

**AGENDA FOR THE UNIT APPROVAL COMMITTEEs MEETING FOR THE VSEZ  
& PRIVATE SEZs OF ANDHRA PRADESH, TELANGANA UNDER THE CHAIRMANSHIP OF  
SHRI M.SRINIVAS, IRSME, ZONAL DEVELOPMENT COMMISSIONER TO BE HELD ON  
10.05.2023 THROUGH WEBEX**

**VSEZ AGENDA – ANDHRA PRADESH**

**Agenda Item No.01:- Ratification of the Minutes of the meeting held on 11.04.2023.**

The minutes of the UAC meeting held on 11.04.2023 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 02 :Proposal of M/s. Hilton Tobaccos Pvt. Ltd. for additional activity in their existing LoA- Reg.**

M/s. Hilton Tobaccos Pvt. Ltd. has informed that they have been granted approval for manufacture of Filter Rods in the UAC meeting held on 11.04.2023, subject to the condition that the same shall be for captive consumption and no DTA sale shall be allowed.

The unit, while referring to the discussion held in the UAC meeting dated: 11.04.2023, has informed that during the discussed it was informed that they won't be allowed to sell the products into DTA, but they will be allowed for self-use (captive consumption), as well as for Export. But, in the approved minutes placed on the website of VSEZ, the proposal was approved for the manufacture and for captive consumption but permission was not granted for export of the same.

In this connection, the unit has informed that they intend to export the Filter Rods manufactured by them.

In this regard kind reference is invited to the extract of the minutes of the UAC meeting held on 11.04.2023 which is re-produced below: .

“The Approval committee after due deliberations, approved the proposal for inclusion of additional activity i.e. manufacture of filter rods for Cigarettes subject to the condition that the entire production of filter rods manufactured shall be for captive consumption and no DTA clearance is allowed”. Accordingly, the approval was conveyed to the unit.

Now, the unit has requested for consideration of their request to allow them to export the Filter Rods manufactured by them.

Accordingly, the proposal is placed before UAC for consideration.

**Agenda No.03 : Request of M/s.V.V.Minerals for permission to store the material in the premises of their Unit – Ratification - Reg.**

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M/s.V.V.Minerals has informed that their sister concern M/s.Arima Minerals is engaged in the processing of Minerals and they are not having enough covered storage space to store the

materials (minerals) as such the same are lying in the open yard exposed to sun and rain. As a result the material is getting dampened and damaged due to intermittent rains.

Keeping in view of the above, M/s.V.V.Minerals has requested for permission to store the materials of their sister concern temporarily for a period of one year as they are having enough space for the above purpose.

The request has been forwarded to the Specified Officer for inspection of the premises earmarked to store the material of M/s.Arima Minerals.

The Specified Officer, VSEZ has inspected the premises proposed to store the materials and gave a report dated: 24.04.2023. The Specified Officer has informed that the request of the unit may be considered for a limited period of one year as a special case.

Based on the request of the unit and the Inspection report of the Specified Officer, the request of the M/s.V.V.Minerals to store the material of M/s.Arima Minerals in the premises of the unit has been considered by the Development Commissioner and approval was conveyed to the unit vide Ltr. dated: 02.05.2023 subject to ratification of the UAC.

In view of the above, the approval granted by the Development Commissioner, VSEZ vide letter dated: 02.05.2023 to M/s.VV Minerals to store the material of M/s.Arima Minerals in their premises for a temporary period of one year is placed before the Unit Approval Committee for ratification.

**Agenda No.04 : M/s.V.V.Minerals for permission for inclusion of additional products under Warehousing – Reg.**

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M/s.V.V.Minerals has informed that their sister concern M/s.Arima Minerals is engaged in the processing of Minerals and they are not having enough covered storage space to store the materials (minerals) as such the same are lying in the open yard exposed to sun and rain. As a result the material is getting dampened and damaged due to intermittent rains.

Keeping in view of the above, M/s.V.V.Minerals has requested for permission to store the materials of their sister concern temporarily for a period of one year as they are having enough space for the above purpose.

The request of M/s. V V Minerals has been forwarded to the Specified Officer, VSEZ to inspect the premises and to submit the report.

The Specified Officer has inspected the premises proposed to store the materials and gave a report dated: 24.04.2023. The Specified Officer has informed that the request of the unit may be considered for a limited period of one year as a special case subject to the following :-

1. Approval of surrendering the request (warehousing)
2. The space is added as additional storage space in the LoA of M/s. Arima Minerals
3. Maintenance of proper book of accounts for storage as well as movement of goods by M/s.Arima Minerals at both the places.

M/s.V.V.Minerals pursuant to the inspection, has informed that they have been granted approval for warehousing permission for the following products :

1. Granite Slabs
2. Granite Monuments
3. Granites
4. Table Top Granite
5. Marble
6. Basmati Rice
7. Woven Fabrics
8. Carton Box, Cooking Oil
9. Lubricant Oil
10. Garments
11. Furniture
12. Cement

The unit has informed that due to certain difficulties they are not in a position to render warehousing services in respect of these products and hence requested for surrendering/deletion of the above products and requested for inclusion of the following products for warehousing.

1. Garnet
2. Ilmenite
3. Zircon
4. Rutile
5. Silimanite
6. Leucoxene

M/s.VV Minerals intend to render warehouse services to their sister concern unit to store their material as they do not have enough covered storage space.

After the inspection by the Specified Officer, VSEZ they have decided to surrender (deletion) of the products which were permitted earlier for warehousing as they have not undertaken any warehousing activity with respect to the above products. Now, they want to include the following products under warehousing wherein they will be able to render the warehousing services.

1. Garnet
2. Ilmenite
3. Zircon
4. Rutile
5. Silimanite
6. Leucoxene

The unit is having Warehousing approval to store the materials of the clients and dispatch them as per their instructions. As the approval granted earlier is a specific approval to warehouse only certain products which the unit has not undertaken any activity of warehousing those products. Hence the unit requested to delete them and include the above products.

The proposal of the unit for deletion of the products mentioned and inclusion of the above products under warehousing is placed before UAC for consideration.

**PVT SEZ AGENDA – ANDHRA PRADESH**

**Agenda Item No.01:- Ratification of the Minutes of the meeting held on 11.04.2023.**

The minutes of the UAC meeting held on 11.04.2023 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. 02 : Request of M/s. Pharmazell (india) Pvt Ltd , a unit in RamkyPharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.**

M/s. Pharmazell (India) Pvt Ltd has requested for inclusion of the following additional product in the LoA:-

S.No	Name of the product	ITC code No.	Annual Capacity
01	ISAVUCONAZONIUM SULFATE IH	29341000	500 gm

The unit has informed that the above product is being manufactured initially under the category “ R & D product for validation purpose (around 500 gm) which was duly approved in the CFO issued by APPCB and will go for commercial lots based on the orders received from their customers. The above product doesn't fall under the prohibited items.

The unit has submitted that the said quantities are within the approved and permitted limits only as per the CFO and they will comply with the same and enclosed copy of the CFO issued by APPCB. The unit proposed to manufacture the above product in their existing production / R&D blocks only. Hence no additional investment is required.

The unit has submitted the Process details, Critical Equipment required, Raw Materials consumed and their Consumption coefficients.

The unit has submitted Drug License for the above product in Form CT-11 issued by Central Licencing Authority dated 20.03.2023 for examination , Test and Analysis. The unit also submitted Consent order No. APPCB/VSP/152/HO/CFO/2021 dated :09.04.2021 issued by APPCB, Vijayawada.

The above product with ITC HS code 2934100 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. 03 : Request of M/s. Pfizer Healthcare India Pvt Ltd , a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.**

M/s. Pfizer Healthcare India Pvt. Ltd a unit in Ramky Pharma SEZ, Parawada, has requested for inclusion of the following additional products in the existing LoA. The unit has been advised to submit Drug Controller License copy and CFE/CMP from the AP Pollution Control Board Authorities vide this office letter dated 31.03.2023.

In response, the unit has submitted copy of License Retention Certificate vide File No. HMF07-14051/274/2023-Admn-DCA dated 02.03.2023 valid from 30.03.2023 to 29.03.2028 issued by Drug Control Department. With reference to CFE/CFO, the unit has informed that their unit is a Sterile Injectable Manufacturing unit (Formulation unit) ,falling under Orange Category of Industries. The APPCB does not issue product specific approval in the case of Formulations of Pharma Products. Hence there is no requirement of CFO/CFE for every additional product in the case of Formulations.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	Annual Capacity (in Nos.)
1	Potassium Acetate Injection, USP, 100 mEq/50 mL (2 mEq/mL) (50mL fill in 50 mL single dose vial)	Injectable	30049099	20,00,000
2	Potassium Acetate Injection, USP, 40 mEq/20 mL (2 mEq/mL) (20mL fill in 30 mL single dose vial)	Injectable	30049099	10,00,000

The unit has informed that they have taken order to manufacture the above product. In this regard they have submitted process flow chart, Route of Synthesis and List of Raw materials. The unit has submitted that the above products are free for export and submitted copy of draft ITCHS Export Policy, 2019 in respect of above ITCHS codes as a proof.

The above product with ITC HS code 30049099 are free for export 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. 04 : Request of M/s. Aragen Life Sciences Pvt LTd , a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.**

M/s. Aragen Life Sciences Pvt LTd. a unit in Ramky Pharma SEZ, Parawada, vide letter dated. 05.04.2023 has requested for inclusion of following additional products in the existing LoA. :

S. No	Name of the Product	Intermediate/AP I	ITC HS Code	Annual Capacity IN KG
1	N-((S)-6-amino-1-(((S)-1-(((S)-1-(((R)-1,6-diamino-1-oxohexan-2-yl)amino)-1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)amino)-1-oxohexan-2-yl)palmitamide [CDS-0348/STG-01]	Intermediate	2902 90 90	1
2	N-((S)-6-amino-1-(((S)-1-(((S)-1-(((R)-1,6-diamino-1-oxohexan-2-yl)amino)-1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)amino)-1-oxohexan-2-yl)palmitamide di-hippurate [CDS-0348/STG-02]	Intermediate	2912 29 90	1
3	(2-(benzyloxy)-4-methoxy-6-methylpyridin-3-yl)methanaminium benzoate	Intermediate	2933 29 90	1000

The unit has informed that the above products are Intermediates hence Drug Licence is not required. The above products are Custom Chemical Synthesis (CCS) products covered in CFO file No. APPCB/11022/17/2021-Tec-CFO-APPCB at SI.No.33 of License copy. The unit has submitted APPCB renewal copy of consent and authorisation order dated 23.08.2022.

Unit has submitted the Process details, Critical Equipment required, Raw Materials consumed and their Consumption coefficients.

The above product with ITC HS code 2902 90 90 , 2912 29 90 and 2933 29 90 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.

**Agenda Item No. 05 : Request of M/s. Deccan Fine Chemical (India) PVt Ltd, a unit in M/s. Deccan Fine Chemical (India) PVt Ltd SEZ, Visakhapatnam for inclusion of additional products in the LoA.**

M/s. Deccan Fine Chemical (India) PVt Ltd.a unit in Deccan Fine Chemicals SEZ, Payakaraopeta, Visakhapatnam vide letter dated. 05.04.2023 has requested for inclusion of the following additional products in the existing LOA.

S.No	Product Name	ITCHS Code	Annual capacity (in MT)
1	Mandipropamid (2-(4-chloro-phenyl)-N-[2-(3-methoxy-4-prop-2-	38089290	50 MT

	ynyloxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide)		
2	Disulfure (4,4'-dithiobis(5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-1H-pyrazole-3-carbonitrile)	29331990	200MT
3	CS-Cholcone (4-((2E)-3-(3,5-dichloro-4-fluorophenyl)4,4,4trifluorobut-2-enoyl)-N-[(4R)-2-ethyl-3-oxo-1,2-oxazolidin-4-yl]-2-methylbenzamide)	29349990	200 MT
4	MFBA (3-Methyl-benzamido-2-fluoro-benzoic acid)	29163990	30 MT
5	MY-100 (OXAZICLOMEFONE)	38089390	15 MT
6	Proquinazid (6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one)	38089290	50 MT

The unit has informed that there will not be any change in the installed capacity even after adding the new products, as the new products will be manufactured within the overall capacity. Permitted earlier. And there is no additional investment and no change in export turnover and export obligation as the export of new products also will be within the overall export projections submitted earlier.

The unit has submitted following undertaking:

- The above products are not appearing in the list of Montreal protocol on substances that deplete the Ozone layer.
- The above items are not prohibited (or) negative (or) otherwise banned (or) figured in the list of SCOMET items for export.

The unit has submitted that they have obtained permission/NOC from Pollution Control Board of A.P. for the above products as per provisions in the relevant Act/Laws.

As verified from APPCB copies , the products at SI.No 1, 2 & 4 are having approvals for below mentioned capacities and SI.No. 3,5 & 6 are not showw in the APPCB copies.

S.No	Product Name	ITCHS Code	Annual capacity (in MT)
1	Mandipropamid (2-(4-chloro-phenyl)-N-[2-(3-methoxy-4-prop-2-ynyloxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide)	38089290	50 MT
2	Disulfure (4,4'-dithiobis(5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-1H-pyrazole-3-carbonitrile)	29331990	200MT
3	MFBA (3-Methyl-benzamido-2-fluoro-benzoic acid)	29163990	30 MT

The above product with ITC HS code 38089290, 29331990 and 29163990 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 above products for broad banding, diversification, enhancement of capacity of production, change in the items of manufacture or service activity

**Agenda Item No. 06 : 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	Sapropterin Dihydrochloride Tablets	100 mg	Mil	0.07	30049099
2	Mycophenolate Mofetil Capsules USP	250 mg	Mil	5.33	30049099
3	Prednisolone Tablets USP	5 mg	Mil	0.44	30049099
4	Pantoprazole Sodium for Delayed-Release Oral Suspension	40 mg	Mil	0.94	30049099
5	Methocarbamol Tablets USP	500 mg	Mil	27	30049099
6	Mycophenolate Mofetil Tablets USP	500 mg	Mil	27	30049099
7	Methylprednisolone Tablets USP	4 mg	Mil	13.3	30049099
8	Methylprednisolone Tablets USP	16 mg	Mil	0.132	30049099
9	Diazepam Tablets USP	2 mg	Mil	8.43	30049099
10	Diazepam Tablets USP	5 mg	Mil	26.96	30049099
11	Diazepam Tablets USP	10 mg	Mil	16.93	30049099
12	Budesonide Controlled Ilea Release Capsules	3 mg	Mil	1.03	30049099

The unit has submitted Drug License Copy issued by DCA, GOAP videl FORM -28 dated:01.04.2021 valid upto 31.03.2028. The unit has furnished flow charts and NFE for each category of the proposed product. The proposed Annual projections for the above products are Export of USD 61,59,431 USD, Import of USD 6,12,945 and NFE of USD 55,46,486.



The above products 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 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. 07 : Request of Dr. Reddy's Laboratories LTd, CTO SEZ Process unit-01, a unit in Dr. Reddy's Laboratories LTd SEZ, Ranasthalam, Srikakulam for inclusion of additional products in the LoA.**

Dr. Reddy's Laboratories LTd, CTO 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	AnnualCapacity IN KG	Apprx value of the goods(Rs)
1	Relugolix	API	29339900	114 KG	7.47 Crores

The unit has submitted Test License in Form-29 issued by Drug Control Authority of the above product for a quantity of 114 Kgs 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. As the drug licences obtained is for R & D for the above product which falls under SI.38 of CFO and the proposed capacity falls within the limits.

The above product with ITC HS code 29339900 is free for export 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. 08- Request of M/s. Mylan Laboratories Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional product in the LoA - Reg.**

M/s. Mylan Laboratories Limited a unit in Ramky Pharma SEZ, Parawada, has requested for inclusion of following additional product in the existing LoA:

S. No	Name of the product	Intermediate /API/Bulk Drug	HSN Code	Annual Capacity (IN Kgs.)
1.	Olsalazine Sodium	API	29183090	2000 kgs.
2.	Dabigatran Etexilate Mesylate	API	29332990	60000 Kgs

The unit has been advised to furnish the copy of CFE/CMP from the APPCB. The unit vide letter dated 24.04.2023 has informed that the proposed product is part of **validation products** and which was covered in their CFO File No. APPCB-11022/104/2020-TEC-CFO-APPCB as validation products can be manufactured **66.67 Kgs per day** (Table No.3 at Sl.No.10).

The unit has submitted Drug License for the above products in respect of vide File No. HMF07-14051/1813/2022-ADMIN-DCA dated: 01.03.2023 valid upto: 28.02.2026 and File No. HMF07-14051/681/2023-ADMIN-DCA dated: 26.04.2023.

The unit has also informed that there are no changes in projection value either in products or raw materials and NFE. The unit has also declared that the materials are not figuring in the list of prohibited or restricted items.

The above product with ITC HS code 29183090 and 29332990 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.

Proposal placed before UAC for consideration.

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