODE AT 11.00 AM

VSEZ AGENDA - AP

Agenda Item No.AP-167.01 :- Ratification of the Minutes of the meeting held on 10.07.2023.

The minutes of the UAC meeting held on 10.07.2023 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

Agenda Item No.AP-167.02 : Request of Dr. Reddy's Laboratories Ltd. FTO-VII Plot No. P1 to P9 for inclusion of new product in the LoA – reg.

Dr. Reddy's Laboratories Ltd. FTO-VII has requested for inclusion of following products in the existing LoA.

SI.No.	Item of manufacture	37yw0w2w2	Qty. as per DL	Probable ITC (HS)
1	Cabozantinib tablets 20 mg	Tablets	10,50,000	30049099
2	Cabozantinib tablets 40 mg	Tablets	10,50,000	30049099
3	Cabozantinib tablets 60 mg	Tablets	10,50,000	30049099
4	Palbociclib Tablets 75 mg	Tablets	7,20,000	30049099
5	Palbociclib Tablets 100 mg	Tablets	7,20,000	30049099
6	Palbociclib Tablets 125mg	Tablets	7,20,000	30049099

The unit has informed that they have been regularly including new products for manufacture in the LoA in addition to the products already included.

The unit has submitted <u>Test License in Form-29</u> issued by Drug Control Authority in respect of the products at S.Nos 1, 2 & 3 exclusively <u>for the purpose of</u> R & D formulation development/manufacturing of Exhibit batches.

Further, the unit has submitted <u>Test License in Form- CT-11</u> issued by Central Drugs Standard Control Organisation (Hyderabad Zone) in respect of the products at S.Nos 4, 5 & 6 exclusively <u>for the purpose of Examination</u>, <u>Test and Analysis</u>.

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 submitted the process flow chart for manufacture of the above drugs.

The unit has furnished the copies of Drug License in respect of the above product vide File No. HMF07-14051/980/2023-ADMIN-DCA dated 06.062023 and CT 11/HZ/23/000566 dated 16.05.2023 which shall be in force for three years from the date of issue.

As the product proposed falls under the category of Formulation hence CFE/CMP is not applicable in the instant case.

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

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

Accordingly, the proposal is placed before UAC for consideration.

PVT SEZs - ANDHRA PRADESH

Agenda Item No.AP-167.03 :- Ratification of the Minutes of the meeting held on 10.07.2023.

The minutes of the UAC meeting held on 10.07.2023 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.

Agenda Item No.AP-167.04: Request of M/s. Eisai Pharmaceuticals India Pvt Ltd, a unit in Visakha Pharmacity LTd, SEZ, Parawada, Visakhapatnam for inclusion of additional product in the LoA.

M/s. Eisai Pharmaceuticals India Pvt Ltd vide letter dated. 17.07.2023 has requested for inclusion of the following additional product in the existing LoA. Earlier the unit has requested for inclusion of the following additional product and the unit has been advised to submit copy of the Drug License issued in the name of the product which is proposed to be exported and to submit the proposal alongwith the above to place the same in the next UAC meeting.

The unit has submitted copy of Drug License dated 02.07.2023 issued in the name of Methycobal (Brand name) issued by Drug Licensing Authority Vijayawada for export which is valid upto 14.04.2025.

S. No	Name of the	Product	Intermediate/API/Forumulation	ITC HS Code	Annual Capacity
1	Methycobal	500 mcg	Formulation	30049099	300 Million
	Tablets				
	(Generic	Name:			
	Mecobalamin	Tablets			
	500 mcg)				

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 unit has submitted copy of the consent granted by APPCB for manufacturing the product **Methycobal Tablets** which is mentioned in Point No. 7 under Formulation segment (Qty of 400 Million per Annum).

Further the unit vide email dated 18.07.2023 has informed that with regard to the consent granted by pollution control board for manufacturing the product **Methycobal 500 mcg Tablets** as mentioned in Point No. 7 under Formulation segment for 400 Million tablets, but they have not applied for inclusion of additional product for any quantity with respect to Methycobal 500 mcg Tablets earlier.

The unit has 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 30049099 are free for export as per Schedule 2-Export Policy, ITC(HS)2018.

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

The proposal is placed before Approval Committee for consideration.

Agenda Item No.AP-167.05 :- Proposal of M/s. Anjalee Granites Pvt Ltd, a unit in M/s. APIIC Ltd. Building Product SEZ for inclusion of additional product in the LoA-Reg.

M/s. Anjalee Granites Pvt Ltd has requested for inclusion of the following additional products in the LoA for Manufacturing and Trading Activity.

The unit has been granted LOA for Manufacturing activity vide this office LOA dated 22.04.2010 and for undertaking Trading Activity vide this office LOA dated 19.09.2011 and 29.07.2022.

The unit has requested for inclusion of the following additional products under **Manufacturing Activity**:

S. No	Name of the product	ITC HS Code	Annual Production Capacity
1	Multitier Saw Diamond Ropes (for captive consumption and sale purpose)	84641010	6,00,000 Liner Meter
2	Dimensional Dressed Granite Blocks, Marble Blocks, Quartzite Blocks (for their captive use and sale purpose)	25161200 25151210 25062090	18,000 Cubic Meters
3	Quartzite Slabs	68029900	12,00,000 SFT

The unit has requested for inclusion of the following additional products in the LoA under **Trading Activity**:

S. No	Name of the product	ITC HS Code			
1	Multitier Saw Diamond Ropes	84641010			
2	Quartzite Slabs	68029900			

The unit has informed that they will demarcate separate space within the SEZ Unit premises for the above purpose and maintain separate books of accounts for different activity..

FOREX Balance sheet for current Block (Rs. in Lakhs)

Items	2021-22	2022-23	2023-24	2024-25	2025-26	Total
Free on Board value of Exports in first 5 years	6000	6000	7000	7500	7500	34000
Foreign Exchange Outgo on for the first five years *	4000	4000	5000	5000	5000	23000
Net Foreign Exchange earnings for the first five years [1-2]	2000	2000	2000	2500	2500	11000

The Unit has submitted the Projections for next five years:-

(Rs. in Lakhs)

						,	
	2022-23	2023-	2024-	2025-26	2026-	Total (Rs,	Total
		24	25		27	in lakhs)	USD (in
							lakhs)
							(US \$
							@Rs.82)
FOB Value	e 8000	8500	9000	9500	10000	45000	548.78
Exports							
Foreign Exchange	e 4000	4200	4400	4600	4800	22000	268.29
Out go on next !	5						
years							
Net foreig	4000	4300	4600	4900	5200	23000	280.49
Exchange							
Earnings for next	5						
years							

The above product with ITC HS codes 84641010, 25161200, 25151210 25062090, 68029900 are free for export as per Schedule 2-Export Policy, ITC(HS)2018.

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

The proposal is placed before Approval Committee for consideration.

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