

AC-75th-Minutes/2016

MINUTES OF THE APPROVAL COMMITTEEs MEETING FOR THE SEZs LOCATED IN VSEZ & OTHER PRIVATE SEZs HELD ON 29.09.2016 AT 3.30 PM AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VSEZ, DUVVADA, VISAKHAPATNAM UNDER THE CHAIRMANSHIP OF SMT SOBHANA K.S.RAO, DEVELOPMENT COMMISSIONER, VSEZ

Present:

1. Dr.G.Trinadh Kumar, Joint Development Commissioner, VSEZ, Visakhapatnam - Special Invitee
2. Shri J. Rambabu, Dy.Commissioner, Central Excise, Visakhapatnam Commissionerate
3. Shri Alok Dwivedi, Dy.DGFT, Visakhapatnam
4. Shri Sree Hari Shankar, Asst.Commissioner, Customs & Central Excise, Visakhapatnam Commissionerate
5. Ms.P.Madhuree, Asst.Commissioner, Customs & Central Excise, Visakhapatnam Commissionerate
6. DR. B.PUNNAM KUMAR, ASST.DGFT, VISAKHAPATNAM
7. SHRI JOSEPH G.PATIL, Asst.Commissioner, Customs & Central Excise
8. Shri G.Laxmi Narasiah, Asst.Commissioner of Labour
9. Shri J.Uma Maheswar, District Industries Centre, Visakhapatnam
10. Ms.A.T.V.Ramadevi, Drug Inspector, Drug Control Authority, AP – Special Invitee

Members Absent :

1. Director, Ministry of Finance (Banking Division), New Delhi.
2. Director, Ministry of Commerce & Industry, New Delhi.
3. The Commissioner, Income Tax, Visakahapatnam

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.

Ratification of the Minutes of the meeting held on 29.08.2016.

The Committee ratified the Minutes of the Joint Meeting of the Approval Committees held on 29.08.2016.

VSEZ

✓ **Agenda Item No.2 :** Request of Dr. Reddy's Laboratories Ltd (unit-VII) in Visakapatnam Special Economic Zone, Duvvada for inclusion of additional products in the LoA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA for the purpose for which the Drug license is issued by the competent authority

S.No.	Product	Capacity	ITC
1	Mitomycin for inj. USP 5 mg/vial, 20 mg/vial and 40 mg/vial	2 millions	30019099

✓ **Agenda Item No.3 :** Request of Dr. Reddys Laboratories Ltd (unit-IX) for inclusion of additional products in the LoA.

The Committee deliberated on the request and approved to include the following additional products.

S.No.	Product	Capacity	CTCH
1	Ethacrynate sodium for injection USP 50 mg/vial	2 millions	30049099
2	Succinylcholine Chloride Injection USP(20 mg/ml)	2 millions	30049099

✓ **Agenda Item No-4:** M/s. Maxworth Minerals India Pvt.Ltd request for inclusion of additional item in LoA-Reg

The committee deliberated and approved the proposal for inclusion of the following products in the LoA.

S.No.	Product	Annual Capacity	CTCH
1	Ilmenite	5000 MT	26140020

✗ **Agenda Item No-5:** Dr. Reddys Laboratories Ltd, (Formulation Tech.ops-IX) has requested for permission for inclusion of additional activity i.e., advanced instrumentation Lab (R&D) for rendering QC/QA related services under broad banding – Reg

The Committee deliberated and approved the request of the DRL (FTO-IX) for inclusion of additional activity i.e., Advanced Instrumentation Lab (R&D) for rendering QC/QA related services under broad banding exclusively for DRL (FTO-IX), VSEZ, Visakhapatnam only.

PRIVATE SEZS

Agenda Item No. 06:- Request of M/s. Divi's Laboratories Ltd, (SEZ Unit) for inclusion of additional product under broad-banding in LOA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA

S.No	Name of the Product	API/INTERMEDIATE	Annual Capacity (In MTs)	ITC CODE NO.
1	CBZ- AMINONITRILE	INTERMEDIATE	1500	29269000

Agenda Item No. 07: Request of M/s. Dr. Reddy's Laboratories Limited, (FTO SEZ Process Unit-01) DRL SEZ, Srikakulam, for inclusion of additional product under broad-banding in LOA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA for the purpose for which the Drug license is issued by the competent authority

S.No	Name of the Product	CAPULE/TABLET/ PELLETS	ITC CODE NO.	Units	Annual Capacity
1	CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE TABLETS 50 MG/500 MG,50 MG/1000MG,150MG/500MG,150 MG/100MG	TABLETS	30049099	Nos.	4000000
2	APIXABAN TABLETS 2.5 MG,5MG	TABLETS	30049099	Nos.	2000000
3	SEVELAMER CARBONATE POWDER FOR ORAL SUSPENSION 2.4G	ORAN SUSPENSION	30049039	Nos.	80000
4	CANAGLIFLOZIN TABLETS 100MG,300MG	TABLETS	30049099	Nos.	2000000
5	POSACONAZOLE DELAYED RELEASE TABLETS 100MG	TABLETS	30049099	Nos.	1000000
6	ALBENDAZOLE TABLETS USP 200MG	TABLETS	30049099	Nos.	10,00,000
7	DIMETHYL FUMARATE DELAYED RELEASE CAPSULES 120 MG ,240MG	CAPSULES	30049099	Nos.	20,00,000
8	RANITIDINE HYDROCHLORIDE CAPSULES 150MG,300MG	CAPSULES	30049099	Nos.	12,40,000
9	DIVALPROEX SODIUM DR CAPSULES (SPRINKLE)125 MG USP	CAPSULES	30049099	Nos.	18,00,000

Agenda Item No.08 : Request of M/s. Hetero Labs Limited (Unit-IX) , a Unit under Hetero Infrastructure SEZ Ltd at Narasapuram Village, Nakkapalli Mandal, Visakhapatnam for inclusion of the following additional products in the LoA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA

S. NO.	ITEM OF MANUFACTURE	INTERMEDIATE	ITC(HS)	Annual CAPACITY
1	7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydro-2(1H)-quinolinone	INTERMEDIATE of ARIPIPRAZOLE	29337900	100 Tons
2	1H-Pyrrole-1-heptanoic acid,2-(4-fluoro phenyl)- β,δ -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino) carbonyl]-, calcium salt(2:1), tri hydrate [R-R*,R*]	INTERMEDIATE of ATORVASTATIN CALCIUM	29339900	100 Tons
3	6-(7-(2-((S)-5-azaspiro[2.4]heptan-6-yl)-1H-imidazol-5-yl)-9,9-difluoro 9H-fluoren-2-yl)-2-((1R,3S,4S)-2-azabicyclo [2.2.1] heptan-3-yl)-1H-benzo[d]imidazole tetrahydrochloride	INTERMEDIATE of LEDIPASVIR	29339900	100 Tons

4	N-methoxy carbonyl-(L)-iso-leucine	INTERMEDIATE of ATAZANAVIR SULFATE	29333990	100 Tons
5	[(1S, 2R)-3-[[[4-Amino phenyl)sulfonyl](2-methylpropyl)amino]-2-hydroxyl-1-(phenyl methyl)propyl]-carbamic acid (3R,3aS,6aR) hexahydrofuro[2,3-b]furan-3-yl ester 2-methyl-2-butanol	INTERMEDIATE of DARUNAVIR AMORPHOUS	29350090	100 Tons

Agenda Item No.09. Request of M/s. Hetero Drugs Limited (Unit-IX) , request for approval of services in terms of Notification No.12/2013 Dated 1.7.2013.

The committee approved the following list of service of the unit in terms of ST Notification No.12/2013 dated:01.07.2013 subject to the services falling in the Uniform List of DoC and limited to the application.

Sl. No.	Name of service	Justification
1	Rent a cab scheme operator' service	Availing these services (buses and cabs) for transport of employees

Agenda Item No.10: Request of M/s. Hetero Labs Limited (Unit-IX) , for approval of services in terms of Notification No.12/2013 Dated 1.7.2013 for following services.

The committee approved the following list of service of the unit in terms of ST Notification No.12/2013 dated:01.07.2013 subject to the services falling in the Uniform List of DoC and limited to the application.

Sl. No.	Name of service	Justification
1	Rent a cab scheme operator' service	Availing these services (buses and cabs) for transport of employees

Agenda Item No.11 : Request of M/s. Honour Lab Limited for approval of services in terms of Notification No.12/2013 Dated 1.7.2013 for following services.

The committee approved the following list of service of the unit in terms of ST Notification No.12/2013 dated:01.07.2013 subject to the services falling in the Uniform List of DoC and limited to the application.

Sl. No.	Name of service	Justification
1	Rent a cab scheme operator' service	Availing these services (buses and cabs) for transport of employees

Agenda Item No.12 : Request of M/s. Pharma Zell (Vizag) Pvt Ltd, for inclusion of additional product under broad-banding in LOA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA for the purpose for which the Drug license is issued by the competent authority

S. NO	NAME OF THE PRODUCT	ITC(HS)	Annual CAPACITY
1	URSODIOL CAPSULES (USP 300 MG) (OR) ACTIGALL	30049099	5,00,000 Nos.
2	URSODIOL TABLETS (USP 250MG & 500 MG)(OR) URSO/URSO FORTE	30049099	10,00,000 Nos.
3	PROPAFENONE HYDROCHLORIDE SR CAPSULES (USP 225 MG,325 MG &425 MG)(OR) RYTHMOL SR CAPSULES	30049099	15,00,000 Nos.

Agenda Item No.13 : Request of M/s. Eisai Pharmaceuticals India Pvt Ltd, a SEZ Unit in M/s Ramky Pharma City (India) Pvt. Ltd for inclusion of additional product under broad-banding in LOA

The committee deliberated and deferred the same as the unit has not furnished the annual capacities and directed to seek the details

✓ **Agenda Item No.14** : Request of M/s. Laurus Labs Pvt Ltd , for change of name of the company.

The Committee deliberated and approved the change of the name of the unit from M/s.Laurus Labs Pvt. Limited to M/s.Laurus Labs Limited.

✓ **Agenda Item No.15** : Request of M/s. Alivira Animal Health Ltd, for inclusion of additional product under broad-banding in LOA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA for the purpose for which the Drug license is issued by the competent authority

S.NO	ITEM OF MANUFACTURE	API/ INTERMEDAI TE	ITC(HS)	ANNUAL CAPACITY
01	N-{5-chloro-4-[(4-chlorophenyl)-cyano methyl]-cyano methyl}-2-methyl phenyl}-2-hydroxy-3,5diiodobenzamide. Closantel base	Intermediate of Closantel Sodium	29420090	105.00 MT
02	Propanedioic acid,2-[(2,2-dimethoxyethyl)amino]-N-(2-phenylethyl)acetamide- PRZI/04A	Intermediate of Praziquanatel	29420090	225.00 MT
03	Propanedioic acid,2-(6-chloro,2,3,4,9-tetrahydro-1h-carbazol-2-yl)methyl, 1,3 dimethyl ester- Stage -I	Intermediate of Carprofen	29420090	12.54 MT
04	Propanedioic acid,2-(6-chloro-9H-Carbazol-2-yl)-2-methyl-1,3-dimethyl ester -Stage -II	Intermediate of Carprofen-	29420090	94.11 MT
05	2-(6-chloro-9H-carbazol-2yl) propanoic acid- Stage -III	Intermediate of Carprofen	29420090	61.17 MT
06	4-amino-6-trichlorovinyl-benzene-1,3-disulfonyl dichloride	Intermediate of Clorsulon	29420090	30.00 MT

- ✕ **Agenda Item No.16** : Request of M/s Brandix Apparel City Pvt Ltd , Developer, Atchutapuram , Visakhapatnam for the construction of Factory & Facility Building (Staging Unit-5) at Plot -c(Part) in their SEZ as part of authorized operation.

The Committee deliberated and approved the request of M/s Brandix Apparel City Pvt Ltd , Developer, Atchutapuram , Visakhapatnam for import/procurement of the following material for construction of Factory & Facility Building (Staging Unit-5) at Plot -c(Part) in their SEZ for a value of Rs. 262.04 lakhs

List of goods required for construction of Factory & Facility Building (Staging Unit-5) at Plot-c(Part) without payment of duty - Build up area 33000 sft					
S.N O	DESCRIPTION OF ITEM	Type of procurement	UOM	Approx Qty	Approx Amount in lakhs (INR)
1	Cement	DTA	MT	150	10.40
2	Steel (Tor Steel & Mild Steel)	DTA	MT	53	19.00
3	RMC Concrete	DTA	CUM	725	29.90
4	1000 Gauge Polythene Damp Proof Membrane	DTA	SQM	5200	1.82
5	Tiles (Wall / Floor & Walk Ways)	DTA/Import	SQM	1762	7.29
6	Granite	DTA	SQM	78	1.30
7	UPVC Pipes & fittings & accessories	DTA	RMT	1690	2.99
8	Sanitary ware & sanitary fittings	DTA	L.S		4.00
9	PVC Pipes & fittings	DTA	RMT	650	2.34
10	Electrical Items (cable & accessories/ internal lighting)	DTA/Import	L.S		6.50
11	Roller Door	DTA/Import	SQM	80	3.00
12	Enamel Painting	DTA	Ltrs	1150	3.50
13	Sewage Motors/pumps	DTA/Import	Lumpsum		4.00
14	UPVC windows and toilet partitions	DTA/Import	Nos	50	3.00

15	SS Wash basins	DTA/Import	Nos	7	2.00
16	PEB Steel Structure & Accessorioses (Steel sturcture / galvanised purlin / high tentile nut & bolts / glass wool/ aluminium Foil / roofing sheet & accessories / GI weld mesh/ fastners / sagrods & other roofing materials)	DTA/Import	Lumpsum		120.00
17	Anchor bolts for steel structure	DTA/Import	Lumpsum		1.00
18	2"x2" GI Mesh (chain link fence)	DTA/Import	SQM	1300	8.00
19	Fire Pumps (deisel enging driven pump / electrical motor driven main fire pump and Jocky Pump) / fire control Panels / hydrant valves/spinklers / hose cabinets/ Hose reals and other accessories	DTA/Import	Lumpsum		32.00
	Total				262.04

X **Agenda Item No.17:** Request of M/s Brandix Apparel India (P) Ltd, Unit-III, a unit in M/s Brandix Apparel City Pvt Ltd, Atchutapuram, Visakhapatnam for approval of Business Auxillary service in terms of Notification No.12/2013 Dated 1.7.2013 for following service

The Committee deliberated and deferred the same in the absence of a clear purpose for which the service is required.

X **Agenda Item No.18 :** Request of M/s. Seeds Intimate Apparel India Pvt Ltd, a SEZ Unit in M/s Brandix India Apparel City SEZ for inclusion of additional activity i.e., Manufacturing Service, under broad-banding in LOA.

The Committee deliberated and approved the proposal for inclusion of additional activity i.e., for rendering Manufacturing Services subject to the following conditions:

1. The raw-material required for rendering the manufacturing services shall be free of cost.

2. **Separate book of Accounts shall be maintained both for manufacturing and manufacturing services.**
3. **The unit shall intimate the date of stoppage of operations of manufacturing activity.**

X **Agenda Item No.19** : Request of M/s. International Trimmings & Label (Vizag) India Pvt Ltd, Unit in Brandix SEZ for inclusion of additional product under broad-banding in LOA

The committee deliberated and approved the proposal for inclusion of the following products in the LoA

Name of the Product	Units	Annual Capacity
Paper Stickers and Paper Tags	Nos	12432000

X **Agenda Item No.20** : Request of M/s. S&S Garments Accessories India Pvt Ltd for inclusion of additional product under broad-banding in LOA.

The committee deliberated and approved the proposal for inclusion of the following products in the LoA

Name of the Product	Units	Annual Capacity
Spiral Metal Boning	Nos	17280000

Agenda Item No.21: Request of RGC, Vice-chairman for approval of services in terms of Notification No.12/2013 Dated 1.7.2013 in respect of "Club Association Service".

The Committee deliberated and approved the request for approval of "Club Association Services" for all the SEZ Developers, Co-Developers and SEZ Units. However, the SEZ Developers, Co-developers and SEZ units shall apply for availing the Service to the DC's office.

SUPPLEMENTARY AGENDA

Agenda Item No.1: Request of M/s..Arunodaya Gran-tech Private Limited for approval for change in constitution of the Board.

The Committee deliberated and approved the change in constitution of the Board.

Agenda Item No.2 : Request of Dr.Reddy's Laboratories Limited (CTO SEZ Process Unit-01) DRL SEZ, Srikakulam, for inclusion of additiona product under broad-banding in LoA

The committee deliberated and approved the product indicated at SI.No. 1 in the following table for inclusion in the LoA for the purpose for which the Drug license is issued by the competent authority and in respect of products indicated at SI.No.2 to SI.No.4 directed to seek clarification on the requirement of huge quantities of material for testing purpose.

SI.No.	Name of the product	API	ITC HS	Annual Capacity
1.	GLATIRAMER ACETATE 1H	API	29420090	5000 Kgs
2.	AMPHOTERICIN B50 mg (LIPOSOML) POWDER FOR SOLUTION FOR INFUSION	API	29420090	5000 Kgs
3.	AMPHOTERICIN B LIPOSOME FOR INJECTION USP 50 MG/VIAL POWDER FOR SOLUTION FOR INFUSION	API	29420090	5000 Kgs
4.	TREPROSTINIL	API	29420090	5000 Kgs.

TABLE AGENDA

Agenda Item No.1 : Ratification of the approval granted to M/s.Alivira Animal Health Limited for inclusion of additional product in the LoA.

The committee ratified the approval granted for inclusion of the following additional product in the Letter of Approval

S.NO	ITEM OF MANUFACTURE	API/ INTERMEDAI TE	ITC(HS)	ANNUAL CAPACITY
01	N-{5-chloro-4-[(4-chlorophenyl)- cyano methyl]-cyano methyl]-2- methyl phenyl}-2-hydroxy- 3,5diodobenzamide. Closantel base	Intermediate of Closantel Sodium	29420090	105.00 MT