



ANDHRA PRADESH POLLUTION CONTROL BOARD
D.No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamalavari Street, Kasturibaipet, Vijayawada – 520010.

Website :www.appcb.ap.nic.in

CONSENT ORDER FOR ESTABLISHMENT

Order No. 297 /APPCB/CFE/RO-VSP/HO/2014

Dt.28.01.2018

Sub: APPCB – CFE – **M/s. Granules Omnichem Pvt., Ltd., Plot No.121/P & 122, JNPC, Parawada, Visakhapatnam** – Consent for Establishment of the Board for **expansion** 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 & CFO order dt. 27.05.2017.
 2) Industry's application received through A.P. OCMMS dt. 27.12.2017.
 3) R.O's inspection report dt. 06.01.2018.
 4) CFE Committee meeting held on 10.01.2018.

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **expansion** within the existing premises to produce the products with installed capacities as mentioned below, with an additional investment of Rs. 160 Crore.

CFE & CFO (CPM) dt. 27.05.2017:

S. No	Name of the Product	Quantity kg/Day	No of Stages	Starting Raw Material	Qty kg/day
	API's				
1	Valsartan	233.33	1	(s)-Methyl N-[(2-cyanobiphenyl-4-yl)methyl]-L-Valinate Hydrochloride (VSV)	222.67
2	Metformin HCl	466.67	1	Dimethylamino hydrochloride	261.3
	Total API's	700.00			
	Drug Intermediates				
3	N-Boc – L – Pyroglutamic Acid ethyl ester (PAC-2)	50.0	1	L-Glutamic acid	21.0
4	8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-8-azabicyclo[3.2.1]octane (BTC-7)	159.67	2	2,5-dimethoxyTHF(DMTHF)	258.0
5	Formyltosylamide (FTA-1)	198.33	1	4-methyl benzene sulfonamide	189.2
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)	25.33	3	Methyl3-(benzyloXY)-1-(2,3-dihydropropyl)-4-oxo-1,4-dihydropyridine-2-carboxylate(DHPM)	33.01
7	4-methoxy-1-(phenylsulfonyl)-2,3-dihydro-1H-pyrrolo[2,3-c]pyridine (BES 6)	16.67	4	FTA	32
8	7-bromo-4-methoxy-1H-pyrrolo[2,3-c]pyridine. Hydrochloride(BES-10)	11.67	1	4-methoxy-1-(phenylsulfonyl)-2-3-dihydro-1H-pyrrolo[2,3-c]pyriidine(BES-6)	18.0
9	2,3,4,6-Tetra-O-Pivaloyl-α-D-glucopyranosylbromide(FBJ-2)*	36.67	1	D-Glucose	14.8
	2,3,4,6-Tetra-O-Pivaloyl-α-D-glucopyranosylbromide(GLU-2)*		1	D-Glucose	15.2

10	Tert-butyl (2S,3R)-3-hydroxy-4-(isobutylamino)-1-phenylbutan-2-yl carbamate (BIN-1)	26.67	1	S,S-BEP-3	29.7
11	2-Piperidinecarboxylic acid, 5-[(phenylmethoxy)amino]-, phenylmethyl ester, (2S,5R)-(ethanedioate) (SAM-0)	11.67	1	Benzyl boc glutamate	13.5
12	Tetrabutylammonium [(2S,5R)-2-Carbamoyl-7-oxo-1,6-diazabicyclo[3.2.1]octan-6-yl] Sulfate(SAM-3)	30.0	1	2-Piperidinecarboxylic acid, 5-[(phenylmethoxy) amino]-, phenylmethyl ester, (2S,5R)-(ethanedioate) (SAM-0)	37.5
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)	33.33	1	Menthylglyoxylate (MGH)	39.2
	Total Drug Intermediates	600.0			
	Total Production Capacity	1300.0			
*	Either FBJ-2 or GLU-2 will be manufactured at any given point of time				

After expansion:

S. No	Name of the Product	Quantity Kg/day	No of Stages	Starting Raw Material	Quantity kg/day
1	Valsartan	233.33	1	(s)-Methyl N-[(2-cyanobiphenyl-4-yl)methyl]-L-Valinate Hydrochloride (VSV)	222.67
2	Metformin HCl	466.67	1	Dimethylamino hydrochloride	261.30
	Total API Quantity	700.00			
3	N-Boc – L – Pyroglutamic Acid ethyl ester (PAC-2)	50.0	1	L-Glutamic acid	21.00
4	8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-8-azabicyclo [3.2.1]octane (BTC-7)	159.67	2	2,5-dimethoxyTHF (DMTHF)	258.00
5	Formyltosylamide (FTA-1)	198.33	1	4-methyl benzene sulfonamide	189.2
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)	47.55	3	Methyl3-(benzyloXY)-1-(2,3-dihydropropyl)-4-oxo-1,4-dihydropyridine-2-carboxylate (DHPM)	61.96
7	4-methoxy-1-(phenylsulfonyl)-2,3-dihydro-1H-pyrrolo[2,3-c]pyridine (BES 6)	16.67	4	FTA	32.0
8	7-Bromo-4-methoxy-1H-pyrrolo[2,3-c] pyridine hydrochloride (BES-10)	17.23	1	BES-6	26.6
9	2,3,4,6-Tetra-O-pivaloyl- α -D-glucopyranosylbromide (FBJ-2)*	50.56	1	Glucose	20.80
	Or				

	2,3,4,6-Tetra-O-pivaloyl- α-D- glucopyranosylbromide (GLU-2)*				
10	Tert-butyl (2S, 3R)-3- hydroxy-4- (isobutylamino)-1- phenylbutan-2-yl carbamate (BIN-1)	26.67	1	S,S-BEP-3	29.7
11	2-Piperidine carboxylic acid, 5- [(phenylmethoxy)amino]-, phenylmethyl ester, (2S,5R)- (ethanedioate) (SAM-0)	25.56	1	Benzyl boc glutamate	27.6
12	Tetrabutylammonium [(2S,5R)-2-Carbamoyl-7- oxo-1,6-diazabicyclo [3.2.1]octan-6-yl] Sulfate (SAM-3)	43.89	1	SAM-0	54.8
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)	33.33	1	Menthylglyoxylate (MGH)	39.2
	Total Drug Intermediates	669.45			
	Total Production capacity	1369.45			

2. As per the application, the above activity is to be located within the existing industry 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 06.01.2018 and observed that the site is surrounded by
 - North** : Plot No : 120 & Part of Plot No:121
 - South** : 30 m wide 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 and verification report of the Regional Officer, hereby issues **CONSENT FOR ESTABLISHMENT FOR EXPANSION** to your activity Under Section 25 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 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 for period of 7 years from the date of issue.**

Encl: Annexure.

MEMBER SECRETARY

To

**M/s. Granules Omnichem Pvt., Ltd., (expn)
Plot No.121/P & 122, JNPC, Parawada,
Visakhapatnam
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 proponent shall obtain Consent for Operation (CFO) from APPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981, before commencement of the trial runs.
2. 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.
3. 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:

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

S. No.	Purpose	CFE & CFO (CPM) order dt. 27.05.2017 KLD	Quantity after expansion KLD
1.	Industrial cooling, boiler feed.	140.00	210.00
2.	Domestic & gardening purposes.	120.00	130.00
3.	Processing, whereby water gets polluted and pollutants are easily bio- degradable.	----	----
4.	Processing, whereby water gets polluted and the pollutants are not easily bio-degradable.	100.70	117.60
	Total	360.70	457.60

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

2. The maximum waste water generation shall not exceed the following:

Sl. No.	Effluent	CFE & CFO (CPM) order dt. 27.05.2017 KLD			Quantity after expansion KLD		
		HTDS	LTDS	TOTAL	HTDS	LTDS	TOTAL
1.	Process	31.00	---	31.00	48.60	---	48.60
2.	Washings	---	10.00	10.00	---	18.00	18.00
3.	Scrubbers	5.00	---	5.00	10.00	---	10.00
4.	Boiler blow down	---	2.00	2.00	---	3.00	3.00
5.	DM Plant	---	15.00	15.00	---	15.00	15.00
6.	RO Rejects & back washes	---	44.80	44.80	---	44.80	44.80
7.	Cooling tower blow down	---	5.00	5.00	---	7.50	7.50
8.	Domestic	---	32.00	32.00	---	47.00	47.00
	Total	36.00	108.80	144.80	58.60	135.30	193.90

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.

3. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
4. 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.
5. 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:

6. The industry shall comply with the following for controlling air pollution after expansion:

Sl. No	Details	Stack 1	Stack 2	Stack 3
a)	Attached to	Coal Boiler	Oil Boiler	D.G sets
b)	Capacity	1 X 6.0 TPH	1 X 4.0 TPH	2 X 1500 KVA DG Set & 1 X 1450 KVA DG Set
c)	Fuel	Coal – 21 TPD	HSD	Diesel – 325 lt/hr
d)	Stack height	40 m		30 m (from ground level)
e)	Control Equipment:	Cyclone separator & bag filter	----	Acoustic enclosures

7. 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.
8. The industry shall provide multi-stage scrubbers to the process vents to control the process emissions. The industry shall provide online pH measuring facility with auto recording system to the scrubbers provided to treat the process emissions.
9. The industry shall provide VOC monitoring system with auto recording facility.
10. The industry shall implement adequate measures to control all fugitive emissions from the plant.
11. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, GoI 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.
12. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
13. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
14. 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:

15. The industry shall comply with the following for disposal of Solid wastes:

S. No	Name of the waste	Qty. as per CFE & CFO order dt. 27.05.2017 kg/day	Total quantity after expansion kg/day	Mode of disposal
1	Organic Solid Waste	1402.19	1446.29	Authorized cement industries for co processing (or) TSDF Parawada Visakhapatnam for incineration
2	Spent carbon	13.33	13.33	
3	In organic solid waste	85.46	96.11	TSDF Parawada for scientific land filling.
4	ETP Sludge	100.00	110	
5	Time expired raw material	22.0	22.0	
6	Off specification products	15.0	15.0	
	Total	1637.98	1702.73	
7	Containers & container liners of hazardous chemicals	600Nos/month	600Nos/month	After detoxification, it shall be disposed to the authorized agencies
8	Waste Oils & Grease	500 LPA	800 LPA	To Authorized Re-processors / Recyclers
9	Spent solvents / mixed spent solvents / Distilled Solvents	130 TPM	160 TPM	Shall be recovered within the premises/disposed to authorized recycling units
10	Coal ash	2.3 TPD	2.3 TPD	Brick manufacturing units

16. 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.
17. The following rules and regulations notified by the MoE&F, Gol shall be implemented.
 - a) Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
 - b) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
 - c) Fly Ash Notification, 2016.
 - d) Batteries (Management & Handling) Rules, 2010.
 - e) E-Waste (Management) Rules, 2016.
 - f) Construction and Demolition waste Management Rules, 2016.

Other Conditions:

18. **The industry shall connect the flow & web camera to APPCB website as committed in the CFE Committee meeting held on 10.01.2018.**
19. Existing green belt shall be maintained all along the boundary & vacant spaces and it shall not be less than 33% of the total area.
20. 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.
21. 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.
22. 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.
23. 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.

MEMBER SECRETARY

To

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