

I/51592/2023

AGENDA FOR THE 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 10.10.2023 THROUGH HYBRID MODE AT 11.00 AM

VSEZ – ANDHRA PRADESH

Agenda Item No.AP-172.01 :- Ratification of the Minutes of the meeting held on 11.09.2023.

The minutes of the UAC meeting held on 11.09.2023 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 SEZs – ANDHRA PRADESH

Agenda Item No.AP-172.02:- Ratification of the Minutes of the meeting held on 25.09.2023.

The minutes of the UAC meeting held on 25.09.2023 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-172.03 : Request of M/s. Dr. Reddy's Lab Ltd, CTO SEZ SEZ Process Unit-01- a unit in Dr. Reddy's Lab Ltd SEZ for inclusion of additional product in the existing LoA - Reg.

M/s. Dr. Reddy's Lab Ltd, CTO SEZ Process Unit-01 vide letters dated 27.09.2023 requested for inclusion of the following additional products in the existing LoA. The details of the products proposed for inclusion is furnished hereunder :-

Sl.No	Item of Manufacture	API	ITCHS Code	Projected Qty (Nos)	Approx. Value of the goods (Rs)
1	FINASTERIDE IP/USP/PH.EUR	API	29420090	1400 KG	78 Cr
2	DUTASTERIDE IP/USP/IH	API	29420090	250KG	24 C

The unit has submitted Drug License copies dated 03.06.2023 for the above products with above quantities. They have submitted APPCB for CFE dated 02.03.2023 .

The unit has submitted the process details, and raw-materials and the same are enclosed to the agenda.

The above product with ITC HS code 29420090 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 terms of manufacture or service activity.

Accordingly, the proposal is placed before the UAC for consideration

Agenda Item No.AP-172.04 : Request of M/s. Ajinomoto Bio-Pharma Services India Pvt Ltd , a unit in M/s Visakha Pharmacy Ltd SEZ for inclusion of additional product in the existing LoA - Reg.

I/51592/2023

M/s. Ajinomoto Bio-Pharma Services India Pvt Ltd vide letter dated 04.10.2023 requested for inclusion of the following additional products in the existing LoA. The details of the products proposed for inclusion is furnished hereunder :-

Sl.No	Item of Manufacture	API/Intermediate	ITCHS Code	Capacity (Kgs/per day)
1	MEGLUMINE	API	29221990	170.00 KG
2	5-(3,5-DIMETHYLPHENYL)-3,4-DIHYDRO-2H-PYRROLE SULFURIC ACID SALT (ATI-4)	Intermediate	29339980	33 KG

The unit has submitted Drug License copy for the product at Sl.1 which is issued for the purpose of examination , Test or Analysis and valid upto 26.06.2026. The unit has submitted an undertaking that for the product at SL.2 stating that the Intermediate product does not require Drug License. They have submitted APPCB for CFE dated 05.03.2023 .

The unit has submitted the process details, and raw-materials and the same are enclosed to the agenda.

The above product with ITC HS codes 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 terms of manufacture or service activity.

Accordingly, the proposal is placed before the UAC for consideration

Agenda Item No.AP-172.05:- Request of M/s. APL Healthcare Ltd, a unit in M/s APIIC Multi Product SEZ, Naidupeta, Nellore for inclusion of additional product in the existing LoA - Reg.

M/s. APL Healthcare Ltd vide letter dated 27.09.2023 has requested for inclusion of the following additional products in the existing LoA. The details of the products proposed for inclusion are furnished hereunder :-

S.No	Material Name	Strength (mg)	UOM	Annual Capacity	ITCHS Code	Net Value (INR)
1	Emtricitabine and Tenofovir Alafenamide Tablets	200mg / 25mg	Millions	0.72	30049099	51,48,222
2	Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets	50mg / 200mg / 25mg	Millions	0.9	30049099	1,78,96,582

The unit has submitted Drug License copies dated 06.09.2022 and 03.06.2023 and APPCB for CFE dated 16.08.2022 for manufacture of Tablets , Capsules, Liquids and Nasal . The unit has submitted the process details, and raw-materials and the same are enclosed to the agenda.

Specified Officer , APIIC MP SEZ has certified in the above letter that the above products are not under Export Restriction list.

In terms of Rule 19(2), approval Committee may also approve proposal for broad banding

I/51592/2023

diversification, enhancement of capacity of production, change in the terms of manufacture or service activity.

Accordingly, the proposal is placed before the UAC for consideration.

APSEZ AGENDA – ANDHRA PRADESH

Agenda Item No.AS-11114-01.

Ratification of minutes of the 113th meeting held on 25.09.2023. Draft minutes were circulated and no comments were received from any of the member of the Committee.

Agenda item No. AS-114-02.

Sub: M/s. Porus Laboratories Private Limited - Request inclusion of Intermediate / R&D product in LoA under broad banding without change in revision in projections –Reg.

Unit information:

- a. Name of the unit : M/s. Porus Laboratories Private Limited
- b. LOA issued vide No. LOA No. 2(21)/APSEZ/2017 dated 14.09.2017
- c. Manufacturing : Speciality Chemicals
- d. Date of DCP : 01.04.2019.
- e. Validity of LOA : 31.03.2024.
- f. Present Status : NFE Positive and effecting exports.

The unit vide letter dated 27.09.2023 has requested this office to accord permission for the following Intermediate / R&D product under broad banding.

S. No	Name of the Product	HS Code	Annual Capacity	Annual Production value Rs. in Lakhs	Drug License issued by Govt. of AP, Drugs Control Admn.
1	Bis(4-hydroxybutyl) terephthalate (BHBT)	29121990	500	41.40	Drug License is not required being a intermediate organic chemical

The unit has furnished the following documents:

1. Process flow chart for the products.
2. List of raw materials for each product.
3. The unit has furnished a copy of CFO issued by AP Pollution Control Board, Vijayawada.

Utilization of R&D status:

in Kgs

S.No.	Name of the Product	Permitted Quantity as per CFO	Permitted quantity so far in UAC	Balance Quantity	Presently Applying	Balance available at present
1.	R&D products	3650 (10kgs per day)	Permitted 3000 kgs.	650	500	150

I/51592/2023

In terms of Rule 19 (2) of SEZ Rules,2006, the Approval Committee may 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 unit has fulfilled the requirements of rule 18 in respect of the inclusion of R&D product in LoA under broad banding.

Under ITC(HS) classification, Schedule 2 and 3 of ITC (HS), the above item are Free for export and there is no prohibition for export.

Request:

The request of the unit for inclusion of Intermediate / R&D product in the LoA, may be considered under broad banding within the existing capacity of the unit and for import / procurement of required raw materials. However, there is no change in the NFE.

The above proposal for Intermedidate / R&D product is placed before the UAC meeting for consideration.

Agenda item No. AS-114-03.

Sub: M/s. Escientia Advanced Sciences Pvt Ltd - Request for inclusion of Intermediate / R&D products in LoA under broad banding without change in revision in projections –Reg.

Unit information :

- Name of the Unit: M/s. Escientia Advanced Sciences Pvt Ltd
- LOA issued vide No. LOA No. 2(17)/APSEZ/2013 dated 21.10.2013
- Manufacturing : APIs(Bulk Drugs) and Fine /Speciality / Basic Chemicals
- Date of DCP : 17.04.2019
- Validity of LOA : 16.04.2024
- Present status: NFE Positive and effecting exports.

The unit vide letter dated 25.09.2023 has requested to accord permission for the following Intermediate /R&D products under broad banding.

S. No	Name of the Product	HS Code	Projected Annual Capacity	Annual Production value in Rs. In lakhs	Drug License issued by Govt. of AP, Drugs Control Admin.
1.	(4R,5R)-4-(5-bromopyridin-3-yl)-5-(2-chlorophenyl)oxazolidin-2-one	29319090	100 KG	122	Drug license not required being intermediate products.

Documents furnished by the Unit:

- Process flow chart for all the products.
- List of raw materials for each products.
- The unit has furnished a copy of CFO issued by AP Pollution Control Board, Vijayawada

Utilization of Intermediate /R&D status:

in Kgs

I/51592/2023

S.No.	Name of the Product	Permitted Quantity as per CFO	Permitted quantity so far in UAC	Balance Quantity	Presently Applying	Balance available at present
1.	Intermediate /R&D products	36500 (100kgs per day)	1857	34643	100	34543

Relevant Provisions:

In terms of Rule 19 (2) of SEZ Rules,2006, the Approval Committee may approve proposals for broad-banding, diversification,enhancement of capacity of production, change in the items of manufacture or service activity, if it meets the requirments of rule 18.

The unit has fulfilled the requirements of rule 18 in respect of the inclusion of R&D product in LoA under broad banding.

Under ITC(HS) classification, Schedule 2 and 3 of ITC (HS), the above item are Free for export and there is no prohibition for export.

Request:

The request of the unit for manufacture of above intermediate/R&D products may be considered under broad banding within the existing capacity of the unit and for import / procurement of required raw materials. However, there is no change in the NFE.

The above proposal for manufacture of intermediate / R&D products is placed before UAC for its consideration.

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