



TELANGANA STATE POLLUTION CONTROL BOARD

Phone: 23887500
Fax: 040-23815631

CONSENT ORDER FOR CFO DIRECT AND HAZARDOUS WASTE
AUTHORIZATION - RED CATEGORY

CONSENT ORDER NO. 240525252342 DATED: 05/09/2024.

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof, Operation of the plant under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation / Renewal of Authorisation under Rule 6 of the Hazardous Wastes (Management, Handling & Transboundary, Movement) Rules 2016 & Amendments thereof)

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974, under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof, and Authorisation under the provisions of HW (MH & TM) Rules, 2016 (hereinafter referred to as 'the Acts', the Rules) and amendments thereof and the rules and orders made there under to M/s. "Ferring pharmaceuticals private limited ,MEDCHAL II,Shamirpet,Lalgadimalakpet,14,Lalgadi Malakpet,500078 " (hereinafter referred to as 'the Applicant /Industry') and the industry is authorized to operate the industrial plant to discharge the Effluents from the outlets and the quantity of Emissions per hour from the chimneys, by operating pollution control equipment, as detailed below,

i) Out lets for discharge of Effluents :

Outlet No.	Description of Outlet	Max Daily Discharge in KLD	Point of Disposal
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ii) Emissions from chimneys:

Chimney No.	Description of Chimney
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iii) HWAutorisation No.240525252342 DATED: 05/09/2024.

HAZARDOUS WASTE AUTHORISATION
(FORM i½ II)
[See Rule 6 (2)]

Ferring pharmaceuticals private limited ,MEDCHAL II,Shamirpet,Lalgadimalakpet,14,Lalgadi Malakpet,500078is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

1. HAZARDOUS WASTES WITH DISPOSAL OPTION :

Name of the Hazardous Waste	Stream	Quantity	Disposal option
-----NIL-----			

2. HAZARDOUS WASTES WITH RECYCLING OPTION :

Name of the Hazardous Waste	Stream	Quantity	RECYCLING option
-----NIL-----			

S.No.	Name of the Product	Capacity	Unit
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This order is subject to the provision of 'the Acts' and the Rules and amendments made thereunder and further subject to the terms and conditions incorporated in the schedule A, B and C enclosed to this order.

This combined order of Consents and Authorization is valid for a period ending with the .August 07, 2024

MEMBER SECRETARY

To
The Managing Director,
M/s.FERRING PHARMACEUTICALS PRIVATE LIMITED,
MEDCHAL II,Shamirpet,Lalgadimalakpet,14,Lalgadi Malakpet,500078,
Pin: 500078

Copy to :

SCHEDULE 1A

SCHEDULE - B

1. Total Water Consumption shall not exceed : 0.00 KLD

S.No.	Purpose	Quantity
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2. The Treated Effluent Discharged/pre-treated effluent sent to CETB shall not exceed the following prescribed standards

Outlet No.	Parameter	Limiting Standard
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3. The Emission shall not exceed the following prescribed standards

Chimney No.	Description of Chimney	Parameter	Emission Standards
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SCHEDULE - C

MEMBER SECRETARY

To
The Managing Director,
M/s.FERRING PHARMACEUTICALS PRIVATE LIMITED,
MEDCHAL II,Shamirpet,Lalgadimalakpet,14,Lalgadi Malakpet,500078,
Pin: 500078



TELANGANA 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 & HW AUTHORIZATION ORDER - ORANGE CATEGORY

Consent Order No: 2007-MDCL/TGPCB/ZOH//TG-iPASS/CFO/2024-874 Date:04.09.2024

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof and Operation of the plant under section 21 of Air (Prevention & Control of Pollution) Act, 1981 and amendments thereof) and Authorization / Renewal of Authorization under Rule 6 of the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016.

CONSENT is hereby granted 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 (hereinafter referred to as 'the Acts') and Authorization under the provisions of HW (M & TM) Rules, 2016 (herein after referred to as 'the Acts' 'the Rules') the rules and orders made thereunder to

M/s. Ferring Pharmaceuticals Pvt. Ltd.,
(In the premises of M/s. Ferring Laboratories (P) Ltd., building),
Plot No. 14, Biotech Park Extn. Phase-II, Lalgadimalakpet (V),
Shamirpet (M), Medchal – Malkajgiri 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:

Sl. No.	Purpose	Max daily discharge	Point of disposal	Limiting Standards
1	Process	2.0 KLD	Shall be sent to Common pre-treatment facility provided by M/s.Ferring Laboratories (P) Ltd. After pre-treatment, shall be sent to CETP, M/s. JETL, Jeedimetla, Medchal-Malkajgiri District for further treatment & disposal.	Inlet standards of CETP as prescribed by the Board.
2	Washing	1.0 KLD		
3	Domestic	2.5 KLD	Shall be sent to common STP provided by M/s.Ferring Laboratories (P) Ltd. After treatment, the treated domestic wastewater is used for greenbelt development within the premises.	pH - 5.5-9.0, Total Suspended Solids - 200.0 mg/l, Oil & Grease - 10.0 mg/l, Biochemical Oxygen Demand (3 days at 27 ⁰ C) - ≤ 10 mg/lit & COD - 250 mg/lit.

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow	Emission Standards
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iii) Hazardous Waste Authorization: (Form – 2) [See Rule 6(2)]:

M/s. Ferring Pharmaceuticals Pvt. Ltd., (In the premises of M/s. Ferring Laboratories (P) Ltd., building), Plot No. 14, Biotech Park Extn. Phase-II, Lalgadimalakpet (V), Shamirpet (M), Medchal – Malkajgiri District is hereby granted an authorization to operate a facility for

collection, reception, storage, transport and disposal of the following wastes with quantities as mentioned below:

S. No.	Name and of the Hazardous / Solid waste	Hazardous / as defined under HWM Rules, 2016	Quantity	Method of Disposal
1.	Used Oils	5.1 of Sch-1	100 LPA	Shall handover waste to M/s.Ferring Laboratories (P) Ltd., for disposal.
2.	Process waste	--	100 Kgs/annum	
3.	Date expired materials	--	250 Kgs/Annum	
4.	Detoxified containers & container liners	--	200 Nos./Annum	
5.	Used Lead acid batteries (NOs)	--	25 Nos	

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

This consent is valid for manufacture the following activity only:

S.No.	Name of the Products and By-products / Activity
1.	R&D in Pharmaceutical Formulation (for sustained release/extended release of drugs only and not for commercial production). Capacity not exceeding 1 kg/day for all the products.

This combined order of Consent & Hazardous Waste Authorization shall be valid for a period ending with **31.08.2034**. *The industry shall pay the consent fees annually from the financial year 2025-26 to till the validity of the consent order.*

The payment of annual consent fee for every financial year (i.e., April to March) within the stipulated time period i.e., 1st quarter of every financial year (April - June) is mandatory for the industry. Failing which, the validity of the Consent Order automatically stands cancelled and operation of industry without valid Consent attracts penal action under the provision of Water Act, Air Act & Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

[Signature]

JOINT CHIEF ENVIRONMENTAL ENGINEER

Encl: Schedules A, B & C

To
M/s. Ferring Pharmaceuticals Pvt. Ltd.,
(In the premises of M/s. Ferring Laboratories (P) Ltd., building),
Plot No. 14, Biotech Park Extn. Phase-II, Lalgadimalakpet (V),
Shamirpet (M), Medchal – Malkajgiri District.
Email Id: balachendar.gundu@ferring.com

Copy to the Member Secretary, TGPCB, 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, TGPCB, Regional Office, Medchal-Malkajgiri District for information. **The EE, RO, Medchal is further directed to ensure that the industry pays the annual consent fees for every financial year (i.e., April to March) within the stipulated time period i.e., 1st quarter of every financial year (April-June) and the EE, RO, Medchal shall report to this office, if any non-compliance by the industry.**

SCHEDULE – A

1. The applicant shall make applications through online for renewal of Consent (under Water & 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 for obtaining Consent & HW Authorization of the Board. The applicant can also apply for Auto Renewal of the CFO atleast 30 days before the expiry of this order as per the procedure and eligibility stipulated in the Board Circular dt.19.11.2015 & 08.12.2015 (available in Board's Website: <http://tspcb.cgg.gov.in/Pages/Circulars.aspx>).
2. 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.
3. The industry may explore the possibility of tapping the solar energy for their energy requirements.
4. 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 Rules, 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 the Air (Prevention and Control of Pollution) Act, 1981.
5. 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 protection of public health and environment.

SCHEDULE - B

Special Conditions:

1. The industry has paid consent fee for a period upto 30.06.2025. The industry shall pay the consent fees annually from the financial year 2025-26 to till the validity of the consent order i.e., upto 31.08.2034.
2. The industry shall pay balance consent fee annually as per the rates notified in GO Ms No. 22. The payment of annual consent fee shall be made at the concerned RO for every financial year (i.e., April to March) within the stipulated time period i.e., 1st quarter of every financial year (April - June) is mandatory for the industry. Failing which, the validity of the Consent Order automatically stands cancelled and operation of industry without valid Consent attracts penal action under the provision of Water Act, Air Act & Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016.
3. The industry either paying annual fee or total fee for consented period, shall pay the balance consent fee as per the revised rates as applicable from time to time.
4. The industry shall take steps to reduce water consumption to the extent possible and consumption shall NOT exceed the quantities mentioned below

S.No.	Purpose	Total Quantity (KLD)
1.	Process	3.0 KLD
2.	Washing	1.0 KLD
3.	Domestic	3.0 KLD
Total		7.0 KLD

5. The industry shall apply and obtain NOC from CGWA in case of drawl of ground water within One month and submit a copy of the same at TGPCB Regional Office, Medchal.
6. The industry should comply with the National ambient air quality standards as per MoEF, GoI notification dated. 18.11.2009 along the premises of the factory as prescribed below:

S. No.	Parameters	Standards in $\mu\text{g}/\text{m}^3$
1	Particulate Matter(PM ₁₀)	100
2	Particulate Matter (PM _{2.5})	60
3	SO ₂	80
4	NOx	80

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

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

7. 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 and amendments thereof.
8. **The industry shall not provide pilot plant activity and shall not go for commercial production without permission of the Board.**
9. The industry shall manufacture only consented products and shall produce within the consented capacities. Under no circumstances, the industry shall manufacture any unconsented products without obtaining CFE & CFO of the Board.
10. The industry shall have minimum of 7 days storage capacity of effluents on above ground level, with-in the premises.
11. The industry shall send the process & washings effluents to Common pre-treatment facility provided by M/s. Ferring Laboratories (P) Ltd. After pre-treatment, shall be sent to CETP, M/s. JETL, Jeedimetla, Medchal-Malkajgiri District for further treatment & disposal duly meeting the inlet standards of CETP prescribed by the Board.
12. The industry shall regularly send the domestic effluents to common STP provided by M/s.Ferring Laboratories (P) Ltd. for further treatment. After treatment, the treated effluents shall be used for gardening duly meeting the prescribed standards.
13. The industry shall provide digital flow meter with totalizer for assessing the quantity of waste water generation and water consumption.
14. The industry shall install wet scrubber followed by carbon adsorption system as Air Pollution Control Equipment (APCE) to suck the fumes emanated during various chemical reactors in the fume cupboards and shall pass them through wet scrubber followed by carbon adsorption system before letting into the atmosphere through common stack.
15. The industry shall not discharge any wastewater outside the premises under any circumstances.
16. The industry shall not cause any air pollution / odour nuisance to the surrounding environment.
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 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.
19. The industry should maintain the following records and the same should be made available to the Board Officials during the inspection.
 - a) Daily production details, RG-I records and Central Excise Returns.
 - b) Quantity of trade effluents generated, treated & disposed.
 - c) Log Books for pollution control systems.
 - d) Daily solid waste generated and disposed to M/s. TSDF, Dundigal.
20. The industry shall maintain good housekeeping with-in the premises.
21. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
22. The industry shall take necessary measures to control fugitive emissions.
23. The industry shall take all precautionary and safety measures during process operations.
24. The industry shall comply with the ambient air quality standards in respect of noise, as stipulated in the Environment (Protection) Rules, 1986.
25. The industry shall comply with all the directions issued by the Board from time to time.
26. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.
27. The conditions stipulated in this order are without any prejudice to rights and contentions of this Board in any Hon'ble court of Law.

SCHEDULE - C
(See Rule 6(2))

**[SPECIAL CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR
HANDLING HAZARDOUS WASTE]**

1. The industry shall give top priority for waste minimization and cleaner production practices.
2. The industry shall not store hazardous waste for more than 180 days as per the Hazardous & other wastes (Management and Transboundary Movement) Rules, 2016 and amendments thereof. The industry shall maintain 7 copy manifest system for transportation of waste generated and copies of receipts of consignee shall be submitted to the Concerned Regional Office. The industry shall maintain proper records for Hazardous 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 & other wastes (Management, Handling & Transboundary Movement) Rules, 2016 and amendments thereof.
3. The industry shall dispose /sell the hazardous waste to only industries/agencies authorised by state Pollution Control Board. The industry shall verify the authorisation of the Board given to the party before disposing its waste to the external party
4. The industry shall maintain proper records for Hazardous Wastes disposal and its concurrence with Authorization. In case of Violation in generation, industry shall submit explanation and obtain amendment in Environmental Clearance/CFE/CFO in this regard.
5. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal. The Waste oils to be sold to the traders and the same shall be disposed to the authorized Reprocessors / Recyclers and Used Lead Acid Batteries shall be disposed to the manufacturers / dealers on buyback basis. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises. The industry shall check the certificate/Authorisation/ order of MoEF issued to the Re-user/Recycler units while disposing the waste oil. The industry shall maintain good housekeeping & maintain proper records for Hazardous Wastes stated in Authorisation.
6. The industry shall dispose the e-waste to authorized recyclers/dismantlers only.
7. The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule B & C of this Order on half yearly basis to Board Office, Hyderabad and concerned Regional Office.

JOINT CHIEF ENVIRONMENTAL ENGINEER

To
M/s. Ferring Pharmaceuticals Pvt. Ltd.,
(In the premises of M/s. Ferring Laboratories (P) Ltd., building),
Plot No. 14, Biotech Park Extn. Phase-II, Lalgadimalakpet (V),
Shamirpet (M), Medchal – Malkajgiri District.



