

**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 09.02.2024
THROUGH WEBEX AT 11.00 AM**

PVT SEZs – ANDHRA PRADESH

Agenda Item No.AP-180.01 :- Ratification of the Minutes of the meeting held on 25.01.2024.

The minutes of the UAC meeting held on 25.01.2024 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-180.01 : Request of M/s. Divi’s Laboratories Limited (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 (SEZ unit) vide ltr dated : 29.01.2024 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 HS Code
01	R & D Products Sacubitril Calcium [Chemical name: 4-[[[(2S,4R)-5-ethoxy-4-methyl-5-oxo-1-(4-phenylphenyl)pentan-2-yl]amino]-4-oxobutanoic acid-Calcium	0.100 MT	2924299 (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	77.1 MT	0.100 MT	22.8 MT

The unit has submitted the above details of Product manufacturing eligibility as per APPCB license dated 19.03.2021 at S.No: 93- R & D Products 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 at around Rs. 2 Cr and there is no additional employment envisaged.

Specified Officer vide letter dated 29.01.024 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-180.03:- Request of M/s. Ajionomoto Bio Pharma Services India Pvt Ltd, a unit in M/s Visakha Pharmacity Ltd SEZ, Parawada, Visakhapatnam for inclusion of additional product in the existing LoA - Reg.

M/s. Ajionomoto Bio Pharma Services India Pvt Ltd vide letter dated 22.01.2024 has requested for inclusion of the following additional products in the existing LoA. The details of the products proposed for inclusion are furnished hereunder :-

Sl. No.	Item of Manufacturing	Probable ITC HS Code	Capacity (Kg's /Per Day)
1	-(4-PHENOXYPHENYL)-1H-PYRAZOLO[3,4-D] PYRIMIDIN4-AMINE (HAI-5/HAI-4)	29335990	33.00
2	(S)-1-tert-Butoxycarbonyl-3-hydroxy piperidine(KED-2)	29333990	33.00

Unit has been requested to submit the details of the quantities permitted by APPCB, utilised and balance available. The unit vide letter dated : 06.02.2024 has submitted the following details related to the approvals and the remaining balance available with them with reference to CFO order.

S.NO	Description	Quantities Planned for Production (Under R&D products category of CFO)						
1	Quantity permitted as per APPCB authorization	1 Ton/month (i.e. 6 tons / 6 months) or 33 Kgs/Per day						
2	Quantity utilized as far against the APPCB approval (Tons)	Jan'24	Feb'24	March'24	Apr'24	May'24	Jun'24	Jul'24
		1	0.25	0	0	0	0	0
3	Balance Quantity available (Tons)	0	0.75	1	1	1	1	1
	Total Qty for approval (in line with R&D approved quantity of CFO)	1	1	1	1	1	1	1
Note: ATI-4 was manufactured in Jan-Feb 2024 under R&D and validation products, for which LOA is in place.								

Unit has submitted an undertaking dated 22.01.2024 that the above products are Intermediate product and do not require Drug License. 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 shown as Others 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-180.04 : Request of M/s Biocon Limited, SEZ Co-Developer of Visakha Pharmacity Limited SEZ – Renewal of Diesel Procurement permission - Reg.

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M/s Biocon Limited, SEZ Co-Developer in Visakha Pharmacity Limited SEZ has requested for renewal of Diesel Procurement permission for next six months i.e from 01.01.2024 to 30.06.2024. In this connection, the Co developer has furnished the consumption details certified by PO and SO concerned for the period i.e from May-23 to October 23.

The Co-Developer has been granted permission for procurement of HSD of 300 KL vide this office letter dated 03.07.2023 for a period of six months i.e upto 09.12.2023.

Co-Developer has been advised to furnish the certificate from Chartered Engineer, Consumption/utilisation statement from SO and Details of Explosive License , capacity , consumption statement etc.

M/s Biocon Limited has submitted the certificate from Chartered Engineer and consumption statement certified by SO upto 9th Decemeber 2023 alongwith following details.

No of Boilers	HSD Boiler 01 Nos
Capacity	10 Ton
Make	Fobes Marshal
Idle Running Consumption of Diesel	100 ltr/Hr
Peak Running consumption of Diesel	800 ltr/Hr
Tank Storage Capacity available in KL	50 KI
Stock Available in KL	41.09 KI
Explosive License	yes

M/s Biocon Limited has requested to grant permission for procurement of 300 KL diesel for next six months.

Accordingly, the proposal is placed before the UAC for consideration

Agenda Item No.AP-180.05 : Request of Mylan Laboratories Limited for change of management/implementing agency and change of name of the unit pursuant to the approval of demerger of the API's Business of Mylan Laboratories Limited to Tianish Laboratories Private Limited by the Hon'ble NCLT – Reg

Mylan Laboratories Limited has submitted a proposal for change of management/implementing agency and change of name of the unit from M/s.Mylan Laboratories Limited to M/s.Tianish Laboratories Private Limited upon demerger of the API's Business of Mylan Laboratories Limited by the Hon'ble NCLT.

M/s.Mylan Laboratories Limited has submitted following point for consideration of their proposal.

1. Mylan Laboratories Limited (“MLL”) and Tianish Laboratories Private Limited (“Tianish”), along with their respective shareholders and creditors, have entered into a scheme of demerger (“Demerger Scheme”) to demerge the active pharmaceutical ingredients business of MLL, which includes the SEZ Unit, (“API Business”) and transfer to M/s. Tianish, and the Demerger Scheme has been approved by the NCLT on August 28, 2023. Copies of the Demerger Scheme and the NCLT Order are attached as Annexure B and Annexure C, please.
2. The NCLT Order was filed with Registrar of Companies in accordance with Section 230(8) of the Companies Act, 2013 by MLL and Tianish on October 6, 2023 and October 5, 2023 respectively.

3. As per the Demerger Scheme and the NCLT Order, the Demerger Scheme shall come into effect on the fulfilment 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 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.
4. As noted in Clauses 5, 6, and 8.3 of the Demerger Scheme, all assets and liabilities of MLL relating to the API Business including the SEZ Unit stand transferred to and assumed by Tianish on and from the date the Demerger Scheme comes into effect.
5. M/s.Mylan Laboratoeis Limited has requested for Endorsement of LOA/Issuance of LOA for SEZ Unit in the name of M/s.**Tianish**.
6. Unit has made reference to Instruction No.109- K-43013(13)/7/2021, and Section 19 of the Special Economic Zone Rules, 2006, to consider their proposal is as below:
 - (a) accord approval for change in the implementing agency in respect of the SEZ Unit from MLL to Tianish, with effect from February 1, 2024;
 - (b) pass necessary orders for transfer of the SEZ registration and LOA in favour of Tianish, to enable Tianish to take over the business of the API Business with effect from February 1, 2024;
 - (c) allow Tianish to procure and use the packing material, manufacturing and packing documents where name of the MLL will be used for the period of 1 year for smooth transition of business to Tianish.

In this connection , unit has furnished following **Confirmations and Undertakings**:

1. The SEZ Unit has a positive cumulative net foreign exchange earnings as of the date of this application. The annual performance report for the last 5 years is attached as Annexure E.
2. The aforementioned demerger and change in implementing agency of the SEZ Unit from MLL to Tianish shall be undertaken in compliance with the requirements stipulated in Instruction No.109, having reference no. K-43013(13)/7/2021.
3. Upon the Demerger Scheme becoming effective, the API Business of MLL shall stand transferred to Tianish and as the new implementing agency, Tianish shall take over all obligations along with the assets and liabilities of the MLL in relation to the API Business. The status of the SEZ Unit will not in any way change due to the change in the implementing agency and all the obligations attached to the SEZ Unit would hereafter be complied by Tianish. Subject to receipt of the approvals contemplated by Clause 19 of the Demerger Scheme, MLL and Tianish propose to consider February 1, 2024 as the date on which the Demerger Scheme shall become effective.
4. **MLL would continue to run the business as aforesaid in trust, till the date the Demerger Scheme becomes effective. Thereafter, all the invoices shall be raised in the name of Tianish.**
5. Additional details about MLL, Tianish and the proposed demerger pursuant to the Demerger Scheme and NCLT Order, are provided in Schedule 1.
6. The aforementioned parties have received the approval from the Department of Pharmaceuticals under the Paragraph 5.2.27 read with Paragraph 4 of Annexure III of the Consolidated FDI Policy Circular 2020 and Paragraph 16.2 of Schedule I read with Rule 19 of the Foreign Exchange Management (Non-Debt Instruments) Rules, for the demerger of the API Business to Tianish on January 2, 2024, and the copy of this approval is attached as Annexure

In this connection, unit has submitted following documents:

- Annexure A: Copy of the LOA
- Annexure B: Copy of the Demerger Scheme
- Annexure C: Copy of the NCLT Order
- Annexure D: Copies of Form INC-28 filed by MLL and Tianish respectively
- Annexure E: Annual performance report for the last 5 years
- Annexure F: Copy of the Department of Pharmaceutical's approval for the demerger
- Annexure G: Certificate of Incorporation of Tianish
- Annexure H: **MLL board resolution and CS certificate**
- Annexure I: **Tianish board resolutions**
- Annexure J: Memorandum and Articles of Association of Tianish
- Annexure K: Undertaking from Tianish agreeing to take over assets and liabilities of MLL
- Annexure L: List of Directors of Tianish (with residential address proof and PAN card)
- Annexure M: CA certificates confirming shareholding pattern of MLL and Tianish
- Annexure N: RoC Forms filed for the appointment of directors of Tianish

Mylan Laboratories Limited (MLL) has submitted a proposal for the demerger of its Active Pharmaceutical Ingredients (API) Business to Tianish Laboratories Private Limited (Tianish).

1. As per the share holding pattern of the company, unit has submitted following details during 20.10.2010 (fro setting up of sez unit in Ramky Pharma SEZ).

Name of the Share holder	Shareholding
Promoters share holding	97.11%
Non-promoter shareholdings	2.89%

Subsequent to the above change, the unit has submitted share holding pattern of Mylan Labs Ltd is as below:

Sl.No	Name of the Share Holder	No of Equity Shares	% holding
1	MP Laboratories(Mauritius) Limited	157402332	64.64%
2	Mylan Luxembourg 2 S.a.R.1	28508547	11.71%
3	Mylan Goup B.V	57601744	23.65%
4	Ms Sarada Kalayani Bhagavati	2	0
5	Mr. Rajeew Mukundan	2	0
6	Mr.Siva Kiran	2	0
7	Mr. B.Nagraj Goud	6	0
	Total	24,35,12,635	

2. Unit has furnished the share holding pattern of Tianish Labs Pvt LTd is as below (upon effectiveness of the scheme of demerger):

Sl.No	Name of the Share Holder	No of Equity Shares(face value of INR 10 each)	% holding
1	Mylan Luxembourg 2 S.A.R.L	1,17,078	11.71%
2	MP Laboratories(Mauritius) Limited	6,46,416	64.64%
3	Mylan Goup B.V	2,36,557	23.65%
		10,00,051	100%

As per the details furnished by the unit, it is observed that the above demerger proposal is related to their Mylan Labs Ltd including DTA, SEZ, EOU and units located in other countries.

As per SEZ rule 19 (2),(provided also that, subject to the provisions of rules 74A) Approval Committee may also approve proposal for change of the entrepreneur of an approved unit, if the incoming entrepreneur undertakes to take over the assets and liabilities of the existing unit.

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

Agenda Item No.AP-180.06 : Request of M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) for inclusion of additional product in the existing LoA - Reg.

M/s. Deccan Fine Chemicals (India)Private Limited (SEZ Unit) vide letter dated 27.01.2024 has requested for inclusion of the following additional products in the existing LoA.

Sl.No.	Item of manufacture	ITC HS Code	Projected Annual Capacity (In MTs.)
1	5-MPDC (5-methylpyridine-2,3-dicarboxylicacid)	Other (29333990) under the heading of ORGANIC CHEMICALS	200
2	MMSC (LDH)/ Lithium Aluminum Layered Double Hydroxide Chlorides	Other (29182090) under the heading of ORGANIC CHEMICALS	20

The unit has informed that there will not be any change in the projections viz imports, exports and NFE and any additional impact upon addition of the above products as the same will be manufactured within the overall capacity permitted earlier.

The unit has informed that they have obtained consent to operate and authorisation order from APPCB vide letter dated 10.01.2024 which is valid upto 30.09.2028. The product indicated at Sl.1 is shown at Sl.No. 137 of APPCB copy at page No.17 as 5-methylpyridine-2,3-dicarboxylicacid for 200 Ton per Annum. Further the unit has informed that quantity of R & D and Pilot plant products also enhanced from 300 MT /year to 500 MT/year.

Further the unit assured that that there will be no change in the projections of Imports, Exports, procurements, NFE projections, and will be well within the value of BLUT NO.26(D)/147/2018/SSSEZ/VSEZ/6678 dt.22.12.2022.

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.
