

**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 11.03.2024
THROUGH HYBRID MODE AT 11.00 AM**

PVT SEZs – ANDHRA PRADESH

Agenda Item No. AP-182.01 : Proposal of M/s .Pfizer Healthcare India Pvt Ltd, a unit in M/s Visakha Pharma City Limited SEZ, Parawada, Anakapalli for Change of Board of Directors – Intimation - Board of Directors –reg.

M/s. Pfizer Healthcare India Pvt Limited has informed that there is change in Board of Directors. It is informed that Ms.Sweta Agarwal has resigned and one new Director Mr. Andrew Mckillop has joined on 25.01.2024.

The unit has submitted the following documents towards change of their Company Board of Directors.

1. Latest/New Board of Directors List
2. Before change Board of Directors List
3. Board of Resolution of Appointment of New/ Additional Director
4. Passport copy of New Director
5. Form No. DIR 12 Signed
6. Board resolutions for acceptance of resignations Director Mr. Sweta Agarwal
7. Form No. DIR 12 Signed for evidence for cessation of Director

List of Directors before and after change :-

SI.No	Name	Desgn.	SI.No.	Name	Desgn.
1.	Andrew David Chatfield	Director	1.	Andrew David Chatfield	Director
2.	Kannan Natarajan	Director	2.	Kannan Natarajan	Director
3.	Vikram Shukla	Director	3.	Vikram Shukla	Director
4.	Fiona MacCarthy	Director	4.	Fiona MacCarthy	Director
5.	Sweta Agarwal	Director	5.	Andrew Mckillop	Add.Director

Request of the unit for change in Board of Directors is placed before the Approval Committee consideration.

Agenda Item No. AP-182.02: Request of M/s Pfizer Healthcare India Pvt Ltd , unit in M/s Visakha Pharma City Limited SEZ, Parawada, Anapalli for inclusion of additional product in the LoA-Reg.

M/s Pfizer Healthcare India Pvt Ltd., has requested for inclusion of the following additional products in the existing LoA.

S. No	Name of the product	Intermediate /API/Bulk Drug	ITC HS Code	UOM	Annual Capacity (in Nos.)
1	Dexmedetomidine Hydrochloride Injection 80mcg/20 mL (4mcg/mL) (20mL in 20mL Glass Vial	Injectable	30049099	VIAL	55,800
2	Dexmedetomidine Hydrochloride Injection 200mcg/50 mL (4mcg/mL) (50mL in 50mL Glass Vial	Injectable	30049099	VIAL	22,500
3	Dexmedetomidine Hydrochloride Injection 400mcg/100 mL (4mcg/mL) (100mL in 100mL Glass Vial	Injectable	30049099	VIAL	11,400

The unit has submitted Test License in Form-29 issued by Drug Control Authority in respect of the above products exclusively for the purpose of R & D/ formulation development/manufacturing of Exhibit batches.

The unit has informed that the Drug licenses is issued for Testing and Analysis purpose and hence there will be no commercial sale of the products until the same is commercialised.

The unit has furnished the copy of Drug License No. HMF07-14051/118/2024-ADMIN-DCA dated 05.02.2024 which shall be in force for three years from the date of issue.

The unit has submitted the copy of the CFE order No. 7589/APPCB/ZO-VSP/VSP/CTO/2023 dated 01.12.2023. The details of the products, quantity permitted, utilised and balance available is furnished hereunder for perusal please.

Dosage Form	Quantity s per CFO	Qty. Manufactured/utilised as on 31.01.2024	Balance Quantity available	Present applying Qty.
Vials	499.920 Millions	143.295 Million	356.625 Millions	0.0897 Millions

Specified Officer, M/s Visakha Pharmacy SEZ has informed that the above products are free for export as per the HSN code of the product.

The unit has submitted process flow chart and List of Raw materials.

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 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 Unit Approval Committee for consideration in terms of the above provision.

Agenda Item No. AP-182.03: Request of M/s Pfizer Healthcare India Pvt Ltd , unit in M/s Visakha Pharma City Limited SEZ, Parawada, Anakapalli has requested for inclusion of additional product in the LoA-Reg.

M/s Pfizer Healthcare India Pvt Ltd has requested for inclusion of the following additional products in the existing LoA.

S.No	Name of the product	Intermediate /API/BulkDrug	ITC HS Code	UOM	Annual Capacity (in Nos.)
1	Aminocaproic acid Injection, USP 5 g/20 mL (250 mg/mL) (20 ml fill in 30mL Vial)	Injectable	30049099	VIAL	41,63,000

The unit has furnished the copy of Drug License in respect of the above products vide File No. HMF07-14051/376/2024-ADMIN-DCA dated 05.03.2024, in which the above product has been permitted to manufacture as an additional item under their Drug Licenses in Form-28 bearing NO. 08/VP/AP/2013/F/R dt. 30.03.2013 and the same is valid upto 29.03.2028.

The unit has submitted the copy of the CFE order No. 7589/APPCB/ZO-VSP/VSP/CTO/2023 dated 01.12.2023. The details of the products, quantity permitted, utilised and balance available is furnished hereunder for perusal please

Dosage Form	Quantity s per CFO	Qty. Manufactured/utilised as on 29.02.2024	Balance Quantity available	Present applying Qty.
Vials	499.920 Millions	156.995 Millions	342.925 Millions	4.163 Millions

The unit has informed that there will be no change in Annual capacity and exports due to addition of the above product.

The unit has submitted process flow chart and List of Raw materials.

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 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 Unit Approval Committee for consideration in terms of the above provision.

Agenda Item No. AP-182.04 : Proposal of M/s.Ace Urban Hitech City Limited SEZ for IT/ITES at Sy.No. 52 & 53/1, Kesarapalli Village, Gannavaram Mandal, Krishna District, Andhra Pradesh for setting up of First Aid Centre/ OHC and providing ambulance facility in their SEZ –reg.

M/s. Ace Urban Hitech City Limited, SEZ Developer for IT/ITES at Sy.No. 52 & 53/1, Kesarapalli Village, Gannavaram Mandal, Krishna District, Andhra Pradesh vide letter dated 10.02.2024 has informed that they intend to set-up a First Aid Centre/Occupational Health Centre (OHC) and also provide an Ambulance in their SEZ for the exclusive use of the SEZ units in Ace Urban IT/ITES SEZ.

In view of the health exigencies occurred on account of COVID-19 pandemic across globe and also considering post Covid health effects and to bring the new normalcy (i.e., encouraging employees working from office), they felt setting up a first aid centre/OHC is very essential.

In this connection, they stated that they have an arrangement with Vijaya Super Speciality Hospital, Vijayawada for providing first aid centre/OHC services along with ambulances facilities for exclusive use of units in Ace Urban IT/ITES SEZ, for which they earmarked about 100 Sft. At Ground Floor, Medha IT Tower, Ace Urban IT/ITES SEZ, for first aid centre/OHC for exclusive use of the SEZ Units. Vijaya Super Speciality Hospital, Vijayawada for providing first aid centre/OHC and ambulance services in Ace Urban IT/ITES SEZ.

As per provision to sub-rule 5 of rule 11 of SEZ Rules, 2006, first aid centres can be created and as per Annexure-1, entry B (1) of Instruction No. 50 dated 15.03.2010 issued by the Govt. of India Ministry of Commerce & Industry, Department of Commerce (SEZ Section), setting-up First Aid centre is a default authorised operation in IT/ITES SEZs, that can be undertaken by the Developers from the date of notification of the SEZ.

Under the Instructions No. 50 dated 15.03.2010, Annexure (B) reads as follows:

“IT/ITES /EH&SW, Biotechnology/Gems and Jewellery SEZ/ handicrafts/Non conventional Energy including solar energy equipments [in addition to those listed at (A)]

1. One First-Aid post or 10-bedded Clinic/Poly Clinic/ Pharmacy/Medical Centre

In pursuance of the above said Instruction No.50 dated 15.03.2010 and Rule 9 and Provision to Sub-rule 5 of rule 11 of SEZ Rules, 2006 they have requested for approval to undertake the below mentioned authorised activity for the exclusive and common use of the SEZ units in Ace Urban IT/ITES SEZ.

1. To operate First Aid Centre/Occupational Health Centre (OHC) in 100 sft. And
2. To provide Ambulance service in Ace Urban Hitech Limited for the exclusive use of SEZ units

Further they have informed that the above services will be provided for use of the units without any charges.

The Specified Officer, M/s. Ace Urban Hitech City Limited, IT/ITES SEZ, Vijayawada has informed that the Developer has earmarked 100 SFT room/space in the Ground Floor besides the existing Canteen, for providing the facility of First Aid Centre/OHC. The proposed room appears to be sufficient for providing /operating the First Aid Centre. The request of M/s.Ace Urban Hitech City Limited may be considered, in terms of sub-rule 5 of Rules 11 of the SEZ Rules, 2006, as the First Aid Centre/ OHC falls under the 'default list of authorized operations' in terms of Instructions No. 50 dated 15.03.2010 issued by the Ministry of Commerce & Industry under Annexure-1(B) and as the services under the First Aid Centre will be exclusively utilized by the employees working in the units in Ace Urban Hitech City SEZ.

The request is placed before Unit Approval Committee for consideration in terms of the above provision

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Agenda Item No. AP-182.05: Request of M/s Alivira Animal Health Limited., a unit in Visakha Pharmacity Ltd., SEZ Parawada, Visakhapatnam for inclusion of additional product in the LoA -reg

M/s Alivira Animal Health Limited has requested for inclusion of the following additional products in the existing LoA.

S. No	Item of Manufacture	API/INTERMEDIATE	PROBABALE ITC(HS)	Annaul Capacity
1	Levamisole	API	29349990	2.4 Kgs

The Unit has submitted drug license copy in the name of the product 'Levamisole for purpose of Examination, Test or Analysis, which is valid upto 15.07.2024.

The unit has furnished the copy of Drug Licenses in respect of the above product vide File No. HMF07-14051/1188/2020-DD-DDCA dated 16.07.2021 which shall be in force for three years from the date of issue.

The unit has submitted a copy of APPCB consent and authorisation order dated 18.06.2021 as per which the above product falls under S.No. 47 for 2.4 Kgs per annum.

S.No.	CFO File No.	Name of the product	Permitted quantity/annum	Utilized so far	Balance available
1	47	Levamisole	73000 Kgs	14.958 Kgs	72985.042 Kgs

The unit has informed that Net Foreign Exchange from the export of the above product estimated around USD 1.60 Lakh with existing facility and manpower hence no additional investment and employment envisaged.

The unit has submitted the Process flowchart, manufacturing process and details of List of Raw materials.

The above product with ITC HS code 29349990 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.

The request of the unit is placed before Unit Approval Committee for consideration in terms of the above provision.