



**ANDHRA PRADESH POLLUTION CONTROL
BOARD**

ZONAL OFFICE :: VISAKHAPATNAM
39-33-20/4/1, Madhavadhara Vuda Colony,
Visakhapatnam - 530018.
Ph : 0891 - 2719380



ORANGE CATEGORY

CONSENT & AUTHORIZATION ORDER

**Consent Order No: 7589/APPCB/ZO-
VSP/VSP/CTO/2023**

01/12/2023

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

**M/s. Pfizer Healthcare India Private Limited,
Plot No.111 & 123 and 116, 117, 118 & 119,
JN Pharmacy, Parawada (M),
Anakapalli District.**

(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	Max Daily Discharge	Point of Disposal
1.	Washings (Raw material & vessels)	110.0 Kilo Liters/Day	To the CETP of Pharmacy after pre-treatment.
2.	QC & Micro lab washings	32.0 Kilo Liters/Day	
3.	Boiler blow down	36.0 Kilo Liters/Day	The industry shall meet the inlet Standards of CETP, Ramky before disposal.
4.	Utility rejects	515.0 Kilo Liters/Day	
5.	Cooling	119.0 Kilo Liters/Day	
6.	Domestic	115.0 Kilo Liters/Day	

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow (m ³ /hr)
1	Attached to 15 TPH High Speed Diesel Fired Boilers – 3 Nos.	----
2	Attached to 2750 KVA DG sets – 6 Nos.	----

3	Attached to 127 HP Hydrant Pump Diesel Engines	----
4	Attached to 240 HP Sprinkler Pump Diesel Engines	----

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

M/s. Pfizer Healthcare India Private Limited, Plot No.111 & 123 and 116, 117, 118 & 119, JN Pharmacy, Parawada (M), Anakapalli District is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

Hazardous Waste with Disposal Option:

S. No	Waste description	Stream	Quantity	Method of disposal
1.	Off Specification products/ Raw materials/ Laboratory chemical wastes	28.4 of Schedule-I	600 MT /annum	Shall be routed through M/s. Andhra Pradesh Environment Management Corporation Limited (APEMCL) so as to send to TSDf for Co-processing/Incineration.
2.	Date expired and discarded products	28.5 of Schedule-I	100 MT/Annum	
3.	Exhaust air or gas cleaning residues (Soot particle from Chimney)	35.1 of Schedule-I	4.0 MT/Annum	
4.	Spent Ion Exchange resins from water treatment plant	35.2 of Schedule-I	10 MT/Annum	
5.	Process residues and waste (including used PPE)	28.1 of Schedule-I	200 MT/Annum	
6.	Waste or residue containing oil (Oil filters, spill absorbents, etc)	5.2 of Schedule-I	4.0 MT/Annum	
7.	Empty barrels/containers /liners contaminated with hazardous Chemicals/wastes	33.1 of Schedule-I	5.0 MT/Annum	
8.	Sludge from wet scrubbers	37.1 of Schedule-I	1.0 MT/Annum	
9.	Sludge from ETP tanks	35.3 of Schedule-I	12 MT/Annum	Shall be routed through M/s. Andhra Pradesh Environment Management Corporation Limited (APEMCL) so as to send to TSDf for Co-processing/Incineration/Land filing.
10.	Spent carbon from water treatment plant	28.3 of Schedule-I	2.0 MT/Annum	

Hazardous Waste with Recycling Option:

S. No	Waste description	Stream	Quantity	Method of disposal
1.	Used oil/Spent oil in MT	5.1 of Schedule-I	15 MT /annum	Shall be routed through M/s. Andhra Pradesh Environment Management Corporation Limited (APEMCL) so as to send to authorized Re-processors / Recyclers /TSD/ to the Cement industries for co-processing.
2.	HDPE Carboys/Drums & MS Drums (after detoxification) in Nos.	33.1 of Schedule-I	9000 No's/annum	Shall be disposed to authorized recyclers after detoxification through M/s. Andhra Pradesh Environment Management Corporation Limited (APEMCL).

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

S. No.	Products	Quantity
1.	Terminal Sterilized vials	26.66 Millions / Month
2.	Terminal Sterilized ampoules	4.75 Millions / Month
3.	Aseptic filled vials	8.33 Millions / Month
4.	Dry powder lyophilized vials	1.92 Millions / Month

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 & Hazardous Waste Authorization shall be valid for a period ending with the **31.12.2028**.

DR P.PRASADA RAO, JCEE(PRR)-ZO-VSP,
O/o JOINT CHIEF ENVIRONMENTAL ENGINEER7 -APPCB

To
M/s. Pfizer Healthcare India Private Limited,

**Plot No.111 & 123 and 116, 117, 118 & 119,
JN Pharmacy, Parawada (M),
Anakapalli District.**

- Copy to Environmental Engineer, Regional Office, Visakhapatnam for information and to ensure compliance.

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 CTO and exhibit the CTO order at a prominent place in the factory premises.
5. Not withstanding 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 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.
7. 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 CTO conditions for obtaining Consent & HW Authorization of the Board. 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.
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 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.

SCHEDULE-B**SPECIAL CONDITIONS:**

1. The industry shall develop and maintain greenbelt to meet 33 % of total area.
2. The industry shall not cause any odour nuisance to the nearby habitation.
3. The industry shall follow the recommendations of the PESO/ Fire NOC of APSDRFSD.
4. The industry shall install online VOC meters at strategic locations with data logging facility.
5. The industry shall not handle/store Radio Active Substances within industry premises.

WATER POLLUTION:

6. The source of water being ground water / bore well. The following is the permitted water consumption:

S No.	Purpose	Quantity
1.	Process	755.0 Kilo Liters/Day
2.	Boiler feed	298.0 Kilo Liters/Day
3.	Cooling	850.0 Kilo Liters/Day
4.	Gardening	95.0 Kilo Liters/Day
5.	Domestic	135.0 Kilo Liters/Day
	Total	2133.0 Kilo Liters/Day

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

7. The industry shall comply the following effluent standards based on the disposal points permitted inlet standards of CETP:

Outlet	Parameter	Limiting Standards
1 to 6	Inlet Parameters prescribed by the Board for CETP	

8. The industry shall regularly transport the washings – 110 KLD, QC & Micro lab washings – 32 KLD, boiler blow down – 36 KLD, utility rejects – 515 KLD, cooling blow downs – 119 KLD and domestic wastewater – 115 KLD to CETP of M/s.Ramky Pharmacy (I) Pvt. Ltd., Parawada, Visakhapatnam for proper treatment and disposal.
9. The industry shall collect effluents generated from production blocks into tank in tank and shall be sent to holding tanks constructed above ground level, for neutralization & primary treatment as required before sending to CETP.
10. The industry shall provide separate digital water flow meters to record maximum water consumption and wastewater generation from the industry and shall maintain log registers

- to record wastewater sent to CETP for further treatment.
11. The industry shall provide impervious effluent conveyance lines above the ground level.
 12. The industry shall isolate the storm water drainage system completely from the process areas so that the contamination of storm water is completely prevented.
 13. The industry shall have minimum of 7 days storage capacity of effluents on above ground level, with-in the premises.
 14. The industry shall not discharge any treated/untreated wastewater outside the industry premises/into drain under any circumstances.
 15. The industry shall not install any manufacturing facility for production of bulk drugs without obtaining CTE/CTO of the Board.
 16. The industry shall maintain detoxification facility to detoxify the used drums. After detoxification the treated wastewater shall be sent to CETP along with LTDS effluents.

AIR POLLUTION:

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

Chimney No.	Parameter	Emission Standards
1 to 4	Particulate matter	115. /Nm ³

18. The industry shall meet the occupational Health standards within industry premises and maintain records.
 19. The industry shall maintain separate energy meter for the APCE and maintain log registers to record the energy meter readings pertaining to the operation of the APCE.
 20. The industry shall ensure compliance of the National Ambient Air quality standards notified by MoE&F, GoI vide notification GSR 826(E), dt. 16.11.2009 at the boundary of the premises during regular operation.
 21. 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.
 22. The industry shall take measures to comply with the provisions laid down under Noise pollution (Regulation and Control) Amendment Rules, 2010 dated 11.01.2010 issued by MoE&F, GoI to control the noise to the prescribed levels.

SOLID WASTE:

23. The solid wastes generated shall not exceed the following breakup quantities:

S. No	Solid Waste Generation	Quantity	Method of Disposal
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1.	Plastic scrap including polythene Bags, bottles, pallets, etc	600 MT/Annum	Sold to outside agencies
2.	Glass scrap	720 MT/Annum	Sold to outside agencies
3.	Corrugated Paper Wastes (Paper/Cartons/Fiber drums)	720 MT/Annum	Sold to outside agencies
4.	Wooden scrap	720 MT/Annum	Sold to outside agencies
5.	Cooling Tower Fills	24 MT/Annum	Sold to outside agencies/ To TSDf for Co-processing/Incineration/Recycling
6.	Insulation waste/Thermocol waste	6 MT/Annum	Sold to outside agencies/ To TSDf for Co-processing/Incineration/Recycling
7.	MS/SS/ Aluminum Scrap	720 MT/Annum	Sold to outside agencies
8.	Aluminum attached plastic scrap	24 MT/Annum	Sold to outside agencies
9.	Waste rubber stopper scrap	48 MT/Annum	Sold to outside agencies
10.	Paper waste (paper cups, tissue paper, and other miscellaneous)	300 MT/Annum	Sold to outside agencies
11.	Construction waste/debris	240 MT/Annum	Sold to outside agencies/ To TSDf for Co-processing/Recycling
12.	Garden waste/ debris	120 MT/Annum	Sent to outside agencies
13.	Used batteries in Nos.	1800 No's/annum	APPCB authorized agencies/Manufacturer/dealer on buyback basis
14.	E-Waste in MT	12 MT/Annum	APPCB authorized agencies for reprocessing /Manufacturers

24. The industry shall not dispose the solid waste outside the factory premises, under any circumstances.
25. The industry shall collect the Hazardous waste generated securely and shall lift the hazardous waste to TSDf, Parawada regularly for scientific disposal and submit details regularly to RO, Visakhapatnam.
26. The industry shall dispose off specification products and rejected & expired drug materials to TSDf, Parawada.
27. The industry shall strictly maintain registers pertaining to generation and disposal of off specification products and rejected & expired drug materials.

GENERAL:

28. The unit shall not install new/additional utilities like Boiler, DG set

without permission from the Board.

29. The drums containing chemicals/solvents shall be stored under a roof on elevated platform with provision to collect leakages/spillages in the collection pit.
30. The industry shall have valid PLI policy and shall furnish copy to the Regional Office, Visakhapatnam.
31. The industry shall not cause any water / air pollution / odour nuisance to the surrounding environment.
32. The industry shall take all precautionary and safety measures during process operations
33. 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.
34. The industries and isolated storages that are storing hazardous chemicals less than the threshold quantities mentioned under MSIHC Rules, 1989 shall submit safety certificate to the concerned Regional Office, APPCB.
35. The industry shall submit a copy of the NOC issued by the Andhra Pradesh State Disaster Response and Fire Service Dept., (*APSDRFSD*) at concerned Regional Office, APPCB.
36. The industry shall inventorize the storage quantities of hazardous chemicals (raw materials), products, as per the hazard nature of reactivity / toxicity /flammability / explosive stored/handling in the premises as defined in the Management of Storage, Import of Hazardous Chemicals (*MSIHC*) Rules, 1989 and the details shall be furnished to the Factories Department and to the Regional Office, APPCB on monthly basis duly certifying the same.
37. The industry shall identify major accident hazard chemicals & list out the hazardous chemicals endangered to human health & environment and the details shall be furnished to the Factories Department and to the Regional Office, APPCB time to time duly certifying the same by the industry. Further the industry shall extend training to the working personnels while handling hazardous chemicals for prevention of accidents and necessary antidotes to ensure the safety, as per the MSIHC Rules, 1989.
38. 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.
39. "The industry shall carryout calibration of safety equipments 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. The industry shall install fluorescent Wind Vane at the highest point in the industry premises."
40. The industry shall inventorize the hazardous wastes and its quantities

stored within the industry premises as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (HOWM Rules, 2016) and shall furnish the details to Regional Office, APPCB on monthly basis duly certifying the same by the industry.

41. The industry shall comply with the industry specific standards with respect to process emissions stipulated by the MoEF & CC, GoI, New Delhi from time to time.
42. The industry shall not increase the capacity beyond the permitted capacity mentioned in this order, without obtaining CTE/CTO of the Board.
43. The industry shall maintain the following records and the same shall be made available to the inspecting officers of the Board:

- Daily production details.
- Quantity of Effluents generated, treated, recycled/reused and disposed.
- Log Books for pollution control systems.
- Characteristics of effluents and emissions.
- Hazardous/non hazardous solid waste generated and disposed.
- Inspection book.
- Manifest copies of effluents / hazardous waste.

44. The following rules and regulations notified by the MOE&F, GOI shall be implemented.

- Hazardous and Other Wastes (*Management and Transboundary Movement*) Rules, 2016.
- Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.
- Batteries (*Management & Handling*) Rules, 2010.
- E-waste (*Management*) Rules, 2016.
- Plastic Waste Management Rules, 2016.
- Construction and demolition waste Management Rules, 2016.
- Fly Ash Notification, 2016.
- Solid Waste Management Rules, 2016.

45. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to Regional Office and Zonal Office, Visakhapatnam.

46. The industry shall maintain good housekeeping with-in the premises.
 47. The industry shall develop green belt in all the vacant places. The minimum greenbelt shall be 33% of the total area.
 48. 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.
 49. The Board reserves its right to modify above conditions or stipulate any further conditions and to take action including revoke of this order in the interest of environment protection.
 50. The industry shall submit a compliance report on CTO conditions for

every 6 months as on 01st January and 01st July of every year at Regional Office and Zonal Office.

SCHEDULE – C[See rule 6(2)]

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

1. All the rules and regulations notified by Ministry of Environment and Forests, Government of India under the E (P) Act, 1986 in respect of management, handling, transportation and storage of the Hazardous wastes should be followed.
2. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and other Wastes (*Management and Transboundary Movement*) Rules, 2016 and amendments thereof.
3. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal to the manufacturers / dealers on buyback basis.
4. The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to concern 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.
5. The industry shall maintain proper records for Hazardous Wastes stated in Authorization 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 6(5), 13(8), 16(6) and 20(2) of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules, 2016 and amendments thereof.
6. The authorized person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
7. The person authorized shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorization.
8. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of his authorization.
9. The person authorized shall implement Emergency Response Procedure (ERP) for which this authorization 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.
10. The person authorized 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*".
11. The hazardous and other waste which gets generated during recycling or reuse or recovery or pre-processing or utilization of imported hazardous or other wastes shall be treated and disposed of as per specific conditions of authorization.
12. 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.
13. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.
14. The industry shall submit the compliance of all the conditions stipulated in the CTO & HWA order within 6 months and submit report to Regional Office & Zonal Office.

DR P.PRASADA RAO, JCEE(PRR)-ZO-VSP,
O/o JOINT CHIEF ENVIRONMENTAL ENGINEER7 -APPCB

To

**M/s. Pfizer Healthcare India Private Limited,
Plot No.111 & 123 and 116, 117, 118 & 119,
JN Pharmacy, Parawada (M),
Anakapalli District.**