



TELANGANA STATE POLLUTION CONTROL BOARD

Phone: 23887500
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CONSENT ORDER FOR CFO DIRECT AND HAZARDOUS WASTE
AUTHORIZATION - RED CATEGORY

CONSENT ORDER NO. 220523774188 DATED: 25/06/2022.

(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. "Dfe pharma india private limited ,MEDCHAL II,Shamirpet,Kolthur,PLOT NO 542/2,KOLTHUR,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.220523774188 DATED: 25/06/2022.

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

Dfe pharma india private limited ,MEDCHAL II,Shamirpet,Kolthur,PLOT NO 542/2,KOLTHUR,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 .June 25, 2022

MEMBER SECRETARY

To
The Managing Director,
M/s.DFE PHARMA INDIA PRIVATE LIMITED,
MEDCHAL II,Shamirpet,Kolthur,PLOT NO 542/2,KOLTHUR,500078,
Pin: 500078

Copy to :

SCHEDULE – A

SCHEDULE - B

1. Total Water Consumption shall not exceed : 0.00 KLD

S.No.	Purpose	Quantity
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2. The Treated Effluent Dischrged/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.DFE PHARMA INDIA PRIVATE LIMITED,
MEDCHAL II,Shamirpet,Kolthur,PLOT NO 542/2,KOLTHUR,500078,
Pin: 500078



TELANGANA STATE POLLUTION CONTROL BOARD
ZONAL OFFICE: HYDERABAD

D. Krupanand
Joint Chief Environmental Engineer

H.No.6-3-1219, T.S.No.1, Part, Block "C",
Ward No.91, Begumpet, Umanagar,
Near Country Club, Hyderabad - 500 016
Phone No: 040-23402495
Email: jcee-zhyd-tspcb@telangana.gov.in

CONSENT ORDER & HW AUTHORIZATION – ORANGE CATEGORY

Consent Order No: 1808-RR-II/TSPCB/ZOH/TS-iPASS/CFO/2022-214 Date: 25.06.2022

(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).

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 the rules and orders made thereunder to

M/s. DFE Pharma India Private Ltd.,
Suite No's. 23 & 24/A, 2nd floor, Building No. 270,
M/s. Touchstone Property Developers Private Ltd.,
Sy. No. 542/2 & Part, Kolthur (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:

Outlet No.	Outlet Description	Max Daily Discharge	Point of Disposal	Limiting Standards
1	Washings	0.30 KLD	After pre-treatment in ETP shall be lifted to CETP i.e., M/s. JETL for further treatment and disposal by M/s. Touchstone Property Developers Private Ltd.	Inlet standards of CETP as prescribed by the Board.
2	Domestic effluents	0.25 KLD	Shall be sent to STP provided by M/s. Touchstone Property Developers Private Ltd, After pre-treatment shall be used on land for gardening by M/s. Touchstone Property Developers Private Ltd 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.

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. DFE Pharma India Private Ltd., Suite No's. 23 & 24/A, 2nd floor, Building No. 270, M/s. Touchstone Property Developers Private Ltd., Sy. No. 542/2 & Part, Kolthur (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:

Sl. No.	Name and of the Hazardous / Solid waste	Hazardous / as defined under HWM Rules, 2016	Quantity	Method of Disposal
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This order is subject to the provisions of ‘the Acts’ and the Rules’ and amendments made there under and further subject to the terms and conditions incorporated in the schedule A and B, C enclosed to this order.

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

S. No.	Products & By products	Total Capacity
1.	Diclofenac Tablets	3 Kg/month
2.	Paracetamol Tablets	15 Kg/month
3.	Atenolol Tablets	1 Kg/month
4.	Furosemide Tablets	3 Kg/month
5.	R & D activity in Pharmaceutical Formulation	--

This combined order of Consent & Hazardous Waste Authorization shall be valid for a period ending with the **31.05.2032**. *The industry shall pay the consent fees annually from the financial year 2027-28 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.

Encl: Schedules A, B & C

To
M/s. DFE Pharma India Private Ltd.,
Suite No’s. 23 & 24/A, 2nd floor, Building No. 270,
M/s. Touchstone Property Developers Private Ltd.,
Sy. No. 542/2 & Part, Kolthur (V), Shamirpet (M),
Medchal-Malkajgiri District.
Email: ksrao@talentouchcs.com

JOINT CHIEF ENVIRONMENTAL ENGINEER



Copy 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-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 and Air Acts) and Authorization under HWM Rules **atleast 120 days before the date of expiry of this order**, along with prescribed fee under Water and Air Acts for obtaining consent of the Board **along with detailed compliance to the conditions stipulated in the CFO**.
2. The industry shall 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 etc.
3. a) All the fugitive emissions shall be controlled with proper measures.
b) The applicant shall also install the equipment such as wind speed recorder and wind direction recorder.
4. The applicant shall not change or alter either the quality or the quantity or the rate of the discharge or the route of discharge and shall not change or alter either the prescribed quality or the rate of emission without the previous written permission of the Board.
5. The applicant shall, not later than 30 days from the date of issue of this consent order, certify in writing to the Board that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent. In absence of alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production shall be stopped.
6. Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and/ or violation of standards stipulated in this order **or** the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident, or other unforeseen act or event, the person-in-charge of the premises, from where such discharge / emission occurs or is apprehended to occur shall forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax / email under intimation to the Collector and District Magistrate.
7. In case of such episodal discharges / emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge / emission below the limits prescribed in this order.
8. A good house keeping shall be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers and drains shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way into storm drains or open areas.
9. The applicant shall comply with the directives/orders issued by the Board in this consent order and at all subsequent times without any negligence on his part. The applicant shall be liable for such legal action against him as per provisions of the Law/Act in case if non-compliance of any order/directive issued at any time and/or violation of the terms and conditions of this consent order.
10. The applicant shall furnish to the visiting officer and / or the Board any information regarding the construction, installation or operation of the effluent treatment system/ air pollution control equipment and such other particulars as may be pertinent for preventing and controlling pollution.
11. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability.
12. All the rules & regulations notified by Ministry of Environment and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes shall be followed.
13. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 shall be followed.

14. The applicant shall exhibit the consent order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.
15. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves to it the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and its amendments thereof **and** under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and its amendments thereof to review 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.
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 as per Telangana State Water rules, 1976 and Air Rules 1982, to such authority (herein after 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.

SCHEDULE - B

Special Conditions:

1. The industry has paid consent fee upto 31.05.2027. The industry shall pay the consent fees annually from the financial year 2027-28 to till the validity of the consent order i.e., upto 31.05.2032.
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.	Consumption	Total Consumption
1.	Process & Washing	0.5 KLD
2.	Domestic	0.5 KLD
	Total	1.0 KLD

5. 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 ($\text{PM}_{2.5}$)	60
3	SO_2	80
4	NO_x	80

Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)
Night time (10 PM to 6 AM) - 70 dB (A).

6. The industry shall manufacture only consented products and shall produce within the consented capacities. Under no circumstances, the industry shall manufacture any un-consented products without obtaining CFE & CFO of the Board.
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.

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 treat the waste water in ETP. After pre-treatment shall be lifted to CETP i.e. M/s. JETL for further treatment and disposal by M/s. Touchstone Property Developers Private Ltd duly meeting the inlet standards of CETP as prescribed by the Board.
10. The industry shall send the domestic effluents to the Sewage Treatment Plant (STP) provided by M/s. Touchstone Property Developers Private Ltd. After pre-treatment shall be used on land for gardening by M/s. Touchstone Property Developers Private Ltd within the premises duly meeting the prescribed standards of the Board.
11. The industry shall provide digital flow meters with totalizer for assessing the quantity of waste water disposed in to common effluent collection tank of M/s. Touchstone Property Developers Private Ltd and shall maintain the register.
12. The industry shall suck the fumes emanated during the various chemical reactions in the fume cupboards and pass them through a wet scrubber before letting into atmosphere through common stack.
13. The industry shall not discharge any waste water to outside the factory premises.
14. The industry shall not cause any air pollution/odour nuisance to the surrounding environment.
15. The industry shall not dispose the solid waste outside the factory premises.
16. The industry shall develop greenbelt as per norms i.e 33% of the total area along the boundary of the unit and also in the vacant places within the premises.
17. The industry should maintain the following records and the same should be made available to the Board Officials during the inspection.
 - a) Quantity of effluents generated and lifted to CETP i.e. M/s. JETL through common facility.
 - b) Domestic effluents sent to STP of common facility
 - c) Log Books for pollution control systems.
 - d) Daily solid/hazardous waste generated and disposed
18. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
19. The industry shall comply with all the directions issued by the Board from time to time.
20. 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.
21. The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.
22. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.
23. 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 6 copy manifest system for

transportation of waste generated and copies of receipts of consignee shall be submitted 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 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. DFE Pharma India Private Ltd.,
Suite No's. 23 & 24/A, 2nd floor, Building No. 270,
M/s. Touchstone Property Developers Private Ltd.,
Sy. No. 542/2 & Part, Kolthur (V), Shamirpet (M),
Medchal-Malkajgiri District.