

AGENDA FOR 110th UNIT APPROVAL COMMITTEEs MEETING FOR THE SEZs LOCATED IN VSEZ & OTHER PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 25.10.2019 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

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AGENDA FOR 109th UNIT APPROVAL COMMITTEES MEETING FOR THE SEZs LOCATED IN PRIVATE SEZs OF ANDHRA PRADESH REGION TO BE HELD ON 25.10.2019 AT 11.00 A.M. AT CONFERENCE HALL, ADMINISTRATIVE BUILDING, VISAKHAPATNAM SPECIAL ECONOMIC ZONE, DUVVADA, VISAKHAPATNAM.

PRIVATE SEZs AGENDA

Agenda Item No.1: Ratification of the Minutes of the meeting held on 25.09.2019.

Agenda Item No.2 - Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01, a unit in Dr. Reddy's Laboratories Ltd. Ranastalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.

Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01 in Dr. Reddy's Laboratories Ltd Sector specific SEZ located in Ranastalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

Sl. No.	Item of manufacture	APIs/ Intermediates/ Bulk drug	ITC HS code	UOM	Projected annual Capacity	Projecte d annual exports
1	Pentosan Polysulfate Sodium IH	APIs / Intermediate	29339900	Kgs	500	21.00 crores

The unit has declared that the export/import of the products are not in the restricted/prohibited list of goods in terms of ITC(HS).

In this regard, the unit has submitted the copy of drug licenses vide No. L. Dis. No. 458/DCA/AP/2018 dt.26.05.2018 which was expired on 30.06.2018.

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 UAC for consideration

Agenda Item No.03: Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-01, a unit in Dr. Reddy's Laboratories Ltd Ranastalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.

Dr. Reddy's Laboratories Ltd, FTO, SEZ Process unit-01 a unit in Dr. Reddy's Laboratories Ltd Sector specific SEZ located in Ranastalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

Sl. No.	Item of manufacture	Capsule/Tablet/pellets /inhalation Aerosol/Granules/Sachets/Spray/Capsules	ITC HS code	Projected Annual Capacity	Projected annual exports INR
1	Pentosan Polysulfate Sodium 100 mg	Capsules	3004 9099	9900000	2.1 crores

The unit has declared that the export/import of the products are not in the restricted/prohibited list of goods in terms of ITC(HS).

In this regard, the unit has submitted the copy of drug licenses vide No. L. Dis. No. 3257/P&B/2019 dt.27.06.2019 for purpose of examination, test or analysis and license will be in force for three years from the date of issue.

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 UAC for consideration

Agenda Item No.4 - Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01, a unit in Dr. Reddy's Laboratories Ltd Ranasthalam Mandal, Srikakulam for inclusion of additional products in the existing LoA.

Dr. Reddy's Laboratories Ltd, CTO, SEZ Process unit-01 in Dr. Reddy's Laboratories Ltd Sector specific SEZ located in Ranasthalam Mandal, Srikakulam has requested for inclusion of following additional products in the existing LoA:-

Sl. No.	Item of manufacture	Capsule/Tablet/pellets/inhalation Aerosol/Granules/Sachets/Spray/Capsules/Tubes	ITC HS code	Projected annual Capacity	Projected annual exports INR
1	Nimesulide Gel 1% w/w Nise Gel 20g	Tube	30049099	1700533	183167090
2	Nimesulide Gel 1%	Tube	30049099	1633827	287310439

	w/w Nise Gel 50g				
	Nimesulide Gel 1% w/w Nise Gel 100g	Tube	30049099	181560	41025298

The unit has enclosed drug licenses vide No.L. Dis .No. 4117/P&B/2019 dt.11.09.2019 and same was revised and valid upto 18.01.2020.

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 UAC for consideration

Agenda Item No.05: M/s.GVK Biosciences Private Limited, a unit in Ramky Pharma SEZ, Parawada, Visakhapatnam for inclusion of additional products in the LoA.

M/s.GVK Biosciences Private Limited a unit in Ramky Pharma SEZ, Parawada, has requested for inclusion of following additional products in the existing LoA:-

S. No	Name of the Product	Project code	IISN Code	Annual Capacity in
1	(S,E)-4-(tert-butyldimethylsilyloxy)pent-2-enal	CDS-0062	29420090	500 KG
2	2-(benzyloxy)-3-(chloromethyl)-4-methoxy-6-methylpyridine	CDS-0045	293339999 0	500 KG
3	8-nitro-3,5,6,7-tetrahydro-s-indacen-1(2H)-one(stage-2) 1,2,3,5,6,7-hexahydro-s-indacen-4-amine(stage-3)	CDS-0172	29213099	500 KG
4	2-(2-fluorophenyl)-1,3-dithiane(STG-1) tert-butyl 4-(2-(2-fluorophenyl)-1,3-dithian-2-yl)-4-hydroxypiperidine-1-carboxylate(STG-2) tert-butyl 4-(2-fluorobenzoyl)-4-hydroxypiperidine-1-carboxylate(STG-3) tert-butyl 3-oxo-3H-spiro[benzofuran-2,4'-piperidine]-1'carboxylate(STG-4) tert-butyl(R) -3-(((R)-tert-butylsulfinyl)amino) 3H-spiro(benzofuran-	CDS -0185	29420090	500KG

2,4'-piperidine]-1'-carboxylate(STG-5)

(R)-3H-spiro(benzofuran-2,4'-piperidin]-3-amine dihydrochloride(WHRY016)(STG-6)

As per the application it is observed that unit has not furnished the drug license

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 UAC for consideration
