

	ANDHRA PRADESH POLLUTION CONTROL BOARD	Phone: 0866 - 2436217 Website: www.appcb.ap.nic.in
	D.No. 33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre, Chalamalavari Street, Kasturibaipet, Vijayawada – 520010	

CONSENT ORDER FOR ESTABLISHMENT

Order No. 183 /APPCB/CFE/RO-VSP/HO/2009 07/08/2018

Sub: PCB – CFE - **M/s. Verdant Life Sciences Pvt. Ltd., Plot No. 55, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District** – 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 (Expn.) order dt. 17.11.2016.
 2. Industry's application received through APOCMMS on 10.07.2018.
 3. R.O's inspection report dt. 18.07.2018.
 4. CFE Committee meeting held on 03.08.2018.

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **expansion** to produce the products with installed capacities as mentioned below, with no additional investment.

As per CFE (exp) order dt. 17.11.2016:

S. No.	Products	Quantity (kg/day)
GROUP-A		
1	Telmisartan	166.67
2	Irbesartan	116.67
3	Chlorpheniramine Maleate	433.33
4	Losartan Potassium	133.33
5	Sertraline Hydrochloride	33.33
6	Candesartan Cilexetil	33.33
7	Olmesartan Medoxomil	23.33
8	Mefanamic Acid	66.67
9	Azilsartan	16.67
10	Ofloxacin	266.67
11	Fenbendazole	66.67
12	Rafoxanide	66.67
13	Oxybendazole	33.33
14	Niclosamide	533.33
15	Domperidone Maleate	50.00
GROUP-B		
16	Carisoprodol	100.00
17	Guaifenesin	400.00
18	Rosuvastatin Calcium	1.67
19	Citicoline Sodium	33.33
20	Fexofenadine Hydrochloride	233.33
21	Triclabendazole	33.33
22	Oxyclozanide	40.00

23	Closetel Sodium	66.67
24	Etodolac	33.33
25	Etoricoxib	6.67
26	Lidocaine	16.67
27	Pregabalin	33.33
28	Sofosbuvir	33.33
29	Clorsulon	16.67
30	Valsartan	116.67
Distillation of MLs		
31	Methanol Recovery from Serta Trans CF ML's	3100
32	Sertraline Trans Isomer	540.00
Total		5506.66

The industry shall manufacture any 7 products (from Group A or Group B) at any given point of time with a maximum production capacity of 5506.66 kg/day.

S. No.	Name of By-Product	Quantity in Kg/Day	By-Products from
1	Tributyltin Chloride	113.0	Irbesartan
2	Trityl Chloride	101.0	Irbesartan/ Candesartan
3	Succinimide	41.0	Losartan Potassium
4	Pentafluoro Phenol	13.5	Sofosbuvir

Proposed after expansion:

S. No.	Name of the Product	Quantity kg/day	No. of Stages	Name of the Starting Raw Material	Quantity kg/day
1.	Telmisartan	266.67	3	4-Methyl-6-(1-methyl benzimidazol-2-yl)-2-propyl benzimidazole (BIM)	200.0
2.	Irbesartan	16.67	3	2-Butyl-1,3-diazaspiro-[4,4] non-1-ene-4-one hydrochloride (Spiro compound)	13.3
3.	Chlorpheniramine Maleate	66.67	3	2-Dimethylamino Ethanol	45.5
4.	Losartan Potassium	133.33	3	4'-Bromomethyl -2-biphenylcarbonitrile (OTBB)	96.0
5.	Sertraline Hydrochloride	33.33	2	Cis-Racemate Hydrochloride	83.3
6.	Olmesartan Medoxomil	26.67	3	4-[2-(Trityl tetrazol-5-yl) phenyl]Benzyl bromide (TTBB)	42.2
7.	Mefenamic Acid	33.33	2	2-Chloro benzoic acid	33.3
8.	Azilsartan	16.67	4	Methyl 3-((2'-cyanobiphenyl-4-yl) methyl)-2-ethoxy- 3H-benzo [d] imidazole-4-carboxylate	25.0
9.	Carisoprodol	500.00	2	2-Methyl-2-propyl-N-isopropyl carbonate (CD Base)	500.0

10.	Guaifenesin	500.00	2	Guaiacol	383.3
11.	Valsartan	15.00	3	L-Valine methyl ester hydrochloride	7.0
12.	5-(4-Amino-2-oxo-2H-pyrimidinyl- [1,3] oxathiolane-2-carboxylic acid-2-Isopropyl-5-methyl cyclohexyl ester [Lamivudine Intermediate - CHE]	666.67	3	L (+) Menthol	500.0
13.	Lamivudine	166.67	1	(2R-cis)-5-(4-amino-1,2-dihydro-2-oxo-1-pyrimidinyl)-1,3-oxathiolane-2-carboxylic acid (2S,5R)-menthyl ester (CHE)	333.3
14.	4-chloro benzhydryl piperazine [Levocetirizine Intermediate- LVZ]	33.33	3	4-Chloro benzophenone	38.0
15.	Levocetirizine Dihydrochloride	41.67	3	1-[(4-Chlorophenyl) phenylmethyl] piperazine	37.5

16.	(2R,5S)-5-(4-Amino-5-Fluoro-2-Oxo-2H-Pyrimidin-1-yl)- [1, 3]- Oxathiolane-2-carboxylic acid, 2S-Isopropyl-5R-Methyl-1R-Cyclohexyl Ester [Emtricitabine Intermediate -FCE]	333.33	3	L (+) Menthol	250.0
17.	Emtricitabine	166.67	3	5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)- [1,3] oxathiolane-2-carboxylic acid-2-isopropyl-5-methyl cyclohexyl ester	366.7
18.	Flurbiprofen	50.00	5	2-Fluoro aniline	100.0
19.	4-Bromo-2-fluorobiphenyl [Flurbiprofen Intermediate- BFBP]	33.33	3	2-Fluoro aniline	33.3
20.	Ethyl Oxalyl chloride	166.67	1	Diethyl oxalate	243.3
21.	Sucralfate	33.33	2	Sucrose	5.0
22.	Clopidogrel Bisulphate (Form-II)	33.33	5	2-Chlorophenyl Glycine	58.3
23.	Lopinavir	66.67	2	2,6-Dimethyl phenoxy acetyl Chloride (DPC)	26.7
24.	Low Volume Validation Products	100.00			-
Distillation of MLs					
25.	Methanol Recovery from Sertra trans CF ML's	1550.00	1	Trans Sertraline Methanol CF ML's	2250.0

26.	Sertraline Trans Isomer	270.00	1	Residue with Trans Isomer	750.0
27.	TEA HCl (From Toluene CF ML's)	180.00	1	TEA + Toluene CF ML's (TEA-16%)	840.0
	Total	5500.0 kg/day			

- As per the application, the above activity is to be located within the existing industry premises located at Plot No. 55, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District in an area of 20842 Sq. m (5.16 acres).
- The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer - I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 13.07.2018 and observed that the site is surrounded by

North : Road
South : Porus Labs
East : Road
West : Industrial Plot.

- The Board after careful scrutiny of the application, verification report of the Regional Officer and recommendation of the CFE committee, hereby issues **CONSENT FOR ESTABLISHMENT FOR EXPANSION** to the 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.**
- This Consent Order now issued is subject to the conditions mentioned in Annexure.
- This order is issued from pollution control point of view only. Zoning and other regulations are not considered.
- This order is valid for period of 7 years from the date of issue**

Encl: Annexure.

VIVEK YADAV IAS
MEMBER SECRETARY

To,

M/s. Verdant Life Sciences Pvt. Ltd.,
Plot No. 55, JN Pharma City,
Parawada, Visakhapatnam Dist.
msivrp@verdantpharma.com
plant@verdantpharma.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 JNPC, Parwada and the maximum permitted water consumption is as following:

S. No.	Purpose	Quantity as per CFE Order dt. 17.11.2016 (KLD)	Proposed quantity after expansion (KLD)
1	Process	47.29	47.70
2	Washings (Reactors & Floor Moping)	8.00	8.00
3	Boiler Feed	75.00	75.00
4	Cooling Towers Makeup	15.00	15.00
5	DM Plant Regeneration	1.00	1.00
6	R&D, QC	1.00	1.00
7	Scrubber	2.00	2.00
8	Domestic	7.00	7.00
9	Gardening	3.00	3.00
	Total	159.29	159.70

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	Source	Quantity as per CFE Order Dt. 17.11.2016 (KLD)			Quantity after expansion (KLD)		
		HTDS	LTDS	Total	HTDS	LTDS	Total
1.	Process	21.61	28.79	50.40	49.00	8.20	57.20
2.	Washings	0.00	8.00	8.00	0.00	8.00	8.00
3.	Boiler blow down	0.00	7.00	7.00	0.00	7.00	7.00
4.	Cooling Towers blow down	0.00	3.00	3.00	0.00	3.00	3.00
5.	DM Plant	1.00	0.00	1.00	0.00	1.00	1.00

6.	R&D, Q.C	0.00	1.00	1.00	0.00	1.00	1.00
7.	Scrubber	2.00	0.00	2.00	0.00	2.00	2.00
8.	Domestic	0.00	6.00	6.00	0.00	6.00	6.00
	Total	24.61	53.79	78.40	49.00	36.20	85.20

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.

- Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
- Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in to storm water drains or open areas. All pipe valves, sewers, drains shall be leak proof.

Air:

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

Sl. No.	Details of Stack	Stack 1	Stack 2	Stack 3	Stack 4
a)	Attached to	Boiler	Boiler	Thermic fluid heater	DG Sets
b)	Capacity	1 X 4.0 TPH &	1 X 2.0 TPH (Standby)	2.0 Lakh K. Cal	1 X 250 & 1 X 500 KVA
c)	Fuel	Coal 10 TPD	Coal 10 TPD	Diesel	Diesel
d)	Stack Height	30 m	30 m	20 m	10 m
e)	Control Equipment	MDS & pulsejet Bag filter	MDS & Bag filter	-	Acoustic enclosures & Silencer

- 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.
- The industry shall maintain multi-stage scrubbers properly 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.

8. The industry shall provide VOC monitoring system with auto recording facility.
9. The industry shall implement adequate measures to control all fugitive emissions from the plant.
10. 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.

11. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
12. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
13. 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.

14. **Hazardous / Solid Waste:** The proponent shall comply with the following:

Sl. No.	Name of the waste	Existing Quantity	Total Quantity after expansion	Method of Disposal
1.	Organic residue	1.76 TPD	2.28 TPD	To authorized cement plants for co- processing (OR) TSDF, Parawada, Visakhapatnam for incineration
2.	Spent Carbon	0.13 TPD	0.24 TPD	
3.	Inorganic & Evaporation Salt	2.02 TPD	0.72 TPD	To TSDF Parawada for secured land filling.
4.	ETP Sludge	0.10 TPD	0.20 TPD	
5.	Waste Oils & Grease	500 LPA	500 LPA	To authorized agencies for Reprocessing\ Recycling

6.	a. Detoxified Container/ Liners drums b. HDPE Carboys c. Fibre Drums d. PP Bags	500 No's/ Month - - -	500 No's/ Month 20No's/ Month 30 No's/ Month 200 Kg/ Month	After detoxification shall be disposed to TSDFAuthorized agencies
7.	Spent Mixed Solvents	-	10 KL/ Month	To authorized Recyclers / shall be recovered within the Premises.
8.	Discarded Personal Protective equipment (PPE's)	-	100 Kg/ Month	To TSDF
9.	Boiler Ash	10.0 TPD	10.0 TPD	Shall be sent to brick industries
10.	Used lead acid batteries	4 Nos. / Year	4 Nos. / Year	Shall be sent back to suppliers for buyback of new batteries

15. 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.

16. The following rules and regulations notified by the MoE&F, GoI 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:

17. **The industry shall comply with the following as committed during the CFE committee meeting held on 03.08.2018:**

- a. The industry shall not undertake distillation of Mother Liquors (ML) obtained from other industries as stipulated in the CFO order dt. 19.01.2017.
- b. The industry shall develop greenbelt in the ensuing monsoon to meet the requirement of 33% of the total area.

18. 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.
19. 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.
20. 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
MEMBER SECRETARY

To,

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