



ANDHRA PRADESH POLLUTION CONTROL BOARD
Dr. YSR Paryavaran Bhavan, APIIC Colony Road,
Gurunanak Colony, Autonagar, Vijayawada- 520007
Phone. No.0866-2463200, Website : <https://pcb.ap.gov.in/>



RED CATEGORY
RENEWAL OF CONSENT TO OPERATE & AUTHORIZATION ORDER

Order no.: APPCB-11022/124/2018-TEC-CFO-APPCB Date:04/01/2024

CONSENT is hereby granted to Operation under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation under Rule 6 of the Hazardous & Other Wastes (Management and Transboundary, Movement) Rules, 2016 and the rules and orders made there under (hereinafter referred to as ‘the Acts’, ‘the Rules’) to:

M/s. Dinakara Life Sciences Private Limited,
Plot No. 80 to 85, Industrial Park,
Jaggiahpet (M), NTR District
Email-id: dinakaralifesciences@gmail.com

(Hereinafter referred to as ‘the Applicant’) authorizing to operate the industrial plant to discharge the effluents from the outlets and the quantity of emissions per hour from the chimneys as detailed below:

i. Outlets for discharge of effluents:

Outlet No.	Outlet Description	Quantity (KLD)	Point of Disposal
1.	High TDS (Process)	11.03	<ul style="list-style-type: none"> Shall be stripped off for organic recovery. Stripped effluents for forced evaporation in MEE followed by ATFD. MEE & ATFD condensate shall be send to ETP. MEE & ATFD salts shall be disposed to TSDF through APMC.
2.	Low TDS (Process: 7.76 KLD; Washings: 2.0 KLD; Boiler & Cooling blow down: 6.5 KLD; Scrubbing system: 1.0 KLD)	17.26	<ul style="list-style-type: none"> The Low TDS effluents shall be sent to ETP followed by RO. The RO permeate shall be reused for cooling tower make up. RO rejects shall be treated in the MEE.
3.	Domestic	2.50	Septic tank followed by soak pit

ii) Emissions from chimneys:

Chimney No.	Description of Chimney
1.	Stack attached to 1 X 2 TPH Coal fired Boiler
2.	Stack attached to 1 Lakh K.Cal/hour Thermic Fluid Heater
3.	Stack attached to 1 x 125 kVA D.G. Set
4.	Process emissions

iii) HAZARDOUS WASTE AUTHORISATION (FORM – II) [See Rule 6 (2)]:

M/s. Dinakara Life Sciences Private Limited, Plot No. 80 to 85, Industrial Park, Jaggaiahpet (M), NTR District is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

• HAZARDOUS WASTES WITH DISPOSAL OPTION:

S.No.	Name of waste	Category of the Hazardous waste as per HoW (M & TM) Rules, 2016	Quantity (Kg/day)	Mode of disposal
1.	Inorganic solid waste	28.1 of Schedule-I	112.0	Shall be routed through M/s. APEMC so as to send to TSDF for secured land filling / Co-processing.
2.	Organic residues	28.1 of Schedule-I	327.0	Shall be routed through M/s. APEMC so as to send to Authorized cement industries for co- processing.
3.	MEE Salts	35.3 of Schedule-I	800.0	Shall be routed through M/s. APEMC so as to send to TSDF for secured landfill
4.	Organic evaporated liquid (from MEE stripper)	35.3 of Schedule-I	300.0	Shall be routed through M/s. APEMC so as to send to authorized cement industries for co- processing.
5.	Spent carbon	28.3 of Schedule-I	49.0	
6.	Solvent distillation residue	28.1 of Schedule-I	467.0	

• HAZARDOUS WASTES WITH RECYCLING OPTION:

S.No.	Name of waste	Category of the Hazardous waste as per HoW (M & TM) Rules, 2016	Quantity	Mode of disposal
1.	Detoxified containers	33.1 of Schedule - I	150 Nos./month	Shall be routed through M/s. APEMC so as to send to Traders after detoxification
2.	Waste oil & grease	5.1 of Schedule - I	200 Lts./ annum	Shall be routed through M/s. APEMC so as to send to Authorized recyclers

• **NON-HAZARDOUS WASTES WITH DISPOSAL OPTION:**

S.No.	Name of waste	Quantity	Mode of disposal
1.	Boiler Ash	420 Kg/day	Disposed to brick manufacturers.

This consent order is valid for manufacture the following products along with quantities indicated only:

Sl. No	Name of the Products	Quantity
1.	Bupriopion Hydrochloride	66.67 Kg/day
2.	Clopidogrel Bisulphate	100.00 Kg/day
3.	2,4-Difluoro-2-(1h-1,2,4-Triazole-I-YI) Acetophenone (DFTA)	333.33 Kg/day
4.	Fluconazole	133.33 Kg/day
5.	Itraconazole	100.00 Kg/day
6.	Ketoconazole	100.00 Kg/day
7.	Levocetirizine Di hydrochloride	33.33 Kg/day
8.	Minoxidil	33.33 Kg/day
9.	Ziprasidone Hydrochloride	66.67 Kg/day
10.	Irbesartan	100.00 Kg/day
11.	Telmisartan	100.00 Kg/day
12.	Carisoprodol	100.00 Kg/day
13.	Simvastatin	100.00 Kg/day
14.	Quetiapine Fumarate	100.00 Kg/day
15.	Rivaroxaban	33.33 Kg/day
16.	Memantine HCl	33.33 Kg/day
17.	Cinacalcet Hydrochloride	33.33 Kg/day
	Total (worst combination of any 4 products with production capacity of 20 TPM at any given point of time)	20 TPM (240 TPA)

By-Products:

Sl. No	Name of the By-product	Quantity
1	Hydrogen Chloride	2460.00 KLD
2	Triethylamine Hydrochloride	363.00 KLD
3	Aluminum Chloride Solution	2005.33 KLD*

*** The industry shall ensure that the quantity of Aluminum chloride generated shall not exceed 45 KL/ month (i.e., consented capacity of raw material of M/s. Pharma care, Gannavaram, Krishna District). Accordingly, the production capacity shall be restricted. In case, the aluminum chloride (by product) cannot be used by user agencies due to any market conditions, the industry shall restrict the production and also to dispose the aluminum chloride as waste stream only.**

This order is subject to the provisions of 'the Acts' and 'the Rules' and orders made thereunder and further subject to the terms and conditions incorporated in the schedule A, B & C enclosed to this order.

This combined order of consent to operate & Hazardous Waste Authorization shall be valid for a period ending with the **31st day of July, 2028.**

B SREEDHAR IAS, MS(BS), O/o MEMBER SECRETARY-APPCB

To

**M/s. Dinakara Life Sciences Private Limited,
Plot No. 80 to 85, Industrial Park,
Jaggiahpet (M), NTR District
Email-id: dinakaralifesciences@gmail.com**

Copy to:

1. The Joint Chief Environmental Engineer (FAC), Zonal Office, **Vijayawada** for information and necessary action.
2. The Environmental Engineer, Regional Office, **Vijayawada** for information and necessary action.

SCHEDULE-A

1. Any up-set condition in any industrial plant / activity of the industry, which result in, increased effluent / emission discharge and/ or violation of standards stipulated in this order shall be informed to this Board, under intimation to the Collector and District Magistrate and take immediate action to bring down the discharge / emission below the limits.
2. The industry should carryout analysis of waste water discharges or emissions through chimneys for the parameters mentioned in this order on quarterly basis and submit to the Board.
3. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 should be followed as applicable.
4. The industry should put up two sign boards (6x4 ft. each) at publicly visible places at the main gate indicating the products, effluent discharge standards, air emission standards, hazardous waste quantities and validity of CFO and exhibit the CFO order at a prominent place in the factory premises.

5. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers to review / revoke any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
6. The industry shall ensure that there shall not be any change in the process technology, source & composition of raw materials and scope of working without prior approval from the Board.
7. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.
8. The applicant should make applications through Online for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts and detailed compliance of CFO conditions for obtaining Consent & HW Authorization of the Board.
9. The industry should immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions. Any change in the management shall be informed to the Board. The person authorized should not let out the premises / lend / sell / transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.
10. 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 Appellate authority constituted under Section 28 of the Water(Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air(Prevention and Control of Pollution) Act, 1981.
11. The industry shall be liable to pay Environmental Compensation / Other Environmental Taxes, if any environmental damage caused to the surroundings, as fixed by the Collector & District Magistrate or any other competent authority as per the Rules in vogue.
12. The industry may explore the possibility of tapping the solar energy for their energy requirements.
13. The industry should educate the workers and nearby public of possible accidents and remedial measures.

SCHEDULE-B

The issue of CTO&HWA (Renewal) to the industry was placed in the Consent Management Committee meeting held on 29.12.2023. The industry shall comply with the following conditions:

- a. **The industry shall obtain the PESO license within 3 months.**
- b. **Quantity of Aluminium Chloride Solution shall be restricted to the authorized quantity permitted to M/s. Pharma care (i.e., 45 KLM).**
- c. **The industry shall comply with the Board directions dated 28.08.2023.**

WATER POLLUTION:

1. The source of water is Ground water. The following is the permitted water consumption:

S.No	Purpose	Quantity in KLD
1.	Industrial cooling & Boiler feed	48.50
2.	Processing, whereby water gets polluted and the pollutants are not easily bio-degradable	22.22
3.	Domestic and gardening purposes.	6.00
	Total	76.72

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

2. The industry shall maintain flow meters preferably digital flow meters with totalizes for water and effluent quantity measurements for different streams stipulated in this order.
3. The industry shall segregate the effluents into streams as mentioned in outlets for discharge of effluents.
4. The LTDS and HTDS effluents shall be stored in above ground collection tanks separately.
5. The industry shall not generate any effluents more than the consented quantity.
6. The industry shall not discharge any waste water outside the premises and shall maintain Zero Liquid Discharge system.
7. The consolidated daily records on the details of the following shall be submitted to the Regional office of the Board on every month:
 - a. Effluent generated.
 - b. Quantity of treated effluents evaporated in the Forced Evaporation system.
 - c. Quantity of condensate generation & characteristics.
 - d. Quantity & characteristics of pretreated effluents.
8. The treatment system consisting of stripper, MEE, ATFD system with condenser and Biological ETP shall be operated and maintained properly followed by RO plant. All the units of the treatment system shall be impervious to prevent ground water pollution. The industry shall ensure that units of treatment system shall be above the ground level.
9. The industry shall properly operate and maintain digital flow meters with totalisers at the inlet and outlet of Stripper, MEE, ATFD and for ETP units.
10. The industry shall construct separate storm water drains. No effluents shall be discharged in to the storm water drains.
11. The industry shall maintain 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.
12. Effluents shall not be discharged onland or any water bodies or aquifers under any circumstances. Floor washings shall be admitted into effluent collection system only and shall not be allowed to find their way into storm water drains or open areas.
13. Rain water should not be allowed to mix with either trade or domestic effluents.
14. The industry shall maintain online effluent monitoring system for the prescribed parameters as per CPCB protocol and shall connect the same to CPCB and APPCB websites.
15. **The industry shall maintain rainwater runoff tank with pump for collection and storage of first flush storm water and the same shall be sent to ETP for further treatment. The industry shall maintain dry condition in outside drains during non-rainy season.**

AIR POLLUTION:

16.The emissions shall not contain constituents in excess of the prescribed limits mentioned below:

Chimney No.	Parameter	Emission Standards
1 & 2	Particulate matter	115 mg/Nm ³
	SO ₂	600 mg/Nm ³
	NO _x	300 mg/Nm ³
4	HCl	35 mg/Nm ³
	NH ₃	30 mg/Nm ³
	Sulphuric acid mist	50 mg/Nm ³
	Chlorine	15 mg/Nm ³
Tank farm vents	HCl	35 mg/Nm ³
	NH ₃	30 mg/Nm ³
	Chlorine	15 mg/Nm ³
	Benzene	5 mg/Nm ³
	Toluene	100 mg/Nm ³
	Acetonitrile	1000 mg/Nm ³
	Dichloromethane	200 mg/Nm ³
	Xylene	100 mg/Nm ³
	Acetone	2000 mg/Nm ³

17.The industry shall ensure compliance with ambient air quality standards of PM₁₀ - 100 micro grams/ m³; PM_{2.5} - 60 micro gram/ m³; SO₂ - 80 micro grams/ m³; NO_x – 80 micro grams/m³, (day average standards).

The industry shall comply with National Ambient Air Quality Standards stipulated in CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009 and also the

Noise standards: Day time (6 AM to 10 PM) - 75 dB (A)

Night time (10 PM to 6 AM) - 70 dB (A)

18.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 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Act Rules. 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.

19.The industry shall maintain energy meter to air pollution control equipments connected to boilers and maintain daily records.

20.The industry shall maintain online pH meters to the scrubbers with auto recording facility and shall connect to APPCB website. The details of chemicals consumption used in the scrubber shall be recorded & kept accessible for the inspecting officials of the Board.

21.The evaporation losses in solvents shall be controlled by taking suitable measures, which include:

- i. Chilled brine circulation to effectively reduce the solvent losses into the atmosphere.
- ii. Transfer of solvents by using pumps and closed conveyance instead of manual handling.
- iii. Closed centrifuges be used due to which solvent losses are reduced drastically.
- iv. The reactor vents connected with primary & secondary condensers to catch the solvent vapours.
- v. All the solvent storage tanks are connected with vent condensers to prevent solvent vapours.
- 22. The industry shall not use odour causing substances such as Mercaptan or cause odour nuisance in the surroundings.
- 23. The industry shall maintain VOC meters with real time data transmission facility through internet of things (IoT) and connect of APPCB.
- 24. The industry shall take measures to maintain the ambient air quality within the stipulated standards.
- 25. The industry shall install multi gas detectors (such as NH₃, Chlorine and other toxic gases) with data loggers at production block and main gate to know the concentrations in the ambient air in the factory premises.

GENERAL:

- 26. The industry shall not manufacture new products and not exceeding the permitted quantity, other than those mentioned in this order.
- 27. The industry shall comply with the tolerance limits mentioned in MoEF notification dated 09.07.2009 and **MoEF & CC notification vide G.S.R. 541(E) dt. 06.08.2021 for Bulk Drug and Formulation (Pharmaceutical).**
- 28. The industry shall maintain the elevated concrete platform for storing all the drums containing chemicals / residues / mixed solvents / wastes to prevent ground water contamination.
- 29. The industry shall maintain dyke wall with leachate collection pit to Hazardous waste storage shed.
- 30. The industry shall maintain the following records and the same shall be made available to the inspecting officers of the Board:
 - a. Daily production details.
 - b. Quantity of Effluents generated, treated, recycled/reused and disposed through marine out fall.
 - c. Log Books for pollution control systems.
 - d. Characteristics of effluents and emissions.
 - e. Hazardous/non-hazardous solid waste generated and disposed.
 - f. Inspection book.
 - g. Manifest copies of effluents / hazardous waste.
- 31. The industry shall develop and maintain greenbelt atleast in an area of 33% of the total area.
- 32. The industry shall comply with the Standard Operating Procedure (SoP) and Checklist of Minimal Requisite Facilities for Utilization of Spent Solvent for Recovery of Solvent specified for Solvent Recovery Units issued by CPCB from time to time. The total cumulative losses of solvents shall not be more than 5% of the solvent on annual basis from storage inventory.
- 33. The industry shall comply with SoPs issued by CPCB time to time for all the wastes.
- 34. System of leak detection and repair of pump / pipeline shall be installed in the plant and immediate response team shall be identified for preventive maintenance.
- 35. The industry should submit mock drill report carried out at least once in six months, as required under the Manufacture, Storage and Import of Hazardous Chemicals Rules,

1989.

36. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Board.
37. The industry shall comply with the Regulation of Persistent Organic Pollutants Rules, 2018 notified by the MoEF&CC Notification vide G.S.R. 207 (E) dated 30.05.2018. As per the notification, the following 7 chemicals are prohibited to manufacturer, trade, use, import and export:
 - a. Chlordecone,
 - b. Hexabromobiphenyl,
 - c. Hexabromodiphenyl ether and heptabromodiphenyl ether (commercial octa-BDE),
 - d. Tetrabromodiphenyl ether and pentabromodiphenyl ether (commercial penta-BDE),
 - e. Pentachlorobenzene,
 - f. Hexabromocyclododecane and
 - g. Hexachlorobutadiene.
38. The industry shall renew the PLI policy which includes Environmental Relief Fund (ERF) and submit copy to RO, Vijayawada on yearly base.
39. **The industry shall maintain digital display boards at publicly visible places at the main gate indicating the products manufactured Vs permitted quantities, Treated effluent concentrations Vs discharge standards, Stack emission & AAQ concentrations Vs standards, hazardous waste generation, disposed, stock Vs permitted quantities and validity of CTO; and exhibit the CTO order at a prominent place in the factory premises, as per Hon'ble Supreme Court order.**
40. The industry shall submit Half yearly compliance reports to all the stipulated conditions in Environmental Clearance (EC), Consent to Establishment (CTE) and Consent to Operation (CTO) through website i.e., <https://pcb.ap.gov.in> by 1st of January and 1st July of every year. The first half yearly compliance reports shall be furnished by the industry and second half yearly compliance reports shall be the audited through MoEF&CC recognized and National Accreditation Board for Laboratory Testing (NABL) accredited third party.
41. Any other directions / circulars / notices issued by CPCB, MoEF&CC and APPCB shall be followed from time to time.
42. The conditions are stipulated without prejudice to the rights and contentions of this Board in any Hon'ble Court of Law.

Special conditions:

43. The industry shall operate with valid NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (APSDRFSD) and submit a copy at concerned Regional Office, APPCB.
44. The industry shall prepare a safety report and carry out an independent safety audit report of the respective industrial activities including chemical storages / isolated storages by an expert not associated with such industrial activity as required under Rule 10 of MSIHC Rules, 1989 and get it approved by the Factories Dept., and submit the compliance along with copy of the safety report, safety audit report and safety certificate at concerned Regional Office, APPCB.
45. The industry shall extend training to the working personnel for the prevention of accidents and necessary antidotes to ensure safety, as per the MSIHC Rules, 1989.
46. The industry shall carry out calibration of safety equipment and leak detection systems at regular intervals and shall certify the same with the Factories Department. That

certified copy shall be submitted to the APPCB, Regional Office.

47. The industry shall install fluorescent Wind Vane at the highest point in the industry premises.
48. The industry shall submit Risk analysis and risk assessment covering worst scenario clearly describing impact within the industry premises and outside the industry premises and emergency response system.
49. The industry shall submit the copy of the safety audit report and On-Site / Off Site Emergency Plans as applicable after being certified by the Factories Department to the APPCB, Regional Office from time to time, if the storage quantity of hazardous chemicals is equal to or, in excess of the threshold quantities specified in schedule 2 & 3 of MSIHC Rules, 1989.

SCHEDULE – C

[See rule 6(2)]

[CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR HANDLING HAZARDOUS WASTES]

1. The authorised person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorised by the State Pollution Control Board.
3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorisation.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. The person authorised shall implement Emergency Response Procedure (ERP) for which this authorisation is being granted considering all site-specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;
6. The person authorised shall comply with the provisions outlined in the Central Pollution Control Board guidelines on “Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty”.
7. It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility. An application for the renewal of an authorisation shall be made as laid down under these Rules. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.
8. The industry shall comply with the provisions of HWM Rules, 2016 in terms of interstate transport of Hazardous Waste and manifest document prescribed Under Rule 18 and 19 of the HWM Rules, 2016.
9. **The industry shall not store hazardous waste for more than 90 days as per the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.**
10. **The industry shall store Used / Waste Oil in a secured way in their premises till its disposal to the manufacturers / dealers on buyback basis.**
11. The industry shall transport the hazardous waste to cement industries only through vehicle fitted with GPS tracking system.
12. The industry shall maintain 7 copy manifest system for transportation of waste generated and a copy shall be submitted to concerned Regional Office of APPCB. The

driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter should carry a Transport Emergency (TREM) Card.

13. The industry shall maintain proper records for Hazardous and Other Wastes stated in Authorisation in Form-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form-4 as per Rule 20 (2) of the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.
14. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.

B SREEDHAR IAS, MS(BS), O/o MEMBER SECRETARY-APPCB

To

**M/s. Dinakara Life Sciences Private Limited,
Plot No. 80 to 85, Industrial Park,
Jaggaiahpet (M), NTR District.**