



TELANGANA STATE POLLUTION CONTROL BOARD

Phone: 23887500
Fax: 040-23815631

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

CONSENT ORDER NO. 220524067304 DATED: 30/11/2022.

(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 & Rules') and amendments thereof and the rules and orders made there under to M/s. "Mylan pharmaceuticals private limited., global biologics r & d, Building 450, Phase-1, Sy. No. 230-243, M/s MN Science & Technology Park, Genome Valley, Turkapally (V), Shameerpet (M), Medchal District. " (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.220524067304 DATED: 30/11/2022.

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

Mylan pharmaceuticals private limited., global biologics r & d, Building 450, Phase-1, Sy. No. 230-243, M/s MN Science & Technology Park, Genome Valley, Turkapally (V), Shameerpet (M), Medchal District. 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 .September 30, 2027

MEMBER SECRETARY

To
The Director,
M/s.MYLAN PHARMACEUTICALS PRIVATE LIMITED., GLOBAL BIOLOGICS R & D ,
Building 450, Phase-1, Sy. No. 230-243, M/s MN Science & Technology Park, Genome Valley, Turkapally (V), Shameerpet (M),
Medchal District. ,
Pin: 500101

Copy to :

SCHEDULE 1A

SCHEDULE - B

1. Total Water Consumption shall not exceed : 2.00 KLD

S.No.	Purpose	Quantity
1	Washing	1.4
2	Domestic	0.6

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 Director,
M/s.MYLAN PHARMACEUTICALS PRIVATE LIMITED., GLOBAL BIOLOGICS R & D, ,
Building 450, Phase-1, Sy. No. 230-243, M/s MN Science & Technology Park, Genome Valley,
Turkapally (V), Shameerpet (M), Medchal District. ,
Pin: 500101



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
Email: jcee-zhyd-tspcb@telangana.gov.in

CONSENT & AUTHORIZATION ORDER – RED CATEGORY

Consent Order No:1001-RR-II/TSPCB/ZOH/TS-iPASS/CFO/2022 - 511 Date:24.11.2022

(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) 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. Mylan Pharmaceuticals Pvt. Ltd.,
Global Biologics R & D, Block -1, Building 450,
M/s. MN Park (Formerly M/s. Alexandria 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	Point of Disposal	Limiting Standards
1	Process and Washings effluents	1.4 KLD	Sent to Common Effluent collection tank of MN Park (Earlier M/s. Alexandria Knowledge Park). After pretreatment, shall be lifted to CETP, M/s. JETL, Jeedimetla for further treatment and disposal	Inlet parameters of CETP prescribed by the Board
2	Domestic	0.6 KLD	After treatment in common STP of MN Park (Earlier M/s. Alexandria Knowledge Park), the treated waste water shall be used on land for gardening within 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) - 30.0 mg /l

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. Mylan Pharmaceuticals Pvt. Ltd., Global Biologics R & D, Block -1, Building 450, M/s. MN Park (Formerly M/s. Alexandria 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:

Sl. No.	Name of the Hazardous Waste	Quantity of Hazardous waste	Stream	Disposal Option
1	Spent Organic Solvents	50 Ltrs/day	28.5 of Sch-I	Shall be lifted to M/s.HWM Project (TSDF), Dundigal, RR Dist/ AFRF facilities for pre-processing/cement units for co-processing through M/s. MN Park (Formerly M/s. Alexandria Knowledge Park).
2	Off Specification products	5 Kg/day	28.4 of Sch-I	
3	Date expired, discarded and Off-specified drugs, chemicals samples and medicines, pharma substances, Reagents etc.	5 Kgs/day		
4	Discarded containers – bottles, carboys, cartons, cans, barrels, etc.	10 Nos/day	33.3 of Sch-I	After complete detoxification, shall be sold to authorized dealers/ recyclers or parties through M/s. MN Park (Formerly M/s. Alexandria Knowledge Park).
5	Waste paper, wood, packing materials, cartons, Plastic, butter paper, shoe covers.	5 Kgs/day	--	
6	Samples covers, filter papers, filter discs, connecting pipes, tissue paper, foil, paper cups, rubber stoppers, broken glass ware, discarded laboratory glass ware / plastic containers, laboratory vials, any other laboratory discarded accessories etc.	1 Kgs/day	--	
7	E-Waste	1 Kg/day	--	Shall be sent to E-Waste processing Facilities at Maheswaram, Rangareddy District.
8	Waste from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and industrial laboratories, wastes from production of biological, toxins, dishes and devices used for transfer of cultures	5 Kg/month	---	Shall be sent to M/s. Semb Ramky Pvt Ltd., for further disposal.
9	Needles, syringes, scalpels, blades, glass etc	2 Kg/month		
10	Chemicals used in production of biological, chemicals used in disinfection, as insecticides etc	250 Kg/month		

This consent order is valid for the manufacture of the following products with quantities mentioned below only:

Sl. No.	Product & By product
1.	Biopharmaceutical Research & Development for Biological drug substances and drug products. (No Commercial Production)

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 combined order of Consent and Authorization is valid for a period ending with the **30.09.2027**. *The industry shall pay the consent fees annually from the financial year 2026-27 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


To
M/s. Mylan Pharmaceuticals Pvt. Ltd.,
Global Biologics R & D, Block -1, Building 450,
M/s. MN Park (Formerly M/s. Alexandria Knowledge Park),
Genome Valley, Turkapally (V),
Shameerpet (M), Medchal – Malkajgiri District
E_mail: srinivasbhargav.perla@viatris.com

Copy submitted to the Member Secretary, TSPCB, Board Office, Hyderabad for information.
Copy to the Environmental Engineer, TSPCB, Regional Office, Medchal for information.

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 31.03.2026. The industry shall pay the consent fees annually from the financial year 2026-27 to till the validity of the consent order i.e., upto 30.09.2027.**
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 prescribed below:

Sl. No.	Purpose	Total quantity
1.	Process & Washings	1.4 KLD
2.	Domestic	0.6 KLD
Total		2.0 KLD

The Industry shall maintain separate water meters for the above areas and maintain records.

5. The industry shall comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets 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.
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 ($\text{PM}_{2.5}$)	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).

7. 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.
8. 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.
9. The industry shall not provide pilot plant activity and shall not go for commercial production without permission of the Board.
10. The industry shall send the process and wash effluents to common effluent collection tank of M/s. MN Park (Formerly M/s. Alexandria Knowledge Park).. After pretreatment, the effluents shall be lifted to CETP, Jeedimetla for further treatment and disposal by M/s. MN Park (Formerly M/s. Alexandria Knowledge Park) by duly complying with the inlet standards of CETP prescribed by the Board.
11. The industry shall send the domestic effluents to the common sewage treatment plant provided by M/s. MN Park (Formerly M/s. Alexandria Knowledge Park). After treatment, the treated wastewater shall be used for on land for gardening by duly complying with the standards stipulated by the Board.
12. The industry shall provide digital flow meter with totalizer for assessing the quantity of waste water disposed in to common effluent collection tank of M/s. MN Park (Formerly M/s. Alexandria Knowledge Park), and shall maintain the register.
13. 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 control equipment with Activated carbon adsorption system after Wet scrubbers to control VOC emissions if any.**
14. The industry shall collect Spent Organic Solvents, Off Specification Products and Date expired, discarded and Off-specified drugs, chemicals samples and medicines, pharma substances, Reagents etc. properly and lift these hazardous waste to TSDF, Dundigal, Medchal/ AFRF facilities for pre-processing/cement units for co-processing through M/s. MN Park (Formerly M/s. Alexandria Knowledge Park)..
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 not dispose the solid waste outside the factory premises.
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 trade effluents generated and disposed to common effluent collection tank of M/s. MN Park (Formerly M/s. Alexandria Knowledge Park).
 - b) Log Books for pollution control systems.
 - c) Daily solid waste generated and disposed to TSDF through M/s. MN Park (Formerly M/s. Alexandria Knowledge Park).
19. The industry shall maintain good house keeping & maintain proper records for hazardous waste stated in the authorization.
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 shall take necessary measures to control fugitive emissions.
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. 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.
26. The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.
27. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.
28. 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 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. Mylan Pharmaceuticals Pvt. Ltd.,
Global Biologics R & D, Block -1, Building 450,
M/s. MN Park (Formerly M/s. Alexandria Knowledge Park),
Genome Valley, Turkapally (V),
Shameerpet (M), Medchal – Malkajgiri District.