



TELANGANA STATE POLLUTION CONTROL BOARD

CONSENT ORDER FOR ESTABLISHMENT

ORDER NO. 230124253950

DATED: 02/02/2023.

SUB: TSPCB-Consent for Establishment-M/s. BIOLOGICAL E LTD. , S.F. No. Sy. 542/ Plot No. 4, Kolthur village, Shamirpet Taluk and Medchal ii District - Consent for Establishment of the Board 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. In the reference cited, an application was submitted to the Board seeking Consent for Establishment (CFE) of the Board to establish, with a project cost of Rs. to manufacture following products/activity.

S.No.	Product	Capacity	Unit
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2. As per the application, proposed products are to be manufactured/activity to be carried out atBiological e ltd. , S.F. No. Sy. 542/ Plot No. 4, Kolthur village, Shamirpet Taluk and Medchal ii District

3. The above site was inspected by & Asst. Environmental Engineer, Regional office,T.S Pollution Control Board and observed tha the site is surrounded by

NORTH	
SOUTH	
EAST	
WEST	

- 4.
5. This Consent Order now issued is subject to the conditions mentioned in Schedule 'A' and Schedule 'B'.
6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

MEMBER SECRETARY

To
The Managing Director,M/s.BIOLOGICAL E LTD.,
MEDCHAL II,Shamirpet,Kolthur,Sy. 542/ Plot No. 4,Kolthur,500078,
Pin: 500078

Copy to :

SCHEDULE 1A

SCHEDULE - B

MEMBER SECRETARY

To
The Managing Director,M/s.BIOLOGICAL E LTD.,
MEDCHAL II,Shamirpet,Kolthur,Sy. 542/ Plot No. 4,Kolthur,500078,
Pin: 500078



TELANGANA STATE POLLUTION CONTROL BOARD
ZONAL OFFICE: HYDERABAD

H.No.6-3-1219, TS No.1 Part, Block - C, Ward No.91, Near Country Club,
Uma Nagar, Begumpet, Hyderabad. Phone: 040-23402495
Email: jcee-zhyd-tspcb@telangana.gov.in

CONSENT FOR ESTABLISHMENT – RED CATEGORY

Order No. 1080-RR-II/TSPCB/ZO-HYD/CFE/TS-iPASS/2019 - 675 **Date:02.02.2023**

Sub: TSPCB – ZOH – CONSENT FOR ESTABLISHMENT (CFE) for Expansion –
M/s. Biological E Limited, Sy.No. 542/P, Biotech Park, Phase-II extension, Kolthur (V), Shameerpet (M), Medchal - Malkajgiri District – Consent for Establishment of the Board under Sec.25 of Water (Prevention and Control of Pollution) Act, 1974 and under Sec.21 of Air (Prevention and Control of Pollution) Act, 1981 – Issued – Reg.

- Ref:**
1. CFE Order 1080-RR-II/TSPCB/ZO-HYD/CFE/TS-iPASS/2019-741, Dated: 18.03.2019.
 2. CFO Order 1080-RR-II/TSPCB/ZOH/CFO/TS-iPASS/2022-845, Dated: 02.03.2022 valid upto 31.10.2026.
 3. Industry's CFE (Expansion) application received through TS-iPASS online portal on 04.01.2023 at TSPCB, Regional Office, Medchal.
 4. TSPCB, Regional Office, Medchal verification report dated:30.01.2023 and received by Zonal Office, Hyderabad on 30.01.2023.
 5. CFE Committee meeting held on 01.02.2023 at TSPCB, Zonal Office, Hyderabad.
 6. Industry's letter dt.02.02.2023 submitting revised water balance.

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1. In the reference 3rd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for expansion for additional products with production capacities as mentioned below, with project cost (for expansion) of **Rs.123.1606 Crores**.

Sl. No	Products	Existing Capacity as per CFO order dt.02.03.2022	Proposed Expansion	Total Capacity (After Expansion)
	<u>API Products:</u>			
1	Noscapine IP/BP/EP/JP/USP	30000 Kgs /Annum	--	30000 Kgs /Annum
2	NoscapineHCl BP/EP/JP	4000 Kgs /Annum	--	4000 Kgs /Annum
3	Papaverine Hydrochloride BP/USP	10000 Kgs /Annum	--	10000 Kgs /Annum
4	Heparin Sodium IP/BP/USP	16,500 Kgs /Annum	--	16,500 Kgs /Annum
5	Enoxaparin Sodium USP	7000 Kgs /Annum	--	7000 Kgs /Annum
6	Anidulfungin	--	1987 Kgs/ annum	1987 Kgs/ annum
7	Dalbavancin	--	691 Kgs/ annum	691 Kgs/ annum
8	Daptomycin	--	7776 Kgs/ annum	7776 Kgs/ annum
9	Fidaxomycin	--	8640 Kgs/ annum	8640 Kgs/ annum
10	Pimercolimus	--	1814 Kgs/ annum	1814 Kgs/ annum
11	Vancomycin	--	37440 Kgs/ annum	37440 Kgs/ annum

	<u>Formulations:</u>			
1	Heparin Sodium IP/BP/USP 1000 IU/mL vials	1,20,000 Liters/Annum	--	120000 liters/annum
2	Heparin Sodium IP/BP/USP 5000 IU/mL vials			
3	Enoxaparin Sodium USP 100mg/MI	1,00,000 Liters/Annum	--	1,00,000 Liters/Annum
4	Dalteparin Sodium 2500 IU	28,000 Liters/Annum	--	28,000 Liters/Annum
5	Anti-Snake Venom Serum	23,000 Liters/Annum	--	23,000 Liters/Annum
6	Daptomycin injectable 350/500mg	550 Kg/annum	--	550 Kg/annum
7	Fosaprepitant Dimeglumine injectable 150 mg	100 Kg /annum	--	100 Kg /annum
8	Neostigmin Methyl sulfate injectable 0.5/1.0 mg	8600 liters/annum	--	8600 liters/annum
9	Glycopyrrolate injectable 0.2 mg	8200 liters/annum	--	8200 liters/annum
10	Doxercalciferol Injection 2 mcg/mL (SDV) 4mcg/2ml (MDV) 4mcg/2ml (SDV)	3260 Liters/annum	--	3260 Liters/annum
11	Icatibant Injection 30 mg /3mL (10 mg /mL)	120 liters/annum	--	120 liters/annum
12	Furosemide Injection 20mg/40mg/100mg	13 Kgs/annum	--	13 Kgs/annum
13	Pantoprazole sodium for Injection (40mg/vial)	3113 Liters/annum	--	3113 Liters/annum
14	Sodium Nitroprusside Injection 50mg/2ml	120 Liters/annum	--	120 Liters/annum
15	Succinylcholine Chloride Injection 200mg/10ml	7500 Liters/annum	--	7500 Liters/annum
16	Teriparatide Injection 600 mcg/ 2.4 mL	240 liters	--	240 liters
17	Ferric Carboxy Maltose Injection 750 mg/ 15 mL (50 mg/mL)	250 liters/annum	--	250 liters/annum
18	Isosulfan Blue Injection 1% 50mg/5mL	120 liters/annum	--	120 liters/annum
19	Suggamadex Injection	250 LPA	--	250 LPA
20	Calcitonin salmon Injection	250 LPA	--	250 LPA
21	Acetaminophen Injection	250 LPA	--	250 LPA
22	Zinconotide Palmitate Injection 500 mcg/20 mL (25 mcg/mL); 100 mcg/1 mL and 500 mcg/5 mL	250 LPA	--	250 LPA
23	Ketorolac Tremethamine Injection 15 mg/m	250 LPA	--	250 LPA
24	Phytanadione Injection 1 mg/0.5 mL	250 LPA	--	250 LPA
25	Paliperidone Palmitate Injectable suspension	250 LPA	--	250 LPA

26	Dalteprain Sodium (API)	300 Kgs/annum	--	300 Kgs/annum
27	Methyl prednisolone	--	50 LPA	50 LPA
28	Amphotericin B	--	150 LPA	150 LPA
29	Semaglutide	--	50 LPA	50 LPA
30	Glucagon	--	50 LPA	50 LPA
31	Triamcinolone acetate injection	--	450 LPA	450 LPA
32	Liraglutide Injection, 18 mg/ 3 mL (6 mg/mL)	--	300 LPA	300 LPA
33	Dalbavancin for injection 500 mg/vial	--	600 LPA	600 LPA
34	Cyanocobalamin Inj. 1 mg/ml	--	600 LPA	600 LPA
35	Sodium Thiosulfate Injection USP	--	1500 LPA	1500 LPA
36	Vancomycin Hydrochloride for Injection USP	--	2500 LPA	2500 LPA

- As per the application, the above activity is to be located within the existing premises i.e., **Sy.No. 542/P, Biotech Park, Phase-II extension, Kolthur (V), Shameerpet (M), Medchal - Malkajgiri District.**
- The above site was inspected by the Environmental Engineer & Assistant Environmental Engineer-II, Regional Office, Medchal, T.S.Pollution Control Board on 27.01.2023 and found that the industry is surrounded by **East:** Existing M/s. Biological E Ltd. followed by approach Road followed by Open lands; **West:** Approach Road followed by Open lands; **North:** M/s. Biological E Ltd. Open lands; **South:** M/s. Biological E Ltd. Open lands.
- The Board, after careful scrutiny of the application, verification report of Regional Officer, Medchal, recommendation by the CFE Committee meeting held on **01.02.2023** at TSPCB, Zonal Office, Hyderabad, hereby issues CONSENT FOR ESTABLISHMENT (CFE) for expansion to the industry, under Section 25 of Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of Air (Prevention and Control of Pollution) Act, 1981 and the rules made there under. This Order is issued to manufacture the products mentioned at para (I) only.
- This Consent Order now issued is subject to the conditions mentioned in Schedule 'A' and Schedule 'B'.
- This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

Encl: Schedules "A & B".

To
M/s. Biological E Limited,
Sy.No. 542/P, Biotech Park,
Phase-II extension,
Kolthur (V), Shameerpet (M),
Medchal - Malkajgiri District.
E-mail: veeramohan.annamalai@biologicale.com

JOINT CHIEF ENVIRONMENTAL ENGINEER

Copy submitted to the Member Secretary, TSPCB, Board Office, Hyderabad for information.
Copy submitted to The General Manager, District Industries Centre, Near ORR, Keesara, Medchal-Malkajgiri District, Collectorate Complex, Hyderabad – 500083.
Copy to the Environmental Engineer, TSPCB, Regional Office, Medchal for information.

SCHEDULE – A

1. **This order is valid for a period of 5 years from the date of issue.** Progress on implementation of the project shall be reported to the concerned Regional Office, T.S. Pollution Control Board once in six months. The consent of the Board shall be exhibited in the factory premises at a conspicuous place for information of the inspecting officers.
2. The proponent shall obtain Consent for Operation (CFO) from TSPCB, as required Under Sec.25/26 of the Water (Prevention and Control of Pollution) Act, 1974 and under sec. 21/22 of the Air (Prevention and Control of Pollution) Act, 1981, before commencement of the activity.
3. The proponent shall ensure that there shall not be any change in the process technology and scope of working without prior approval from the Board.
4. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Hon'ble Courts, Collector and District Magistrate as Civil liability
5. The rules and regulations notified under Environmental Acts by the MOEF&CC and by the Ministry of Law and Justice, GOI, regarding the Public Liability Insurance Act, 1991 shall be followed.
6. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control Acts.
7. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and amendments thereof, to review any and/or all the conditions imposed herein, to modify conditions or stipulate any further conditions and to take action including revocation of this order in the interest of public health and environment.
8. 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 the State 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.

SCHEDULE – B

1. **The industry shall not carry out any activity pertaining to manufacturing of synthetic drug/API and shall be bio-technology based only.**
2. The source of water is provided by Bore well/Pubic Supply and the maximum permitted water consumption shall not exceed the following quantities:

S. No.	Purpose	Existing Capacity as per CFO order dt.02.03.2022	Proposed Expansion	Total Consumption (After Expansion)
1.	Process & Washings	109 KLD	210 KLD	319 KLD
2.	Boiler feed	40.0 KLD	70 KLD	110 KLD (recycled water-99 KLD)
3.	Cooling(make up) and chillers	31.0 KLD	60 KLD	91 KLD (Recycled water)
4.	Softener Regeneration	--	8 KLD	8 KLD
5.	Domestic	21.0 KLD	20 KLD	41 KLD (recycled water- 39 KLD)
6.	Gardening	20.0 KLD	10 KLD	30 KLD (Recycled water)
	Total	221.0 KLD	378.0 KLD	599.0 KLD (Fresh water- 340 KLD and recycled water- 259 KLD)

3. The maximum waste water generation (KLD) shall not exceed the following:

S. No	Wastewater generation	Existing Capacity as per CFO order dt.02.03.2022	Proposed Expansion	Total wastewater generation (After Expansion)
1.	Process & washings	54.7 KLD	HTDS-80.5 KLD LTDS-108.0 KLD	HTDS-80.5 KLD LTDS-162.7 KLD
2.	Boiler Blow Down, cooling tower bleed off	10.5 KLD	20 KLD (HTDS)	30.5 KLD (HTDS)
3.	Domestic	17.0 KLD	20 KLD	37 KLD
	Total:	82.2 KLD	228.8 KLD	310.7 KLD

Effluent source	Effluent source	Standards to be complied	Mode of final disposal
Process & washings	HTDS-80.5 KLD LTDS-162.7 KLD	Inlet parameters of CETP prescribed by the Board.	After treatment in ETP, treated water shall be further treated in three stage RO plants. RO permeate shall be used for utilities like cooling and boiler feed, flushings. RO rejects shall be sent to M/s. JETL, Jeedimetla for further treatment and disposal.
Boiler Blow Down, cooling tower bleed off	30.5 KLD		
Domestic	37 KLD	pH – 5.5 to 9.0 TSS – 200 mg/L BOD – 30 mg/L Oil & Grease – 10 mg/L.	After treatment in STP, treated water shall be utilized on-land for gardening within the premises duly meeting the standards.

4. The industry shall treat the process & wash, boiler blow down, Cooling bleed off effluents in ETP. After treatment in ETP, treated water shall be further treated in three stage RO plants. RO permeate shall be used for utilities like cooling and boiler feed, flushings etc. RO rejects shall be sent to M/s. JETL, Jeedimetla for further treatment and disposal.
5. The industry shall upgrade the existing treatment system to treat the expansion capacity as committed vide letter dt.02.02.2023. The industry shall explore the possibility of providing the ZLD system for the process and washing effluents.
6. The industry shall provide STP of capacity 50 KLD to treat the domestic effluents generated and the treated effluents shall be utilized on-land for gardening within the premises duly meeting the standards.
7. The industry shall comply with the following for controlling air pollution:

S.No.	Details of Stack	Stack 1 & 2	Stack 3 & 4	Stack 5 & 6	Stack 7 & 8
		After Expansion			
a)	Attached to:	HSD / Furnace Oil Boiler	Furnace Oil Boiler	D.G Set	D.G Set
b)	Capacity	4 TPH (2 Nos.) (One Standby)	5 TPH (2 Nos.) (One Standby)	1500 KVA (4 Nos)	2000 KVA (2 Nos)
c)	Fuel form: Solid / Liquid/ gaseous	HSD / Furnace Oil	Furnace Oil	Diesel	Diesel
d)	Stack height:	30m	30m	$H = h + 0.2 (KVA)^{0.5}$ H = height of the stack from GL in mtrs. h = height of the building where DG set is installed, in mtrs.	
e)	Air Pollution Control Equipment	--	--	Acoustic enclosure	Acoustic enclosure

f)	Standards to be complied	SPM – 115 mg/Nm ³	SPM – 115 mg/Nm ³	
		SO ₂ – 600 mg/Nm ³ . At 6% dry O ₂ , for solid fuel and 3% dry O ₂ for liquid fuel	--	--
		NOx – 600 mg/Nm ³ . At 6% dry O ₂ , for solid fuel and 3% dry O ₂ for liquid fuel	--	--

8. The Solid wastes generated shall not exceed the following breakup quantities:

S. No	Name and quantity of the Hazardous waste	Hazardous / as defined under HWM Rules, 2016	Existing Capacity as per CFO order dt.02.03.2022	Proposed Expansion	Total quantity (After Expansion)	Method of Disposal
1	In organic and organic solid waste	28.1 of Sch-I	600 Kgs/day	--	600 Kgs/day	Shall be sent to M/s.HWMP(TSDF, Dundigal, Medchal District/ AFRF facilities for pre-processing/ cement units for co-processing
2	ETP sludge	35.3 of Sch-I	50 Kgs/day	100 Kgs/day	150 Kgs/day	
3	Spent Carbon	--	2.2 Kgs/day	--	2.2 Kgs/day	
4	Biomass	--	--	1600 Kgs/day	1600 Kgs/day	
5	Bio-Medical waste	--	100 Kgs/day	100 Kgs/day	200 Kgs/day	Shall be sent to Common Bio Medical Waste Treatment Facility(i.e.,M/s.G.J.M ulticlave (India) Pvt. Ltd.,
6	Waste oils	5.1 of Sch-I	1000 LPM	2000 LPM	3000 LPM	Shall be sent to authorized Re-Processors / Re – Cyclers of waste oil.
7	Spent Solvents	--	120 Ltrs/day	120 Ltrs/day	240 Ltrs/day	Shall be sent to authorized Re-processors/Re-cyclers.
8	Boiler Soot (from Furnace Oil/HSD Boiler)	--	5.5 Kgs/day	6.5 Kgs/day	12 Kgs/day	Shall sent to authorized brick /Cement industries.

9. The industry shall collect hazardous waste and lift these waste as per the disposal option given above.

10. The industry shall collect Biomedical Waste properly and lift these waste to Common Bio Medical Waste Treatment Facility i.e., M/s. G.J.Multiclave (India) Pvt. Ltd.

11. The industry shall not discharge any wastewater outside the premises under any circumstances.

12. The industry shall not cause any air pollution / dust nuisance to the surrounding environment.

13. The industry shall develop 33% of the total area as thick green belt all along the boundary of the unit and also in the vacant places with all tall growing trees with wide leaf area.

14. The industry shall comply with all the Rules and Regulations specified in Water (P&C of P) Act, 1974, Air (P&C of P) Act, 1981 and Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016.

15. The industry shall not manufacture any extra products or extra capacities without obtaining CFE/CFO of the Board.

16. The industry shall not take up trial production without obtaining Consent for Operation of the Board.

17. Rain Water Harvesting (RWH) structure (s) shall be established on the plant site so that the ground water is recharged by the storm water.

18. The industry shall comply with Rules & Regulations notified by Ministry of Law and Justice, Govt. of India, regarding the Public Liability Insurance Act, 1991.
19. The industry shall comply with all the directions issued by the Board from time to time.
20. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.

 **JOINT CHIEF ENVIRONMENTAL ENGINEER**



To
M/s. Biological E Limited,
Sy. No. 542/P, Biotech Park,
Phase-II extension,
Kolthur (V), Shameerpet (M),
Medchal - Malkajgiri District.

