

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

Dt: 02.08.2019

CONSENT ORDER FOR ESTABLISHMENT

Order No. 201 /APPCB/CFE/RO-VSP/HO/2010

Sub: APPCB – CFE - M/s. Porus Laboratories Pvt. Ltd., Plot No. 64, 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 expansion order dt. 22.06.2018.

- 2) Industry's application received through A.P. Single Desk Portal on 30.06.2019.
- 3) R.O's inspection report dt. 06.07.2019.
- 4) CFE Committee meeting held on 18.07.2019.
- 5) Industry's Ir. dt. 18.07.2019.
- 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, without any additional investment.

As per CFE expansion order dt. 22.06.2018:

SI. No	Product Name	Quantity (Kg/Day)
1.	Ciprofloxacin Hydrochloride	1333.33
2.	Sumatriptan Succinate	16.67
3.	Metformin Hydrochloride	1666.67
4.	Venlafaxine Hydrochloride	33.33
5.	Clopidogrel Hydrogen Bisulfate	166.67
6.	Enrofloxacin	1000.00
7.	Pioglitazone Hydrochloride 33.33	
8.	Gabapentin	66.67
9.	p-Phenolphthalein bisphenol (or) 2-Phenyl-3,3-Bis (4-Hydroxy Phenyl) Phthalimide (PPPBP)	5000.00
10.	Phenolphthalein (PP)	1166.67
11.	4-Nitro-N-methyl phthalimide (4-NPI)	6666.67
12.	2,2-Bis[4-(N-methyl phthalimido-4-oxy)phenyl] propane [BI (or) Bisimide]	13333.33
13.	Tetramethyl bisphenol acetone (TMBPA Powder)	1000.00
14.	Tetrabromobisphenol-A (TBBPA)	33.33
15.	Silicone Resin	50.00
16.	1-Methyl-3-[methyl(phenyl carbonyl)amino] butyl benzoate (AB-Donor)	50.00

17.	(4,4'-(3,3,5-Trimethyl cyclohexane-1,1-diyl) bisphenol (BPI)	15.00		
18.	9,9'-Bis (Methoxymethyl) fluorene (BMMF)	20.00		
19.	Benzofuro [2,3-b] benzofuran-3,8-diol,5a, 10b-dihydro-5a,10b-diphenyl (DCBP)	15.00		
20.	Spiro[fluorene-9,9'-xanthene]-3',6'-diol (FBP)	15.00		
21.	PPPBP-Diepoxy	15.00		
22.	Capped 0.09 IV Bifunctional PPO (SA-9000)	1000.00		
23.	R&D Products	10.00		
Gran	Grand Total			
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Intermediates:

SI. No	Product Name	Qty. as per CFE (expansion) order dt. 22.06.2018
a).	From Sumatriptan Succinate	
i.	Sumatriptan base	14
b).	From Pioglitazone Hydrochloride	
i.	2-(5-Ethyl-2-pyridyl)ethanol	24
ii.	4-[2-(5-Ethyl-2-pyridyl)ethoxy] benzaldehyde	30
iii.	5-[4,2-(5-Ethyl-2-pyridyl)ethoxy] benzilidine-2,4-thiazolidinedione	36.66
iv.	Pioglitazone base	33.33
c).	From Clopidogrel Hydrogen Bisulfate	
i.	2-Thiophene ethylamine	150
ii.	Methyl-[2-(2-thienyl)ethylamino]-2-chlorophenyl acetate	333.33
iii.	D,L-Clopidogrel base	300
iv.	S (+) Clopidogrel base	141.65
d).	From Gabapentin	
i.	1,1-Cyclohexane diacetic anhydride	110
ii.	1,1-Cyclohexane diacetic acid-N-hydroxylimide	100
iii.	N-Benzenesulfonyloxy-1,1-cyclohexane diacetic acidimide	151.32

By-products:

SI. No	By-product Name	Qty. as per CFE (expansion) order dt. 22.06.2018	By-product from
1	Piperazine HCl ML's	7805.33	Ciprofloxacin HCl
2	N-Ethyl Piperazine HCl ML's	6066	Enrofloxacin
3	Spent Sulfuric Acid	54897.8	4-Nitro-N-methyl phthalimide (4-NPI)
4	Sodium Nitrite	3066.66	2,2-Bis[4-(N-methylphthalimido -4- oxy)phenyl]propane [BI (or) Bisimide]

After expansion:

CI	After expansion:			Starting Raw Material			
SI. No	Product Name	Quantity (kg/day)	Number of stages	Name	Quantity (kg/day)		
1.	Ciprofloxacin Hydrochloride	1333.33	2	Q-Acid	1253.3		
2.	Sumatriptan Succinate	16.67	3	4-Hydrazino-N-methyl benzene methane sulfonamide Hydrochloride	20		
3.	Metformin Hydrochloride	1666.67	1	Dicyanodiamide	1050		
4.	Venlafaxine Hydrochloride	33.33	1	1-[-Amino-1-(4- methoxyphenyl) ethyl] cyclohexanol	31.7		
5.	Clopidogrel Hydrogen Bisulfate	166.67	5	Thiophene ethanol	166.7		
6.	Enrofloxacin	1000.00	2	Q-Acid	940		
7.	Pioglitazone Hydrochloride	33.33	6	5-Ethyl-2-methyl pyridine	21.7		
8.	Gabapentin	66.67	4	1,1-Cyclohexane diacetic acid	126.7		
9.	p-Phenolphthalein bisphenol (or) 2-Phenyl-3,3-Bis (4- Hydroxy Phenyl) Phthalimide (PPPBP)	5000.00	2	Phthalic anhydride	2264.2		
10.	Phenolphthalein (PP)	1166.67	1	Phthalic anhydride	604.8		
11.	4-Nitro-N-methyl phthalimide (4-NPI)	6666.67	2	Phthalic anhydride	5333.3		
12.	2,2-Bis[4-(N-methyl phthalimido-4-oxy)phenyl] propane [BI (or) Bisimide]	13333.33	2	Bisphenol A	6266.6		
13.	Tetramethyl bisphenol acetone (TMBPA Powder)	1000.00	1	Acetone	230.8		
14.	Tetrabromobisphenol-A (TBBPA)	33.33	1	Bisphenol A	15.0		
15.	Silicone Resin	50.00	1	Octamethylcyclotetrasilox ane-D4	67.0		
16.	1-Methyl-3-[methyl(phenyl carbonyl)amino] butyl benzoate (AB-Donor)	50.00	3	Acetylacetone	24.0		
17.	(4,4'-(3,3,5-Trimethyl cyclohexane-1,1-diyl) bisphenol (BPI)	15.00	1	Dihydroisophorone	9.0		
18.	9,9'-Bis (Methoxymethyl) fluorene (BMMF)	20.00	2	Fluorene	63.2		
19.	Benzofuro [2,3-b] benzofuran- 3,8-diol,5a, 10b-dihydro- 5a,10b-diphenyl (DCBP)	15.00	1	Benzil	15.0		
20.	Spiro[fluorene-9,9'-xanthene]-3',6'-diol (FBP)	15.00	1	Fluorenone	15.0		
21.	PPPBP-Diepoxy	15.00	1	PPPBP	15.0		

22.	Capped 0.09 IV Bifunctional PPO (SA-9000)	1000.00	1	1,5-Bis-(2,6-dimethyl-4-hydroxyphenyl)-penta-(2,6-dimethyl-1,4-phenyleneoxide)	1000.0
23.	2,2-Bis[4-(N-methyl phthalimido-3-oxy)phenyl] propane [3,3-BI (or) 3,3-Bisimide]	3333.33	2	Bisphenol A	1566.7
24.	R&D Products	10.00			
	Grand Total (Total Products)	36040.0			

By-products:

SI. No	By-product Name	Proposed Quantity (Kg/Day)	By-product from
1	Piperazine HCl ML's	7805.33	Ciprofloxacin HCl
2	N-Ethyl Piperazine HCl ML's	6066	Enrofloxacin
3	Spent Sulfuric Acid	54897.8	4-Nitro-N-methyl phthalimide (4-NPI)
4	Sodium Nitrite	3666.7	2,2-Bis[4-(N-methylphthalimido -4- oxy)phenyl]propane [BI (or) Bisimide]

Intermediates:

SI.	Name	Production Quantity
No.	Name	(kg/day)
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d).	From Gabapentin	
i.	1,1-Cyclohexane diacetic anhydride	110
ii.	1,1-Cyclohexane diacetic acid-N-hydroxylimide	100
iii.	N-Benzenesulfonyloxy-1,1-cyclohexane diacetic acidimide	151.32

- 2. As per the application, the above activity is to be located within the existing industry premises located at Plot No. 64, JNPC, Parawada, Visakhapatnam in an area of 5.75 acres.
- 3. The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 04.07.2019 and observed that the site is surrounded by

North : Road followed by Verdant South : Road followed by Veerchemie

East : Road followed by M/s. Suven Life Sciences Ltd

West: M/s. Quagen Pharma India Pvt. Ltd

- 4. The Board, after careful scrutiny of the application, verification report of the Regional Officer and recommendations of the CFE Committee, hereby issues **CONSENT FOR ESTABLISHMENT FOR EXPANSION** to the project 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 a period of 7 years from the date of issue.

Encl: Annexure.

MEMBER SECRETARY

То

M/s. Porus Laboratories Pvt. Ltd., (expn) Plot No. 64, JNPC, Parawada, Visakhapatnam. gphanichaitanya@poruslabs.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 trail 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:

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

SI. No.	Purpose	Qty. as per CFE (expansion) order dt. 22.06.2018 (KLD)	Quantity after expansion (KLD)
1	Process	129.90	146.80
2	Washings (Reactor, Containers and floor moping)	10.00	10.00
3	Boiler	163.00	163.00
4	Cooling Towers make-up	25.00	25.00
5	DM Plant	1.00	1.00
6	R&D, Q.C	2.00	2.00
7	Scrubber	2.40	2.40
8	Domestic	5.00	5.00
9	Gardening	3.00	3.00
	Total	341.30	358.20

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

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

SI. No	Source	Qty. as per CFE (expansion) order dt. 22.06.2018 (KLD)		Quantity after expansion (KLD)			
		HTDS	LTDS	Total	HTDS	LTDS	Total
1	Process	53.8	40.7	94.5	65.40	44.20	109.60
2	Washings (Reactor, Containers and floor moping)		10.0	10.0		10.0	10.0
3	Boiler		11.0	11.0		11.0	11.0
4	Cooling Towers blow down		3.0	3.0		3.0	3.0

5	DM Plant		1.0	1.0		1.0	1.0
6	R&D, Q.C		2.0	2.0		2.0	2.0
7	Scrubber	2.4	0	2.4	2.4	0	2.4
8	Domestic		4.5	4.5		4.5	4.5
	Total	56.20	72.20	128.40	67.80	75.70	143.50

Treatment & disposal:

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

- 6. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
- 7. The industry shall properly operate and maintain online real time monitoring system along with web camera facilities and shall ensure that it is connected to APPCB / CPCB websites as per CPCB directions.
- 8. 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:

9. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after expansion:

As per CFE order dt. 22.06.2018:

SI.No	Details	Stack 1	Stack 2	Stack 3	Stack 4	Stack 5
a)	Attached to	Coal fired	Coal fired	Thermic	Hot oil	D.G. Sets
		boiler	boiler	fluid heater	Boiler	
b)	Capacity to	1x 12	1x 5 TPH	6.0 Lakhs	1.0 Lakhs	1 x 750 KVA
		TPH	(standby)	Kilo calorie	Kilo	&
					calorie	1 x 320 KVA
c)	Fuel	Coal	Coal	Coal	Diesel	HSD
d)	Stack height	30 m	30 m	30 m	20 m	3.4 m
	_					Above roof
e)	Control	MDC &	MDC &	MDC		Silencer &
	Equipment	Bag filter	Bag filter			Acoustic
		-	-			enclosures

After expansion:

SI.No	Details	Stack 1	Stack 2	Stack 3	Stack 4	Stack 5
a)	Attached to	Coal fired boiler	Coal fired boiler	Thermic fluid heater	Thermic fluid heater	D.G. Sets
b)	Capacity to	1x 12 TPH	1x 5 TPH	6.0 Lakhs Kilo calories	6.0 Lakhs Kilo calories	1 x 750 KVA, 1 x 320 KVA & 1 x 1010 KVA
c)	Fuel	Coal	Coal	Coal	Coal	HSD
d)	Stack height	30 m	30 m	30 m	30 m	3.4 m Above roof
e)	Control Equipment	MDC & Bag filter	MDC & Bag filter	MDC	MDC	Silencer & Acoustic enclosures

- 10. 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.
- 11. The industry shall properly operate and maintain the monitoring system to all the stacks / vents in the plant. Regular monitoring shall be carried out and report shall be submitted to the Regional officer.
- 12. 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.
- 13. The industry shall properly operate and maintain VOC monitoring system with auto recording facility.
- 14. The industry shall implement adequate measures to control all fugitive emissions from the plant.
- 15. 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.
- 16. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
- 17. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.

- 18. 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 / Hazardous Waste:

19. The industry shall comply with the following for disposal of Solid waste:

S. No	Name of solid waste	Consented as per CFE dt.	After expansion	Method of disposal
		22.06.2018		
1.	Process Organic Residues and Distillation Bottom Residue (kg/day)	6531	3644	To the authorized Cement industries for co-processing (or) TSDF, Parawada for incineration
2.	Spent Carbon (kg/day)	919	919	
3.	Inorganic Solid Waste (kg/day)	1542	1542	To TSDF, Parawada for secured land filling.
4.	ETP Sludge (kg/day)	150	150	
5.	Spent solvents (KLD)		173	Recovery within the premises / to authorised agency for recovery.
6.	Mixed spent solvents (KLD)	9	9	To authorized recovery units / Authorized cement plant for co-processing.
7.	Waste Oils & Grease (lit/Annum)	300	300	To authorized Re-processors / Recyclers / to the Cement industries for co-processing in the kiln.
8.	Glass Bottles / Scrap (kg/month)		50	•
9.	a. Detoxified Containers / drum liners (Nos/Annum)	1000	1200	
	b. HDPE carboys (Nos/Annum)	1000	1200	To outside agencies, after complete detoxification for re-use/ recycle.
	c. Fiber drums (Nos/ Annum)	1000	1200	
	d. PP Bags (kg/Annum)	1000	1200	

10.	Used Lead acid batteries (Nos/year)	10	10	To dealers on buy back system
11.	Insulation Waste (kg/annum)		50	Sent to authorized agencies (or) TSDF, Parawada / Cement Industries
12.	Thermocol Waste (kg/annum)		100	TSDF / Cement Industry / Authorized recyclers
13.	PPFRP Waste (kg/annum)		50	TSDF / Authorized recyclers / Cement Industry
14.	Boiler Ash (kg/day)	27200	27200	To Brick Manufacturers.

- 20. 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.
- 21. The following rules and regulations notified by the MoEF&CC, Gol 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.

Other Conditions:

- 22. If the capacity of CETP, JNPC is not sufficient in future, then the additional capacity of the products issued in this order, that generate the excess quantity of effluent, than the quantity permitted based on the area of the industry shall be withdrawn.
- 23. Existing green belt shall not be disturbed due to the proposed expansion. Thick green belt shall be developed 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 i.e. 1.9 acres in the present monsoon.
- 24. 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.

- 25. 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.
- 26. 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.
- 27. 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. Porus Laboratories Pvt. Ltd., (expn) Plot No. 64, JNPC, Parawada, Visakhapatnam. gphanichaitanya@poruslabs.com