



TELANGANA STATE POLLUTION CONTROL BOARD

Phone: 23887500
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CONSENT & HWA ORDER (RENEWAL) - RED CATEGORY

CONSENT ORDER NO. 230824326159 DATED: 17/03/2023.

(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.

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. "Alembic pharmaceuticals ltd., building 2700 ,MEDCHAL II,Shamirpet,Turkapally,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) HWA Authorisation No.230824326159 DATED: 17/03/2023.

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

Alembic pharmaceuticals ltd., building 2700 ,MEDCHAL II,Shamirpet,Turkapally,500078 is 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 .March 17, 2023

MEMBER SECRETARY

To

The Deputy General Manager,

M/s.ALEMBIC PHARMACEUTICALS LTD., BUILDING 2700,

MEDCHAL II,Shamirpet,Turkapally,500078,

Pin: 500078

Copy to :

SCHEDULE 1A

SCHEDULE - B

1. Total Water Consumption shall not exceed : 6.50 KLD

S.No.	Purpose	Quantity
1	Others Process and Washings	4.5
2	Domestic	2

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 Deputy General Manager,
M/s.ALEMBIC PHARMACEUTICALS LTD., BUILDING 2700,
MEDCHAL II,Shamirpet,Turkapally,500078,
Pin: 500078



TELANGANA STATE 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
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CONSENT & AUTHORIZATION ORDER - ORANGE CATEGORY

Consent Order No: 1284-RR-II/TSPCB/ZOH/TS-iPASS/CFO/2023- 600 Date: 05.01.2023

(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 (herein after referred to as 'the Acts' 'the Rules') the rules and orders made thereunder to

**M/s. Alembic Pharmaceuticals Ltd.,
Lab Suite No. 111, 112, 113, 114 123-124 & 132, Building 450,
MN Science & Technology Park Pvt. Ltd.,
(Earlier AKP Knowledge Park), Genome Valley,
Turkapally (V), Shameerpet (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 (After Expansion)	Point of Disposal	Limiting Standards
1	Process & Washings	6.3 KLD	Shall be sent to Common Effluent collection tank of MN Park (Earlier M/s.Alexandria Knowledge Park). After pretreatment, shall be lifted to CETP i.e, M/s. JETL for further treatment and disposal	Inlet parameters of CETP prescribed by the Board.
2	Domestic effluents	3.0 KLD	Shall be sent to common STP provided by (Earlier M/s.Alexandria Knowledge Park). After treatment used for onland for gardening within the premises.	pH - 5.5-9.00, Total Suspended Solids - 200.00 mg /l, Oil and Grease - 10.00 mg /l, Biochemical Oxygen Demand (3 days at 27 ⁰ C) - 30.00 mg /l

ii) Emissions from chimneys:

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

M/s. Alembic Pharmaceuticals Ltd., Lab Suite No. 111, 112, 113, 114 123-124 & 132, Building 450, MN Science & Technology Park Pvt. Ltd., (Earlier AKP Knowledge Park), Genome Valley, Turkapally (V), Shameerpet (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 & Quantity of the Hazardous Waste &	Stream	Quantity (After Merger)	Mode of disposal
1.	Waste powder collected from floor sweeping, Dust extraction	28.1 of Sch-I	7 Kg/day	Sent to TSDF/AFRF facilities/ cement units for co-processing through M/s MN Science & Technology Park Pvt. Ltd.,
2.	Thermo coal	28.1 of Sch-I	500 Kg/Month	
3.	Used Silica Gel	28.2 of Sch-I	15kg/month	
4.	Discarded lab samples	33.1 of Sch-I	30 Kgs/day	
5.	Discarded tablets from process	28.4 of Sch-I	24 Kgs/day	
6.	Plastic materials, Gloves,	33.1 of Sch-I	230.0 Kgs/month	
7.	Spent & Mixed Solvent	28.6 of Sch-I	356 Ltrs/Day	Sent to authorized solvent recovery units/ AFRF facilities/ cement units for co-processing through M/s MN Science & Technology Park Pvt. Ltd.,
8.	Broken Lab Glassware & Used glassware	33.1 of Sch-I	45 Kgs/day	After detoxification, Authorized agencies / dealers for Recycling & Reprocessing units through M/s. MN Science & Technology Park Pvt. Ltd.
9.	MS/Plastic Drums	33.1 of Sch-I	20 Nos/Month	Shall be disposed to plastic waste recycling unit through
10.	Batteries	17 of Sch-I	32 No's/ 3 Years	Buy back basis through M/s MN Science & Technology Park Pvt. Ltd.,

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 and C enclosed to this order.

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

Sl. No.	Product & By product (After Expansion)
1	“Research & Development activities on Pharmaceutical Formulation” (No Commercial Production)

This combined order of Consent & Hazardous Waste Authorization shall be valid for a period ending with the **31.10.2032**. *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.


JOINT CHIEF ENVIRONMENTAL ENGINEER

Encl: Schedules A, B & C

To

**M/s. Alembic Pharmaceuticals Ltd.,
Lab Suite No. 111, 112, 113, 114 123-124 & 132, Building 450,
MN Science & Technology Park Pvt. Ltd.,
(Earlier AKP Knowledge Park), Genome Valley,
Turkapally (V), Shameerpet (M), Medchal- Malkajgiri District
Email: srinivasa.chaturvedula@alembic.co.in**

1. Copy submitted to the Member Secretary, TSPCB, Board Office, Hyderabad for information.
2. Copy to the General Manager, District Industries Centre, Near ORR, Keesara, Medchal-Malkajgiri District, Collectorate Complex, Hyderabad – 500083.
3. 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 & 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 CFO order issued vide order dt.23.11.2017 for M/s Alembic Pharmaceuticals Ltd and CFO order dt. 30.01.2016 & 16.07.2018 issued to M/s AG Research Private Limited and the activities are merged and fresh combined order issued.**
2. **The industry has paid consent fee for a period upto 31.03.2025. 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 31.10.2032.**
3. **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.**
4. **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.**
5. 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 quantity (After Expansion)
1.	Process & Washing	6.5 KLD
2.	Domestic	3.5 KLD
	Total	10.0 KLD

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	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).

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 regularly send the process and wash effluents after sterilisation to common pretreatment facility provided by M/s. MN Science & Technologies Park Pvt. Ltd., (Earlier M/s. AKP Knowledge Park). After pretreatment, treated effluents shall be lifted to the CETP, Jeedimetla by duly complying with the inlet standards of the CETP prescribed by the Board.
10. The industry shall provide minimum 7 days storage capacity of effluent on the above ground level with in premises.
11. The industry shall send the domestic effluents to Common Sewage Treatment Plant of M/s. MN Science & Technology Park Pvt. Ltd., (Earlier M/s. AKP Knowledge Park). After pretreatment, the effluents shall be utilized for onland for gardening within the premises duly complying the standards stipulated by the Board.
12. The industry shall provide digital flow meters with totalizer for assessing the qualities of waste water disposed into common effluents collection tank of M/s. MN Science & Technology Park Pvt. Ltd., (Earlier M/s. AKP Knowledge Park) & shall maintain the register.
13. The industry shall collect the Hazardous waste properly & dispose these wastes as per the authorisation through M/s. MN Science & Technology Park Pvt. Ltd., (Earlier M/s. AKP Knowledge Park).
14. The industry shall suck the fumes emanated during the various chemical reactions in the fume hoods and pass them through a wet scrubber before letting into atmosphere through common stack. **The industry shall upgrade the wet scrubbers with Activated Carbon Adsorption system within 3 months to control the VOC emissions if any.**
15. The industry shall not discharge any waste water to outside the factory premises
16. The industry shall not cause any air pollution/odour nuisance to the surrounding environment.
17. 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.
18. 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 sent to CETP i.e., M/s. JETL, Jeedimetla
 - b) Log Books for pollution control systems.
 - c) Daily solid waste generated and disposed to TSDF, Dundigal.
19. The industry shall maintain good housekeeping with-in the premises.
20. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
21. The industry should regularly carry out monitoring of Environmental Parameters, audit them and should submit report to the Board twice in a calendar year.
22. The industry shall take all precautionary and safety measures during process operations.
23. The industry shall comply with the ambient air quality standards in respect of noise, as stipulated in the Environment (Protection) Rules, 1986.
24. The industry shall comply with all the directions issued by the Board from time to time.

25. This order is issued to the industry without prejudice to the action taken by the Task Force of the Board.
26. 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 its amendment thereof.
3. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal.
4. The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors / Recyclers. 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 dispose Used Lead Acid Batteries to the manufacturers / dealers on buyback basis.
5. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.
6. The industry shall maintain good housekeeping & 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
7. 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.
8. 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.
9. The industry shall dispose the e-waste to authorized recyclers / dismantlers only.

JOINT CHIEF ENVIRONMENTAL ENGINEER

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To
M/s. Alembic Pharmaceuticals Ltd.,
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