

**MINUTES OF THE APPROVAL COMMITTEEs MEETING FOR THE PRIVATE SEZs in Andhra Pradesh held on 20.08.2020 at 11.00 AM through Webex under the CHAIRMANSHIP of Shri A RAMA MOHAN REDDY,IFS DEVELOPMENT COMMISSIONER, VSEZ**

**Present:**

1. Dr. Ramesh B.N, Jt.DGFT, DGFT, Visakhapatnam
2. Shri V.R.S.Sastry, Asst.Commissioner, Customs, Visakhapatnam
3. Shri A.V.Ramana Reddy, Superintendent, Central Tax, Visakhapatnam
4. Shri Md.Rehman, Superintendent, Central Tax, Visakhapatnam

**Special Invitee :**

**Smt. D.Kalyani, Drug Inspector, Drugs Department, Visakhapatnam**

**MembersAbsent :**

1. Commissioner, Income Tax, Visakhapatnam
2. Director, Ministry of Finance (Banking Division), New Delhi.
3. Director, Ministry of Commerce & Industry, New Delhi.
4. The GM, DIC, Visakhapatnam
5. ADC(Labour), VSEZ, Visakhapatnam

**PVT SEZs**

The Development Commissioner, VSEZ and Chairperson, Approval Committee welcomed the Members and apprised them briefly about the proposals placed before the Committee for their consideration. The items listed in the Agenda were discussed and following decisions were taken.

**Agenda Item No.1:** Ratification of the Minutes of the meeting held on 21.07.2020.

**The Committee ratified the Minutes of the Unit Approval Committee Meeting held on 21.07.2020.**

**Agenda Item No. 02 :** Request of M/s. Eisai Pharmaceuticals India Pvt. Ltd for inclusion of additional product under broad-banding in LOA

**The Committee deliberated and advised the unit to furnish the NFE Projections and process the same on file.**

S.No	Name of the Product	Category of Business	Annual capacity	ITCHS Code
1	EdoxabanTosylate	API	1000 KGs	29420090

**Agenda Item No. 03 :** Request of M/s. Eisai Pharmaceuticals India Pvt. Ltd for inclusion of additional product under broad-banding in LOA

**The Committee deliberated and advised the unit to furnish the details of the quantity to be made and process the same on file.**

S.No	Name of the Product	Category of Business	ITCHS Code
1	Research ^& Development <b>PPAR: Pyrazole derivative</b>	Research &Development	29331990

**Agenda Item No. 04** : Request of M/s. Natco Pharma Limited for inclusion of additional product under broad-banding in LOA.

**The Committee deliberated and approved the request of the Unit for inclusion of the following product in the LoA**

S.No	Name of the Product	Tablets/ Capsule	ITC HS	UOM	Projected quantity
1	Lanthanum Carbonate Chewable Tablets 750mg, 1000mg	Tablets	30049099	Nos	0.24 Million

**Agenda Item No. 05** : Request of M/s. Honour Lab Limited for inclusion of additional product under broad-banding in LOA.

**The Committee deliberated and approved the request of the Unit for inclusion of the following product in the LoA**

S.No	Item. of. manufacture	API/Bulk/ Drug/ Intermediate	ITC HS	UOM	Projected Annual capacity in kgs
1	FAVIPIRAVIR	API	29339990	KG	50

**Agenda Item No. 06:** Request of M/s. Dr. Reddy's Lab Ltd, CTO SEZ Process Unit-01, unit in Dr. Reddy's Lab Ltd SEZ for inclusion of additional product under broad-banding in LOA.

**The Committee deliberated and approved the request of the Unit for inclusion of the following product in the LoA**

S.No	Name of the Product	API / Intermediate/ Bulk Drugs	ITC CODE NO.	UOM	Projected annual capacity
1	FAVIPIRAVIR	API / Intermediate	29339990	Kgs	250.00
2	Diroximelfumrate	API / Intermediate	29420090	Kgs	1000.00

**Agenda Item No.07:-** M/s. Natco Pharma Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.

**The Committee deliberated and approved the request of the Unit for inclusion of the following product in the LoA**

Sl.No.	Item of manufacture	Tablet / Capsule	ITC HS code	Annual Capacity
1	Lanthanum Carbonate Chewable Tablets 250 mg, 500 mg	Tablets	30049099	1.8 Million Nos.

**Agenda Item No. 08 :** Proposal of M/s PharmaZell (India) Pvt Ltd , unit in M/s Ramky Pharma City (India) Ltd SEZ for enhancement of production capacity in LOA

**The Committee deliberated and approved the request of the unit for enhancement of the production capacity in respect of the following product as under subject to the condition that the unit shall submit the Drug Licence immediately.**

S.No	Name of the Product	Existing capacity	Enhanced capacity
1	5-AMINO SALICYLIC ACID	450.00 MT	750.00 MT

**Agenda Item No. 09:-** Request of M/s.Divi's Laboratories Limited (SEZ Unit), a unit in M/s.Divi's Laboratories Limited SEZ, Visakhapatnam for inclusion of additional products in the LoA.

**The Committee deliberated and ratified the permission granted by this office vide letter dated: 07.08.2020 in respect of the following product.**

S. No	Name of the product	API/ Nutraceuticals	Annual Production Capacity	ITC code No.
1	FAVIPIRAVIR	API	500 Kgs.	29242990

**Agenda Item No. 10:-** Request of M/s. Aurobindo Pharma Limited, unit in APIIC, Multiproduct SEZ for inclusion of additional product under broad-banding in LOA

**The Committee deliberated and approved the request of the unit for inclusion of the following additional products in the LoA**

S.NO	Item of Manufacture	Strength (mg)	UoM	Annual Capacity (in Millions)
1	Bumetanide Tablets USP	0.5	Tablets	4.01
2	Bumetanide Tablets USP	1	Tablets	24.43
3	Bumetanide Tablets USP	2	Tablets	15.59
4	Buspirone Hydrochloride Tablets USP	5	Tablets	63.25

5	Buspirone Hydrochloride Tablets USP	10	Tablets	178.13
6	Clobazam Oral Suspension	2.5 mg/mL	Suspension	0.18
7	Memantine Hydrochloride Extended-Release Capsules	7	Capsules	1.32
8	Memantine Hydrochloride Extended-Release Capsules	14	Capsules	2.15
9	Memantine Hydrochloride Extended-Release Capsules	21	Capsules	1.22
10	Memantine Hydrochloride Extended-Release Capsules	28	Capsules	10.23
11	Mesalamine Extended Release Capsules USP	0.375 g	Capsules	46.99
12	Methocarbamol Tablets USP	750	Tablets	93.09
13	Sitagliptin Tablets	25	Tablets	11.48
14	Sitagliptin Tablets	50	Tablets	44.81
15	Sitagliptin Tablets	100	Tablets	170.44
16	Varenicline Tablets	0.5	Tablets	3.38
17	Varenicline Tablets	1	Tablets	54.19
18	Mirtazapine Tablets 15 mg. - 30Bottle	15MG	Tablets	171.95
19	Mirtazapine Tablets 15 mg. - 500Bottle	15MG	Tablets	93.27
20	Mirtazapine Tablets 15mg 30ct	15mg	Tablets	23.76
21	Mirtazapine Tablets 15mg 500ct	15mg	Tablets	19.8
22	Mirtazapine Tablets 30 mg. - 30Bottle	30MG	Tablets	82.36
23	Mirtazapine Tablets 30 mg. - 500Bottle	30MG	Tablets	36.36
24	Mirtazapine Tablets 30mg 30ct	30mg	Tablets	20.68
25	Mirtazapine Tablets 30mg 500ct	30mg	Tablets	11.88
26	Mirtazapine Tablets 45 mg. - 30Bottle	45MG	Tablets	40.05
27	Mirtazapine Tablets 45 mg. - 500Bottle	45MG	Tablets	14.46
28	Mirtazapine Tablets 45mg 30ct	45mg	Tablets	5.26
29	Mirtazapine Tablets 45mg 500ct	45mg	Tablets	0.66
30	Losartan Potassium Tablets-100mg	100	Tablets	89
31	Sulfamethoxazole and Trimethoprim Oral Suspension USP200/40mg Per 5ML.	200/40	OS	0.02
32	Dolutegravir,Lamivudine and Tenofovir 50mg+300mg+300mg Disproxil Fumarate Tablets	50+300+300	Tablets	105

**Agenda Item No.11**:-Request of M/s. Mylan Laboratories Limited,Unit-10,Ramky Pharmacy(I) Ltd SEZ, Parwada has requested , for inclusion of additional product under broad-banding in the LOA. for export-Reg.

**The Committee deliberated and ratified the permission granted by this office vide letter dated: 13.08.2020 in respect of the following product**

S.No	Name of the Item for trading	/API/ Intermediate	ITC CODE NO.	Annual capacity( (Potential)
1	FAVIPIRAVIR	API/ Intermediate	29242990	<b>135 Kgs</b>
2	HYDROXYCHLOROQUINE SULPHATE / HYDROXYCHLOROQUINE SULFATE	API/ Intermediate	29334900	50 MT

**TABLE AGENDA**

**Agenda No.1** : Request of M/s.Divi's Laboratories Limited (SEZ Unit) for inclusion of additional products in the existing LoA

The Committee deliberated and approved the request of the unit for inclusion of the following additional product in the LoA

Sl.No.	Name of the Product	API/Intermediate	ITCHS Code	Annual Capacity
1.	5,5-dimethyl-1,3,2-dioxathiane 2,2-dioxide	Intermediate	29349990	50000 MT

**Agenda No.2** : Request of M/s.Alvira Animal Health Limited a unit in M/s.Ramky Pharma City SEZ for inclusion of additional product in the existing LoA

The Committee deliberated and advised the unit to furnish the details of NFE projections in respect of the product and to process the request on file.

Sl.No	Item of Manufacture	API/Intermediate	ITC HS Code	Annual Capacity
1.	Imidocarb Dipropionate	API	29333990	5000 Kgs

**Agenda No.3** : - Request of M/s.GranulesOmnichem Pvt. Limited relating to project expansion  
– Intimation for approval – Reg.

**The Committee deliberated and taken note of the project expansion and the additional investment and NFE projections and approved the same.**

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S.No.	Item of manufacture	API/ Intermediate	ITC HS code	Annual Capacity
1	TrihydroxytriazineCarbonitrile ((2R,3R,4S,5R)-(4- Aminopyrrolo[2,1,f][1,2,4]triazine-7- yl)-3,4,-dihydroxy-5- (hydroxymethyl)tetrahydrofuran-2- carbonitrile)	Intermediate	29339900	<b>10 Tons</b>