

I/56233/2024

**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 25.01.2024
THROUGH WEBEX AT 11.00 AM**

PVT SEZs – ANDHRA PRADESH

Agenda Item No.AP-179.01 :- Ratification of the Minutes of the meeting held on 10.01.2024.

The minutes of the UAC meeting held on 10.01.2024 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-179.02 : Request of M/s. Divi's Laboratories Limited (DSN SEZ unit), a unit in M/s. Divi's Laboratories Limited for inclusion of additional products in the existing LoA - Reg.

M/s. Divi's Laboratories Limited (DSN SEZ unit) vide ltr dated 11.01.24 has requested for inclusion of the following additional product in the LoA. The details of the products proposed for inclusion is furnished hereunder :-

S.No	Name of the product to be covered under R&D	Annual production Capacity (MT) (under R& D products only,)	ITC Code No (Certified by Specified officer)	Eligibility TPA (APPCB) (Ton Per Annum) under R&D	Quantity already availed of other products- under R&D	Present applying Qty.	Balance Available at R&D
01	Dolutegravir intermediate/ FBPO (GSK3184462A)	2.00 MT	29242190 (free)	2 MT	Nil	2 MT	2 MT

The unit has submitted the above details of Product manufacturing eligibility as per APPCB license dated 19.03.2021 at S.No: 57- Dolutegravir for inclusion of additional product manufacturing in their SEZ unit.

Unit has submitted an undertaking that the above products are Intermediate products and do not require Drug License.

The Net Foreign Exchange (NFE) from the export of the above proposed products in the next five years is estimated around Rs. 15 Cr and there is no change in no additional employment envisaged.

Specified Officer vide letter dated 11.01.2024 has submitted that the above proposed products with ITC HS 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-179.03:- Request of M/s. Alivira Animal Health Limited , a unit in M/s Visakha Pharmacy Ltd SEZ, Parawada, Visakhaaptanm for inclusion of additional product in the existing LoA - Reg.

M/s. Alivira Animal Healthcare Ltd vide letter dated 05.01.2024 has requested for inclusion of the following additional products in the existing LoA. The details of the products proposed for inclusion are furnished hereunder :-

I/56233/2024

SI.NO	ITEM OF MANUFACTURE	API/ INTERMEDAITE	PROBABLE ITC(HS)	ANNUAL CAPACITY
1	Levamisole	API	29349990	2.4 kgs

Unit has been advised to furnish quantities availed against the permissible quantities by APPCB. The unit vide letter dated 18.01.2024 has submitted the following details related to approvals and remaining balance available with them with reference to CFO order.

CFO File No	Name of the Product	Permitted Quantity/annum	Utilised So far	Balance Available	Presently applying
47	Levamisole	200 kgs	14.9 kgs	185.1	2.5 kgs

The unit has submitted Drug License copies dated 16.07.2021 in Form -29 wherein the product approved for 2400 Grams and APPCB for CFE dated 18.06.2021. The unit has submitted the process details, and raw-materials and the same are enclosed to the agenda.

Unit has projected Net Foreign Exchange from the export of the above product estimated around USD 1.60 Lakh with existing facility and manpower.

Unit has submitted the above details to Specified Officer for certification regarding HSN code. The above product with ITC HS code 29349990 (other) 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-179.04 : Request of 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.

(i)

M/s. Dr. Reddy's Lab Ltd, CTO SEZ Process Unit-01 vide letter dated 06.10.2023 requested for inclusion of the following additional product in the existing LoA. The details of the product proposed for inclusion is furnished hereunder :-

Sl.No	Item of Manufacture	API	ITCHS Code	Projected Qty (Nos)	Approx. Value of the goods (Rs)
1	VOCLOSPORIN	API	29339990	40 kG	82 Cr

The unit has submitted Drug License copy dated 18.05.2023 for the above product with a quantity for 15 KGs issued in Form-29 for purpose of examination, Test or analysis purpose.

The unit has been advised to submit the APPCB approval granted to the unit. In response, the unit vide letter dated 08.11.2023 has informed that the proposed product 'VOCLOSPORIN' is an R & D product and was applied for inclusion in the R & D category. The unit vide email dated 8.12.23 has submitted CFO copy dated 08.01. 2013.

Request of the unit placed in UAC meeting held on 27.12.2023 and UAC has advised the unit to submit the CFO copy showing the above details for taking further action .

I/56233/2024

Unit vide letter dated 08.1.2024 and 19.01.2024 has informed that they have obtained the test license for the proposed product vide file No.HMF07-14051/850/2-23-Admn-DCA dated 18.05.2023 for the purpose of examination of test/analysis and not for commercial use.

Unit has informed that as per the CFO dated 02.03.2023, they have proposed for manufacturing of R & D products to the tune of **40Kgs per day** (Ref to the point No. 38 R & D Products Pilot Plant/Run products(Bulk drugs & Intermediates). The unit has furnished the details of the approval granted during the year and the details were enclosed to the agenda for perusal. The unit has informed that they are within the limit of the approved quantity for manufacture of R & D products. The details of the approved, utilised and balance available quantities is furnished hereunder for information.

Description of the product as per APPCB	Quantity permitted as per APPCB approval	Quantity utilized so far against the APPCB approval	Balance quantity available	Quantity request for approval at present
R & D Products Pilot Plant Run products(Bulk drugs & Intermediates)	14.6* Ton /Annum	1.274* Ton/Annum	13.326 Ton/Annum	0.04* Ton/Annum

*quantities in Kg's per day is converted in to Ton per annum.

Further the unit has submitted that the test license is given for 15 kgs and they have made request for 45kgs as projected quantities. The unit has requested to consider the quantity as per **the test licenses quantity only** and requested to include 'VOCLOSPORIN' for a quantity of 15 kgs as an additional product in their LOA.

SO, has certified that 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.

(ii) : Request of 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.

Dr. Reddy's Lab Ltd, CTO SEZ SEZ Process Unit-01vide letter dated 21.12.2023 requested for inclusion of the following additional product in the existing LoA. Unit has been advised to submit the details of quantities availed and balance available against their CFE order.

Unit vide letter dated : 19.01.2024 has furnished the details.

The details of the product proposed for inclusion is furnished hereunder :-

Sl.No	Item of Manufacture	API/Bulk Drug	ITCHS Code	Projected Qty (Nos)	Approx. Value of the goods (Rs)
1	Tucatinib	API	29349990	330 Kg	15 Crores

Unit has submitted following details regarding quantity availed and balance available against the APPCB consent order.

Description of the product as per APPCB	Quantity permitted as per APPCB approval	Quantity utilized so far against the APPCB approval	Balance quantity available	Quantity request for approval at person

I/56233/2024

R & D Products Pilot Plant Run products(Bulk drugs & Intermediates	14.6* Ton /Annum	1.274* Ton/Annum	13.326 Ton/Annum	0.33* Ton/Annum
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*quantities in Kg's per day is converted in to Ton per annum.

The unit has submitted Drug License copy dated 16.08.2023 for the above product with a quantity of 14.5 Kgs issued in Form-29 for the purpose of R & D formulation development/manufacture of Exhibit batches.

Unit has submitted CFO copy dated 02.03.2023 for the formulation products which is mentioned in Page No.7 under R & D Products Pilot Plant Run Products (bulk Drugs & Intermediates) (wherein approval is given for 40 Kgs per day).

SO, has certified that the above product with ITC HS code 30049049 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-179.05 : Request of M/s. Wipro Ltd, unit in Wipro Ltd SEZ, Visakhapatnam –Intimation for change in the List of Directors as on November, 2023

M/s. Wipro Limited, unit in Wipro SEZ, Visakhapatnam vide letter dated 09.01.2024 has submitted the list of directors in respect of their unit as on November, 2023.

Unit has informed that one of their Board Director Mr. Ireena Vittal is changed due to retirement and same vacancy was replaced with another person **Mr.Kannan Narayanan Srinivasa** as per the Board Resolution of M/s Wipro Ltd. The details of the board members before and after is furnished hereunder:

Sl.No.	Before	Sl.No.	After
1.	Mr.Rishad A Premji	1.	Mr.Rishad A Premji
2.	Mr.Thierry Delaporte	2.	Mr.Thierry Delaporte
3.	Mr.Azim Hasham Premji	3.	Mr.Azim Hasham Premji
4.	Mr.Ireena Vittal – Retired	4.	Mr.Kannan Narayana Srinivasa – Joined
5.	Dr.Patric John Ennis	5.	Dr.Patric John Ennis
6.	Mr.Patric Lucien Andre Dupuis	6.	Mr.Patric Lucien Andre Dupuis
7.	Mr.Deepika Madhav Satwalekar	7.	Mr.Deepika Madhav Satwalekar
8.	Mr.Tulasi Naidu	8.	Mr.Tulasi Naidu
9.	Ms.Paivi Rekonen	9.	Ms.Paivi Rekonen

Unit has informed that there is no change in the name of the entity, share holder pattern, business management and it is only a change of Director and submitted following requisite documents

1. The list of Directors before and after
2. Copy of Passport of new Director
3. Copy of Board Resolutions
4. Form No. Dir-12

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