

**ANDHRA PRADESH POLLUTION CONTROL BOARD**

D. No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada - 520 010
Website: www.pcb.ap.gov.in

CONSENT ORDER FOR ESTABLISHMENT & OPERATION**Order No. 297 /APPCB/CFE/RO-VSP/HO/2012****30/11/2019**

Sub:APPCB – CFE - **M/s. Granules Omnichem Pvt., Ltd., Plot No.121/P & 122, JNPC, Parawada, Visakhapatnam** – Consent for Establishment of the Board for **Change of Product Mix** under Sec. 25 of Water (P & C of P) Act, 1974 and Under Sec. 21 of Air (P&C of P) Act, 1981 - Issued - Reg.

- Ref:
1. CFE CPM order dt. 27.03.2019.
 2. Industry's application received through A.P. OCMMS on 14.10.2019.
 3. R.O's inspection report dt. 21.10.2019.
 4. CFE Committee meeting held on 25.10.2019.
 5. Industry's Ir. dt. 25.10.2019.
 6. RO's mail dt.04.11.2019 reg remittance of balance CFE & CFO fee.

In the reference 2nd cited, an application was submitted to the Board seeking Consent for
1. Establishment (CFE) for **Change of Product Mix** to produce the products with installed capacities as mentioned below, with an additional project cost of Rs. 5.0 Crores.

As per CFE CPM order dt. 27.03.2019:

S.No	Name of the Product	Quantity kg/day
	API Products	
1	Valsartan	33.33
2	Metformin HCl	550.00
	Total Qty. of API's (A)	583.33*
	Drug Intermediates	
3	N-Boc – L – Pyroglutamic Acid ethyl ester (PAC-2)	96.67
4	8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-8-azabicyclo[3.2.1]octane (BTC-7)	33.33
5	Formyltosylamide (FTA-1)	100
6	(R)-7-(Benzyloxy)-N-(2,4-difluorobenzyl)-4-methyl-6,8-dioxo-3,4,6,8,12,12a-hexahydro-2H-pyrido[1',2':4,5]pyrazino[2,1-b][1,3]oxazine-9-carboxamide –(DTG- 3/DOL-5)	116.67
7	4-methoxy-1-(phenylsulfonyl)-2,3-dihydro-1H-pyrrolo[2,3-c] pyridine (BES 6)	40.00
8	7-bromo-4-methoxy-1H-pyrrolo[2,3-c]pyridine. Hydrochloride (BES-10)	33.33
9	2,3,4,6-Tetra-O-Pivaloyl- α -D-glucopyranosyl bromide (FBJ-2)*	
	2,3,4,6-Tetra-O-Pivaloyl- α -D-glucopyranosylbromide(GLU-2)*	166.67
10	Tert-butyl (2S,3R)-3-hydroxy-4-(isobutylamino)-1-phenylbutan-2-yl carbamate (BIN-1)	266.67

11	2-Piperidinecarboxylic acid, 5-[(phenylmethoxy)amino]-, phenylmethyl ester, (2S,5R)- (ethanedioate) (SAM-0)	39.00
12	Tetrabutylammonium [(2S,5R)-2-Carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]octan-6-yl] Sulfate(SAM-3)	33.33
13	(2R,5S)-((1R,2S,5R)-2-isopropyl-5-methylcyclohexyl) 5-(4-amino-2-oxopyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylate (LAM-5)	100.00
14	(2S)-2-(hydroxymethyl)-1,2-dihydro-3H,8H-2a,5,8a-triazaacenaphthylene-3,8-dione (GPA-807A)	31.67
15	(R)-2-((4-aminopiperidin-1-yl) methyl)-1,2-dihydro-3H,8H- 2a,5,8a-triazaacenaphthylene-3,8-dione hemihydrochloride (GPO-3)	50.00
16	Sodium(3,4-dihydro-2H-pyrano[2,3-c]pyridin-6-yl)(hydroxyl) methane sulfonate (GPO-4)	66.67
17	(7-bromo-4-methoxy-1H-pyrrolo [2,3-c]pyridin-3-yl)(oxo)acetic acid (BES-12)	33.33
18	3-chloro-4-[(3-fluorobenzyl) oxy]aniline (TEC-2)	83.33
	Total Qty. of Drug intermediates (B)	1290.67
	Total Production Capacity (A+B)	1300.00*

The industry shall manufacture any 6 products (both API & Drug Intermediate products) at any given point of time with a maximum production capacity of 1300 kg/day.

By-Products:

S.No	Name of the By-Product	From the product	Quantity (kg)
1	Sponge Palladium	DOL	1.63
2	Palladium Carbon	GPA-807A	8.23

After Change of Product Mix: (As per Ir.dt.25.10.2019)

S. No	Name of the Product	Quantity Kg/day	No of Stages	Starting Raw Material	Quantity kg/day
1	Valsartan	1.67	1	(s)-Methyl N-[(2-cyanobiphenyl-4-yl)methyl]-L-Valinate Hydrochloride (VSV)	27.78
2	Metformin HCl	333.33	1	Dimethylamino hydrochloride	192.26
3	N-Boc – L – Pyroglutamic Acid ethyl ester (PAC-2)	33.33	1	L-Glutamic acid	20.83
4	8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-8-azabicyclo[3.2.1]octane (BTC-7)	50.00	2	2,5-dimethoxyTHF(DMTHF)	62.25
5	Formyltosylamide (FTA-1)	166.67	1	4-methyl benzene sulfonamide	146.66

6	4-methoxy-1-(phenylsulfonyl)-2,3-dihydro-1H-pyrrolo[2,3-c] pyridine (BES 6)	36.67	4	Formyltosylamide (FTA-1)	56.75
7	7-bromo-4-methoxy-1H-pyrrolo[2,3-c]pyridine. Hydrochloride (BES-10)	30.00	1	4-methoxy-1-(phenylsulfonyl)-2-3-dihydro-1H-pyrrolo[2,3-c] pyridine (BES-6)	46.19
8	2,3,4,6-Tetra-O-Pivaloyl- α -D-glucopyranosyl bromide (FBJ-2)**	233.33	1	D-Glucose	103.83
	2,3,4,6-Tetra-O-Pivaloyl- α -D-glucopyranosylbromide(GLU-2)**		1	D-Glucose	95.66
9	Tert-butyl (2S,3R)-3-hydroxy-4-(isobutylamino)-1-phenylbutan-2-yl carbamate (BIN-1)	166.67	1	S,S-BEP-3	156.66
10	2-Piperidinecarboxylic acid, 5-[(phenylmethoxy)amino]-, phenylmethyl ester, (2S,5R)- (ethanedioate) (SAM-0)	200.00	1	Benzyl boc glutamate	20.32
11	Tetrabutylammonium [(2S,5R)-2-Carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]octan-6-yl] Sulfate(SAM-3)	200.00	1	2-Piperidinecarboxylic acid, 5-[(phenylmethoxy) amino]-, phenylmethyl ester, (2S,5R)- (ethanedioate) (SAM-0)	41.45
12	(2R,5S)-((1R,2S,5R)-2-isopropyl-5-methylcyclohexyl) 5-(4-amino-2-oxopyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylate (LAM-5)	33.33	1	Menthylglyoxylate (MGH)	33.33
13	(2S)-2-(hydroxymethyl)-1,2-dihydro-3H,8H-2a,5,8a-triazaacenaphthylene -3,8-dione (GPA-807A)	37.27	4	2-Chloro-6-methoxy-3-nitropyridine	103.20
14	(R)-2-((4-aminopiperidin-1-yl) methyl)-1,2-dihydro-3H,8H- 2a,5,8a-triazaacenaphthylene-3,8-dione hemihydrochloride (GPO-3)	80.00	2	(2S)-2-(hydroxymethyl)-1,2-dihydro-3H,8H-2a,5,8a-triazaacenaphthylene-3,8-dione	59.00
15	Sodium(3,4-dihydro-2H-pyrano[2,3-c]pyridin-6-yl)(hydroxyl) methane sulfonate (GPO-4)	50.00	1	Methyl 3,4-dihydro-2H-pyrano[2,3-c]pyridine-6-carboxylate	51.64
16	(7-bromo-4-methoxy-1H-pyrrolo [2,3-c]pyridin-3-yl)(oxo)acetic acid (BES-12)	18.33	1	7-bromo-4-methoxy-1H-pyrrolo[2,3-c]pyridine Hydrochloride(BES-10)	18.51
17	Methyl 3,4-Dihydro-2H-Pyrano[2,3-C]Pyridine-6-Carboxylate (GPE)	15.33	2	Glycine	31.97
18	Quetiapine Lactam (SER-2)	11.67	2	2-Amino-diphenylsulfide	304.29

*The industry shall manufacture any 6 products including API & Drug Intermediates at point of time so that the maximum production shall not exceed 1300 kg /day.

**Either FBJ-2 or GLU-2 will be manufactured at any given point of time

By-Products:

S.No	Name of the By-Product	From the product	Quantity (kg)
1	Palladium Carbon	GPA-807A	2.75

2. As per the application, the above activity is to be located in the existing premises located at Plot No.121/P & 122, JNPC, Parawada, Visakhapatnam in an area of 12.135 acres.

3. The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 19.10.2019 and observed that the site is surrounded by

North : Plot No : 120 & Part of Plot No:121
South : 30 M wide SEZ internal road followed by hills.
East : Road followed by APEPDCL substation & Ramky Green belt.
West : M/s Eisai Pharma Ltd.

4. The Board, after careful scrutiny of the application, verification report of the Regional Officer and recommendation of CFE committee, hereby issues **CONSENT FOR ESTABLISHMENT AND OPERATION for Change of Product Mix** to the project under Section 25/26 of Water (Prevention & Control of Pollution) Act 1974 and Section 21/22 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is issued to manufacture the products as mentioned at para (1) only.**

5. This Consent Order now issued is subject to the conditions mentioned in the Annexure.

6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

7. **This order is valid upto 31.01.2022 i.e; validity of CFO & HWA order.**

Encl: Annexure.

**VIVEK YADAV IAS, MS(VY), O/o MEMBER SECRETARY-APPCB
MEMBER SECRETARY**

To

**M/s. Granules Omnichem Pvt., Ltd., (CPM)
Plot No.121/P & 122, JNPC,
Parawada, Visakhapatnam.
santhoshkumar.k@granulesomnichem.com
tagore.ps@granulesomnichem.com**

Copy to: 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.

2. The E.E., R.O: Visakhapatnam for information and necessary action.

ANNEXURE

1. The applicant shall provide separate energy meters for Effluent Treatment Plant (ETP) and Air pollution Control equipments to record energy consumed. An alternative electric power source sufficient to operate all pollution control systems shall be provided.
2. The industry shall construct separate storm water drains and provide rain water harvesting structures. No effluents shall be discharged in to the storm water drains.

Water:

3. The source of water is JN Pharmacy, Parawada and the maximum permitted water consumption is as following:

S. No.	Purpose	As per CFE (CPM) order dt. 27.03.2019 (KLD)	Qty after Change of Product Mix (KLD)
1.	Process & Washings	140.70	140.70
2.	Scrubbers		
3.	DM Plant		
4.	RO rejects & Back Washes		
5.	Boiler feed	100.00	100.00
6.	Cooling tower makeup		
7.	Domestic	40.00	40.00
8.	Gardening	120.00	120.00
Total		400.70	400.70

Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned above.

4. The maximum waste water generation shall not exceed the following: (As per lr.dt.25.10.2019)

Sl. No.	Source	As per CFE (CPM) order dt. 27.03.2019 (KLD)			Quantity after CPM (KLD)		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1.	Process	30.30	0	30.3	29.74	0	29.74
2.	Washings	0	10.00	10.00	0	10.00	10.00
3.	Scrubbers	5.00	0	5.00	5.00	0	5.00
4.	Boiler blow down	0	2.00	2.00	0	2.00	2.00
5.	DM Plant	0	15.00	15.00	0	15.00	15.00
6.	RO Rejects & back washes	0	44.80	44.80	0	44.80	44.80
7.	Cooling tower blow down	0	5.00	5.00	0	5.00	5.00
8.	Domestic	0	32.00	32.00	0	32.00	32.00
Total		35.30	108.8	144.10	34.74	108.8	143.54

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for forced evaporation.
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacy for further treatment and disposal
Domestic waste water	---	The overflow of the Septic tank shall be sent to the CETP for further treatment.

5. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
6. The industry shall install online real time monitoring system along with web camera facilities as per the directions of CPCB. The industry shall connect them to APPCB / CPCB websites as per CPCB directions.
7. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. All pipe valves, sewers, drains shall be leak proof.

Air:

8. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after Change of Product Mix:

Sl. No	Details	Stack 1	Stack 2	Stack 3
a)	Attached to	Boiler	D.G set	D.G set
b)	Capacity	1 X 6.0 TPH	1 X 1500 KVA DG Set	1 X 1450 KVA DG Set
c)	Fuel	Coal	Diesel	
d)	Stack height	40 m	8 m.(from ground level)	8 m. (from ground level)
e)	Control Equipment	Cyclone separator & bag filter	Acoustic enclosure with silencer	Acoustic enclosure with silencer

9. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
10. The industry shall properly operate and maintain the monitoring system attached to all the stacks / vents in the plant. Regular monitoring shall be carried out and report shall be submitted to the Regional officer.

11. The industry shall properly operate and maintain multi-stage scrubbers to the process vents to control the process emissions. The industry shall ensure that online pH measuring facility with auto recording system is connected to the scrubbers.
12. The industry shall properly operate and maintain VOC monitoring system with auto recording facility.
13. The industry shall implement adequate measures to control all fugitive emissions from the plant.
14. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, Gol vide notification No. GSR. 826 (E), dated. 16.11.2009 during construction and regular operational phase of the project at the periphery.

The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.

15. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
16. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
17. The evaporation losses in solvents shall be controlled by taking the following measures:
 - i. Chilled brine circulation shall be carried out to effectively reduce the solvent losses into the atmosphere.
 - ii. Transfer of solvents shall be done by using pumps instead of manual handling.
 - iii. Closed centrifuges shall be used to reduce solvent losses.
 - iv. All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours.
 - v. The reactor vents shall be connected with primary & secondary condensers to prevent escaping of solvent vapour emissions into atmosphere.

Solid Waste:

18. The industry shall comply with the following for disposal of Solid wastes: (As per lr.dt.25.10.2019)

S. No	Name of the waste	Quantity as per CFE (CPM) order dt.27.03.2019	Quantity after (CPM)	Mode of disposal
1	Organic Solid Waste	1106.20 kg/day	1077.49 kg/day	To Authorized cement industries for co processing or TSDF
2	Spent carbon	16.67 kg/day	8.33 kg/day	Parawada Visakhapatnam for incineration
3	Inorganic Solid Waste	419.90 kg/day	419.74 kg/day	To TSDF Parawada for secured land filling or Authorized cement

4	ETP Sludge	100.00 kg/day	100.00 kg/day	industries for co processing
5	Time expired /reject Raw Materials	50.00 kg/day	50.00 kg/day	
6	Off Specification products	50.00 kg/day	50.00 kg/day	
7	Used PPE	10.00 kg/day	10.00 kg/day	To TSDF Parawada for secured land filling / incineration
8	Insulation Waste	10.00 kg/day	10.00 kg/day	
9	Used Filter Bags & Filters	20.00 kg/day	20.00 kg/day	
10	Containers & container liners of hazardous chemicals	800 Nos./ Month	800 Nos./ Month	After detoxification, it shall be disposed to the outside agencies
11	Waste Oils & Grease	800 LPA	800 LPA	Authorized Reprocesses /Recyclers
12	Spent Solvents	160 TPM	160 TPM	Shall be recovered within the premises / disposed to PCB authorized recycling units.
13	Coal Ash	2.3 TPD	2.3 TPD	Brick Manufacturing units

19. The proponent shall place the chemical drums and / or any drums in a shed provided with concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.

20. The following rules and regulations notified by the MoEF&CC, GoI shall be implemented.

- a) Regulation of Persistent Organic Pollutants Rules, 2018.
- b) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
- c) Plastic Waste Management Rules, 2016.
- d) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
- e) Fly Ash Notification, 2016.
- f) Batteries (Management & Handling) Rules, 2010.
- g) E-Waste (Management) Rules, 2016.
- h) Construction and Demolition waste Management Rules, 2016.
- i) Solid Waste Management Rules, 2016.
- j) The Public Liability Insurance Act, 1991 and its amendments thereof.

Other Conditions:

21. Existing green belt shall not be disturbed due to the proposed Change of Product Mix. Thick green belt shall be maintained all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.

22. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.
23. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order attracts action under the provisions of relevant pollution control Acts.
24. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control of Pollution) Act, 1981 to revoke the order, to review any or all the conditions imposed herein and to make such modifications as deemed fit and stipulate any additional conditions.
25. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules,1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution)Act,1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

**VIVEK YADAV IAS, MS(VY), O/o MEMBER SECRETARY-APPCB
MEMBER SECRETARY**

To

**M/s. Granules Omnichem Pvt., Ltd., (CPM)
Plot No.121/P & 122, JNPC,
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