



# TELANGANA STATE POLLUTION CONTROL BOARD

Zonal Office, 25-35/11, Tulasi Reddy Complex, 2<sup>nd</sup> Floor,  
Opp. Govt. ITI College, R.C.Puram, Sangareddy District - 502 032.  
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## CONSENT ORDER FOR ESTABLISHMENT – ORANGE CATEGORY

**Order No. RCPM-899/PCB/ZO/RCP/CFE/2022-220124014981**

**Date: 20.09.2022.**

Sub:- PCB – CFE – M/s. Ciro Pharma Pvt Ltd., Plot No.28, Biotech Park, Phase – III, Sy. No. 321/1, Karkapatla Village, Markook Mandal, Siddipet 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. Industry's CFE application received through TSIPASS on 05.09.2022 at TSPCB, RO, RC Puram.
  2. TSPCB, RO, RC Puram verification report received through OCMMS on 13.09.2022.
  3. CFE Committee meeting held on 15.09.2022 at TSPCB, Zonal Office, R.C.Puram.

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- I. In the reference 1<sup>st</sup> cited, an application was submitted to the Board seeking Consent for Establishment (CFE) to set-up a unit with installed capacities as mentioned below, with a project cost of Rs. 19.41 Crores (Rupees Nineteen Crores and Forty One Lakhs only).

Product	Capacity
Tablets	12,00,000 Nos/day
Capsules	2,40,000 Nos/day
Injectables – Liquid	57,600 Nos/day
Injectables Dry Powder (Lyophilized)	15,000 Nos/day
Soft Gelatin Capsules	12,00,000 Nos/day

- II. As per the application, the industry is proposed site is located at Plot No.28, Biotech Park, Phase – III, Sy. No. 321/1, Karkapatla Village, Markook Mandal, Siddipet District.
- III. The above site was inspected by Asst. Environmental Engineer, Regional Office, T.S. Pollution Control Board, RC Puram on 09.09.2022 and found that the industry is surrounded by **North:** Karakapatla Road followed by Open Land ; **East :** Open land followed by Karkapatla village; **South :** 11/33 KVA Substation followed by Open lands; **West :** 11/33 KVA Substation followed by M/s Aspiro Pharma.
- IV. The Board, after careful scrutiny of the application, verification report of Regional Officer, RC Puram, recommendation by the CFE Clearance Committee meeting held on 15.09.2022 at TSPCB, Zonal Office, R.C. Puram, hereby issue CONSENT FOR ESTABLISHMENT 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.
- V. This CFE is issued from pollution control point of view only. Zoning and other regulations are not considered.
- VI. The CFE now issued is subject to the conditions mentioned in Schedule 'A' and 'B'.

*Encl: Schedule 'A' & Schedule 'B'*

To  
M/s. Ciro Pharma Pvt Ltd.,  
Plot No.28, Biotech Park, Phase – III,  
Sy. No. 321/1, Karkapatla (V), Markook (M),  
Siddipet District.

*Copy to the Environmental Engineer, R.O., RC Puram for information and necessary action.*

**JOINT CHIEF ENVIRONMENTAL ENGINEER**



## SCHEDULE – A

1. Progress on implementation of the project shall be reported to the Regional Office of T.S. Pollution Control Board once in six months.
2. Separate energy meters shall be provided for Air pollution Control equipments and effluent treatment plant to record energy consumed.
3. The proponent shall obtain Consents for Operation from TSPCB, as required Under Section 25/26 of the Water (P & C of P) Act 1974 and under Section 21/22 of the Air (P&C of P) Act 1981 before commencement of the activity including trial production.
4. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power under Section 27(2) of Water (Prevention and Control of Pollution) Act 1974 and under Section 21(4) of Air (Prevention & Control of Pollution) Act 1981 to review any or all the conditions imposed herein and to make such alternation as deemed fit and stipulate any additional conditions by the Board.
5. The Consent of the Board shall be exhibited in the factory premises at a conspicuous place for the information of the inspection officers of different departments.
6. Compensation is to be paid for any environmental damage caused by it, as fixed by the Collector and District Magistrate as civil liability.
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. The applicant shall maintain good house keeping. All pipe valves, sewers and drains shall be leak proof. Dyke walls shall be constructed around storage of chemicals.
8. Rain Water Harvesting (RWH) structure(s) shall be established on the plant site. The proponent shall ensure that effluent shall not enter the Rain Water Harvesting structure.
9. There shall not be any perceptible odour outside the industry's premises.
10. The Rules and Regulations notified by Ministry of Law and Justice, GOI regarding the Public Liability Insurance Act, 1991 shall be followed.
11. The industry shall comply with emission limits for DG sets of capacity upto 800 KW as per the notification G.S.R.520 (E), dated 01.07.2003 under the Environment (protection) Amendment Rules, 2003 and G.S.R.448 (E), dated 12.07.2004 under the Environment (protection) second Amendment Rules, 2004. In case of DG sets of capacity more than 800 KW shall comply with emission limits as per the notification G.S.R.489 (E), dated 09.07.2002 at serial No.96, under the Environment (Protection) Act, 1986.
12. The industry shall comply with ambient air quality standards of PM<sub>10</sub> (particulate Matter size less than 10µm) – 100 µg/m<sup>3</sup>; PM<sub>2.5</sub> (Particulate Matter size less than 2.5µm) – 60 µg/m<sup>3</sup>; SO<sub>2</sub> – 80 µg/m<sup>3</sup>; NO<sub>x</sub> – 80 µg/m<sup>3</sup>, outside the factory premises at the periphery of the industry. Standards for other parameters as mentioned in the National Ambient Air Quality Standards of CPCB Notification No.B29016/20/90/PCI-I, dated 18.11.2009 shall be complied.  
The following noise level standards shall be complied:  
Noise Levels : Day time (6 AM to 10 PM) - 75 dB (A)  
Night time (10 PM to 6 AM) - 70 dB (A)
13. The industry shall provide a minimum stack height (H) to the DG sets as per the following formula.  
$$H = h + 0.2 \sqrt{KVA}$$
  
KVA = Total generation capacity, h = Height of building where DG Set is installed.
14. All the rules and regulations notified by Ministry of Environment, Forests & Climate Change (MoEF&CC), Govt. of India in respect of noise pollution control measures shall be followed to avoid nuisance to public.
15. Telangana State Pollution Control Board reserves the right to review, impose additional condition or conditions, revoke, change or alter the terms and conditions of this Order. Also the Board reserves the right to withdraw the CFE without any prejudice/ notice on receiving any complaints by the Board regarding Environmental Pollution problems caused by the industry.
16. 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 to such authority (hereinafter referred to as the appellate Authority) constituted under Section 28 of the Water (Prevention and control of Pollution) Act, 1974 and section 31 of Air (Prevention and control of pollution) Act, 1981.
17. As per the provisions of the Section 19 of the (TS-iPASS) Act, 2014 (Act No. 3 of 2014), the applicant shall be penalized with fine as prescribed by the government from time to time as well as rectification of the defect if he / she or the organization as the case may be fails to comply with the conditions or undertaking in self certification given to the Nodal Agency.

**SCHEDULE – B**

1. This Order is valid for a period of five years from the date of issue.
2. The source of water is Bore well. The industry shall take steps to reduce water consumption to the extent possible and consumption shall not exceed the quantities mentioned below:

<b>Purpose</b>	<b>Quantity</b>
Process	50 KLD
Washings	40 KLD
Boiler feed	20 KLD
Others QC and R &D	3 KLD
Scrubbers	3 KLD
Cooling water makeup	14 KLD
Domestic	20 KLD
Greenbelt	15 KLD
<b>Total</b>	<b>165 KLD</b>

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

<b>Purpose</b>	<b>Quantity</b>
Process Low TDS	25.0 KLD
Washings	10.0 KLD
Others RO Rejects	10.0 KLD
Others QC and R & D	3.0 KLD
Boiler blow down	3.5 KLD
Cooling bleed off	3.0 KLD
Domestic	15.0 KLD
<b>Total</b>	<b>69.5 KLD</b>

4. Effluent treatment and final disposal:

<b>Purpose</b>	<b>Quantity</b>	<b>Point of final disposal</b>	<b>Limiting Standards (mg/l except pH)</b>
Process & washings, Boiler Blow down, Cooling tower bleed off and DM plant regeneration / RO Rejects	54.5 KLD	CETP i.e., M/s. PETL, Patancheru, Sangareddy District / M/s. JETL, Jeedimetla, Quathbullapur (M), Medchal-Malkajgiri District.	Inlet Standards of CETP
Domestic	15 KLD	Onland for irrigation within the industry's premises after treatment in STP.	pH: 6.5 to 8.5, TSS - 200, TDS-2100 mg/l, BOD (3 days at 27 <sup>0</sup> C) - 100.0 mg / l, Oil & Grease- 10.

5. The proponent shall comply with the following for controlling air pollution.

<b>S. No</b>	<b>Details of Stack</b>	<b>Stack 1</b>	<b>Stack 2</b>
a)	Attached to	Oil fired boiler	DG Set
b)	Capacity	2.0 TPH	1010 KVA
c)	Fuel	Oil	HSD
d)	Stack Height	30 mtrs	As per condition no. 13 of schedule 'A' of this CFE order.
e)	Details of Air Pollution Control Equipment	Suitable Air Pollution Control Equipment	Acoustic enclosure
f)	Standards to be complied with	SPM – 115 mg/Nm <sup>3</sup>	SPM – 115 mg/Nm <sup>3</sup>

6. A sampling port with removable dummy of not less than 15cm 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.
7. The Solid wastes generated shall not exceed the following breakup quantities:

Sl. No.	Description of the solid Waste	Quantity	Category as per the HWM Rules	Point of Disposal
1.	Waste oil	600 LPA	5.1 of Schedule – I	Shall be disposed to Board's Authorized Recycler / Reprocessor OR TSDF i.e., M/s. Hyderabad Waste Management Project, Dundigal (V), Dundigal Gandimaisamma (M), Medchal-Malkajgiri District / Alternate Fuel & Raw Material Facilities (AFRF) for pre processing.
2.	ETP Sludge	5 TPM	35.3 of Schedule – I :	Shall be sent to TSDF i.e., M/s. Hyderabad Waste Management Project, Dundigal (V), Dundigal Gandimaisamma (M), Medchal-Malkajgiri District / Alternate Fuel & Raw Material Facilities (AFRF) for pre processing.
3.	Off Specification product	50 Kg/Month	28.6 of Schedule – 1	
4.	Rejected Tablets	50 Kg/Month	28.6 of Schedule – 1	
5.	Expiry Tablets	50 Kg/Month	28.6 of Schedule – 1	
6.	Detoxified Container & Container liners of Hazardous chemicals and Waste	5 TPM	33.3 of Schedule – I	Shall be disposed to Authorized Parties after detoxification.
7.	HDPE Drums	500 Nos/Month	33.3 of Schedule – I	

8. The industry shall construct above ground level RCC tanks for collection / storage of trade effluents and arrest ground water pollution due to leaks/crack of pipes, tanks and spillages etc.
9. The industry shall not cause any spillages / discharges of chemicals/ effluents on ground. The drums containing chemicals & wastes shall be stored on elevated platform provided with leachate/spillages collection pit. In no case the drums shall be stored on naked ground.
10. The industry shall install the air pollution control equipment i.e., scrubbers to control the process emissions generated during the formulation activities.
11. The industry shall provide the pretreatment facility for treatment of trade effluents before sending to CETP.
12. The industry shall obtain membership from CETP i.e., M/s PETL, Patancheru, Sangareddy District / M/s. JETL, Jeedimetla, Quathbullapur (M), Medchal-Malkajgiri District before applying for Board's CFO for disposal of waste water generated from the process section.
13. The industry shall provide elevated closed shed with leachate collection pit for storage of hazardous waste.
14. The industry shall construct the STP for the treatment of domestic effluents. After treatment, the treated effluents shall be used for onland for gardening within the industry premises.
15. The industry shall take membership with TSDF i.e., M/s. Hyderabad Waste Management Project, Dundigal (V), Dundigal Gandimaisamma (M), Medchal-Malkajgiri District / Alternate Fuel & Raw Material Facilities (AFRF) for pre processing for disposal.
16. The industry shall provide suitable Air Pollution Control Equipment to the oil fired boiler of capacity 2.0 TPH to control the flue gas emissions.

17. The industry shall not cause any air pollution / dust emissions / odour nuisance in the nearby environment.
18. The industry shall not discharge any wastewater outside the plant premises under any circumstances.
19. The industry shall develop greenbelt such that it shall not be less than 33% of total area, preferably along the all sides of industry site.
20. The industry shall provide flow meters to measure the actual water consumption and waste water discharge and maintain a log register to record the readings.
21. The industry shall provide separate energy meter to the air pollution control system and maintain a log register to record the readings.
22. The industry shall maintain good house keeping within the plant premises.
23. The following rules and regulations notified by the MoEF&CC, GOI shall be implemented.
  - a. Hazardous and other wastes (Management and Transboundary Movement) Rules, 2016 and amendments thereof.
  - b. Manufacture, Storage and import of Hazardous Chemicals Rules, 1989 and amendments thereof.
  - c. Batteries (Management & Handling) Rules, 2001 and amendments thereof.
  - d. E-Waste (Management & Handling) Rules, 2016 and amendments thereof.
  - e. Plastic Waste (Management & Handling) Rules, 2016 and amendments thereof.
  - f. Construction & Demolition Waste (Management & Handling) Rules, 2016 and amendments thereof.
24. The industry shall comply with all the directions issued by the Board from time to time.
25. The Board reserves its right to modify above conditions or stipulate any additional conditions including revocation of this order in the interest of environment protection.
26. 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.

To  
M/s. **Ciro Pharma Pvt Ltd.,**  
**Plot No.28, Biotech Park, Phase – III,**  
**Sy. No. 321/1, Karkapatla (V), Markook (M),**  
**Siddipet District.**



