

**AGENDA FOR THE APPROVAL COMMITTEEs MEETING FOR VSEZ
& PRIVATE SEZs OF ANDHRA PRADESH UNDER THE CHAIRMANSHIP OF SHRI SRINIVAS
MUPPAALA, IRSME, ZONAL DEVELOPMENT COMMISSIONER TO BE HELD ON 23.02.2024
THROUGH WEBEX AT 11.00 AM**

PVT SEZs – ANDHRA PRADESH

Agenda Item No.AP-181.01 :- Ratification of the Minutes of the meeting held on 09.02.2024.

The minutes of the UAC meeting held on 09.02.2024 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-181.02 : Request of M/s. APL Health Care Limited, unit in APIIC Limited, Naidupeta SEZ for inclusion of Addl. Products - Reg.

M/s. APL Health Care Limited vide ltr. dated : 14.02.2024 has requested for inclusion of the following additional products in the LoA. The details of the products proposed for inclusion are furnished hereunder :-

S.No	Product Name	Strength (mg)	Dosage Form	Annual Capacity (in millions)
1	Haloperidol Tablets USP	0.5	Tablets	4.02
2	Haloperidol Tablets USP	5	Tablets	17.68
3	Haloperidol Tablets USP	10	Tablets	11.06
4	Haloperidol Tablets USP	1	Tablets	5.84
5	Haloperidol Tablets USP	2	Tablets	5.76
6	Mycophenolic Acid Delayed-Release Tablets	180	Tablets	11.35
7	Mycophenolic Acid Delayed-Release Tablets	360	Tablets	9.21
8	Nitrofurantoin oral suspension	50mg /5mL	Oral suspension	0.04
9	Trazodone Hydrochloride Tablets USP	150 mg	Tablets	8.40
10	Trazodone Hydrochloride Tablets USP	300 mg	Tablets	2.10

The unit has submitted the copies of the Drug LicenseNo.04/NLR/AP/2016/F/CC, dated: 01.04.2021 in Form-25 valid upto 31.03.2026. HMF07-19024/283/2023-DD-DDCA dated:02.01.2024, HMF07-19024/16/2024-DD-DDCA dated: 29.01.2024, HMF07-19024/182/2023-DD-DDCA dated:19.10.2023,HMF07-19024/286/2023-DD-DDCA dated:11.01.2024 and HMF07-19024/288/2023-DD-DDCA dated:22.01.2024.

The unit has submitted copy of the CFE Order No.255/APPCB/ZO/VJA/CFE/2022 dated:16.08.2022. The details of the products, quantity permitted, utilised and balance available is furnished hereunder for perusal please.

Sl.No.	Dosage Form	Quantity as per CFO	Qty. manufactured/Utilised	Remaining balance
1.	Tablets	850 Millions per month	558.308 millions /month	291.692 millions/month
2.	Liquids	0.4 millions/month	0.353 millions/month	0.047 millions.month

Summary

Dosage Form	Qty available as per CFE order	Qty proposed for inclusion	Balance will be available
Tablets	291.692 millions/month (or) 3500.304 millions/PA	75.42 millions/PA	3424.884 millions/PA
Liquids	0.564 millions/PA	0.04 millions/PA	0.524 millions/PA

The unit has informed with the existing infrastructure, investment and employment the proposed products will be manufactured and there is no requirement of additional investment.

As per the Specified Officer report, the said products are not falling under the restricted/prohibited category for export.

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.

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

Agenda Item No.AP-181.03 : Request of M/s.Divi's Laboratories Limited (DSN SEZ Unit), unit in M/s.Divi's Laboratories Limited SEZ for inclusion of Addl. Products - Reg

M/s. Divi's Laboratories Limited(DSN SEZ Unit) vide ltr. dated : 09.02.2024 has requested for inclusion of the following additional products in the LoA. The details of the product 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)
	<u>R & D PRODUCTS</u>		
01	(R)-5,8-dichloro-7-(methoxy (oxetan-3-yl) methyl) isochroman-1-one / 5,8-Dichloro-7-[(R)-Methoxy(oxetan-3-yl) methyl]-3,4-dihydro-1H-2-benzopyran-1-one (PF-07848500) - Intermediate	1 MT	29329990 (Free)

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
100 MT	77.2 MT	1 MT	21.8 MT

As per APPCB license dated 19.03.2021 at S.No: 93, the details of the products, quantity permitted, utilised and balance available is furnished above for perusal please

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 at around Rs.83 Cr and there is no additional employment envisaged.

Specified Officer vide letter dated 19.12.2023 has submitted that the above proposed product with above ITC HS 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 the UAC for consideration.

Agenda Item No.AP-181.04 : Request of M/s.Aragen Life Sciences Limited, unit in M/s.Visakha Pharma City Limited SEZ for inclusion of Addl. Products – Reg

M/s. Aragen Life Sciences Limited vide ltr. dated : 19.02.2024 has requested for inclusion of the following additional products in the LoA. The details of the product proposed for inclusion is furnished hereunder :-

S. No	Name of the Product	Intermediate/API	HSN Code	Annual Capacity IN KG
1	2-bromo-6-fluorobenzaldehyde (PF-04494988) [CDS-0420/STG-01]	Intermediate	2913 00 90	1000 Kg
2	2-((1r,4S)-4-((benzyloxy)methyl)cyclohexyl)-N-(1-((1S,2R)-2-fluorocyclopropyl)-2-oxo-1,2-dihydropyridin-3-yl)-6-isopropoxy-2H-indazole-5-carboxamide	Intermediate	2933 39 90	450 KG
3	N-(1-((1S,2R)-2-fluorocyclopropyl)-2-oxo-1,2-dihydropyridin-3-yl)-2-((1r,4S)-4-(hydroxymethyl)cyclohexyl)-6-isopropoxy-2H-indazole-5-carboxamide	Intermediate	2933 39 90	350 KG
4	N-(1-((1S,2R)-2-fluorocyclopropyl)-2-oxo-1,2-dihydropyridin-3-yl)-2-((1r,4S)-4-formylcyclohexyl)-6-isopropoxy-2H-indazole-5-carboxamide	Intermediate	2933 99 90	210 KG
5	2-((1r,4S)-4-((4-(3-(2,4-dioxotetrahydropyrimidin-1(2H)-yl)-5-fluoro-1-methyl-1H-indazol-6-yl)piperidin-1-yl)methyl)cyclohexyl)-N-(1-((1S,2R)-2-fluorocyclopropyl)-2-oxo-1,2-dihydropyridin-3-yl)-6-isopropoxy-2H-indazole-5-carboxamide	Intermediate	2933 99 90	110 KG
6	1-(5-fluoro-1-methyl-6-(piperidin-4-yl)-1H-indazol-3-yl)dihydropyrimidine-2,4(1H,3H)-dione 2,2,2-trifluoroacetate	Intermediate	2933 19 99	100.0 KG

Eligibility TPA As per APPCB CFO	Quantity already availed	Present applying Qty.	Balance Available
240 Tons P/A	15.20 Tons	2.22 MT	12.98 MT

As per APPCB CFO dated 23.08.2022 at S.No: 33, the details relating to quantity permitted, utilised and balance available is furnished above for perusal please

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 at around USD 2.83 lakhs (INR Rs.2,32,00,000/-) and there is no additional investment and employment envisaged.

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-181.05: Request of M/s Tianish Laboratories Private Limited for extension of the effectiveness of the name change/change in implementing agency from M/s. Mylan Labs Ltd to M/s. Tianish Labs Pvt Ltd

M/s Tianish Laboratories Private Limited (formerly known as Mylan Laboratories Limited) vide letter dated 20.02.2024 has requested for extension of the effectiveness of the name change/change in implementing agency of M/s.Tianish Laboratories Private Limited upto 29.02.2024 and permit the unit to continue the name of the unit as M/s.Mylan Laboratories Limited to enable them to continue raising invoices at the SEZ unit till 29.02.2024 and for allowing movement of goods (inward and outward) at the SEZ unit in the name of Mylan Labs Ltd till 29.02.2024.

M/s Tianish Laboratories Private Limited informed that since the name of the unit changed to M/s Tiansh Labs Private Ltd from Mylan Labs Ltd vide VSEZ letter dated 14.02.2024, the unit is unable to raise invoices in the name of M/s.Mylan Laboratories Limited.

In this regard, the following details are furnished hereunder for a quick recall of the earlier request for change of name of the unit/change in implementing agency and the present request for extension of the effectiveness of the change of name of the unit/change in implementing agency.

Previous request :

1. M/s.Mylan Laboratories Limited vide letter dated 22.01.2024 has submitted a proposal for change of name of the unit/change in implementing agency upon demerger of the API's Business of M/s. Mylan Laboratories Limited to M/s. Tianish Laboratories Private Limited by the Hon'ble NCLT.
2. As per the Demerger Scheme and the NCLT Order, the Demerger Scheme shall come into effect on the fulfillment of certain identified conditions in Clause 19 of the Demerger Scheme, **which includes the receipt of the approval of the Unit Approval Committee for the transfer of the SEZ Unit to M/s.Tianish.** This application has been made in order to obtain such approval. Subject to, the fulfilment of the aforementioned conditions, the Demerger Scheme is intended to come into effect on **1st Feb 2024.**
3. The request has been placed before the Unit Approval Committee meeting held on 09.02.2024 and the Unit Approval Committee after due deliberations has approved the request of M/s.Mylan Laboratories Limited for change of name of the unit/Change of Implementing agency from M/s.Mylan Laboratories Limited to M/s.Tianish Laboratories Private Limited as per the provisions of DoC instruction No.109 dated : 18.10.2021 and in light of the Hon'ble NCLT order No.29/230/HDB/2023 dated : 28.08.20023 relating to demerger of API business of Mylan Laboratories Limited. The change of name of the unit/change in implementing agency has become effective from 09.02.2024.
4. As per the UAC Approval the unit shall be implemented in the name of M/s. Tianish Laboratories Pvt. Limited subject to the conditions as mentioned in the letter dated 14.02.2024.

Present Request :-

1. M/s.Tianish Labs Private Limited has requested to allow them to continue to raise the invociees in the name of M/s.Mylan Labs Limited till 29.02.2024 and for other activities related to their

business in SEZ i.e., to extend the effectiveness of the name change upto 29.02.2024 instead of from 09.02.2024.

2. M/s.Tianish has informed that due to some problems they are not in a position to implement the effectiveness of the name change with from 09.02.2024 as some statutory compliances are still pending to be completed and in all probability the same will be completed by 29.02.2024. Due to this problem they are not in a position to raise the invoice all the operations were held up.
- 3. Unit has not furnished copies of the board resolution(s) stating the effectiveness of the name change shall be extended upto 29.02.2024.**
- 4. The unit has submitted a letter duly signed by M/s.Mylan and M/s.Tianish without any name, designation, Stamp or Seal of the company**

The request of the unit is placed before Unit Approval Committee.
