TELANGANA STATE POLLUTION CONTROL BOARD



Phone: 23887500 Fax: 040-23815631

DATED: 05/07/2024.

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

CONSENT ORDER NO. 240525248806

DATED: 05/07/2024.

(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 Actsi¿½, `the Rulesi¿½) and amendments thereof and the rules and orders made there under to M/s.", Azurity pharmaceuticals india llp ,MEDCHAL II, Shamirpet, Lalgadimalakpet, Lab Suit No. E 201 " (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 | Point of Disposal |
|---------------|------------------------------|------------------------|-------------------|
| | | in KLD | |

| 11 / 121111551U115 11 U111 C11111111E (| vs: | himnev | from o | Emissions | ii) |
|---|-----|--------|--------|------------------|-----|
|---|-----|--------|--------|------------------|-----|

| Chimney No. | Description of Chimney |
|-------------|-------------------------------|
|-------------|-------------------------------|

iii) HWAuthorisation No.240525248806

HAZARDOUS WASTE AUTHORISATION (FORM � II)

[See Rule 6 (2)]

Azurity pharmaceuticals india llp ,MEDCHAL II,Shamirpet,Lalgadimalakpet,Lab Suit No. E 201 is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

| l. HAZARDOUS WASTE | 'S WITH DISPOSAL (| OPTION : |
|-----------------------|--------------------|----------|
| Name of the Hazardous | Stream | Quanti |

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

| 2. HAZARDOUS WASTE | S WITH RECYCLING O | OPTION: | |
|--------------------------------|--------------------|----------|------------------|
| Name of the Hazardous Waste | Stream | Quantity | RECYCLING option |
| | N | IL | |

| S.No. | Name of the Product | Capacity | Unit |
|-------|---------------------|----------|------|
| | | | |

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 .July 05, 2024

MEMBER SECRETARY

To

The Partner,

M/s.AZURITY PHARMACEUTICALS INDIA LLP,

MEDCHAL II,Shamirpet,Lalgadimalak
pet,Lab Suit No. E201 ,

Pin: 500078

Copy to:

SCHEDULE � A

SCHEDULE - B

1. Total Water Consumption shall not exceed: 7.40 KLD

| S.No. | Purpose | Quantity |
|-------|---------------------------|----------|
| 1 | Others Process & Washings | 5 |
| 2 | Domestic | 2.4 |

2. The Treated Effluent Dischrged/pre-treated effluent sent to CETB shall not exceed the following prescribed standards

| Outlet No. | Parameter | Limiting Standard |
|------------|---------------|--------------------|
| Ounce 110. | 1 at atticici | Difficing Standard |

3. The Emisson shall not exceed the following prescribed standards

| Chimney | Description of Chimney | Parameter | Emission Standards |
|---------|-------------------------------|-----------|---------------------------|
| No. | | | |

SCHEDULE - C

MEMBER SECRETARY

To

The Partner,

M/s.AZURITY PHARMACEUTICALS INDIA LLP,

MEDCHAL II, Shamirpet, Lalgadimalakpet, Lab Suit No. E 201,

Pin: 500078



TELANGANA POLLUTION CONTROL BOARD ZONAL OFFICE: HYDERABAD

H.No.6-3-1219, Sy.No.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 – ORANGE CATEGORY

Consent Order No: 1965-RR-II/TGPCB/ZOH/TG-iPASS/CFO/2024- 5/2 Date:04.07.2024

(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. Azurity Pharmaceuticals India LLP (Formely M/s. Slayback Pharma India LLP)
Lab Suit No. E 201 & N 201/2, Plot No. 4,
Sy. Nos. 101 & 101/2& 340, 1st Floor, Building No.3600,
Neovantage Innovation Park Pvt. Ltd, Genome Valley,
Lalgadimalakpet(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 | Outlet | Max Daily | Point of Disposal | Limiting |
|--------|--------------------|-----------|--|---|
| No. | Description | Discharge | | Standards |
| 1 | Process & Washings | 5.0 KLD | Shall be sent to Common pretreatment facility provided by M/s.Neovantage Innovation Park Pvt. Ltd. After pretreatment, shall be sent to CETP, M/s. JETL, Jeedimetla, Medchal-Malkajgiri District for further treatment & disposal. | Inlet standards of |
| 2 | Domestic | 1.9 KLD | Shall be disposed to common STP provided by M/s.Neovantage Innovation Park Pvt. Ltd. After treatment, the treated domestic wastewater is used for greenbelt development within the premises. | Suspended Solids - 200.0 mg/l, Oil & Grease - 10.0 mg/l, Biochemical Oxygen Demand (3 |

ii) Emissions from chimneys:

| Chimney No. | Description of Chimney | Quantity of Emissions at peak flow | Emission Standards |
|----------------|-------------------------------|------------------------------------|-----------------------|
| | | | |

iii) Hazardous Waste Authorization: (Form – 2) [See Rule 6(2)]:

M/s. Azurity Pharmaceuticals India LLP (Formely M/s. Slayback Pharma India LLP) Lab Suit No. E 201 & N 201/2, Plot No. 4, Sy. Nos. 101 & 101/2& 340, 1st Floor, Building No.3600, Neovantage Innovation Park Pvt Ltd, Genome Valley, Lalgadimalakpet(V), Shameerpet (M), Medchal-Malkajgiri Districtis 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 of the Hazardous / Solid waste | Hazardous / as defined under HWM Rules, 2016 | Quantity | Method of Disposal |
|-----------|---|---|--------------------|--|
| 1 | Waste powder collected from floor sweeping, Dust extraction system, vacuum cleaner | | 240 Kg/month | Sent to TSDF/AFRF facilities/ cement units for co-processing through M/s Neovantage |
| 2 | Discarded Lab samples (solid waste, expired excipients etc) | | 600 Kg/month | Innovation Park Private Limited. |
| 3 | Discarded tablets from process | | 300 Kg/month | |
| 4 | Used Glassware | 33.1 of Sch-I | 900 Kg/month | After detoxification, Authorized agencies/dealers for Recycling &Reprocessing units through M/s. Neovantage Innovation Park. |
| 5 | Plastic materials and Used PPE | | 50 Kg/month | Shall be sent to authorized agencies/parties through M/s.Neovantage Innovation Park. |
| 6 | Spent Solvents | 28.6 of Sch-I | 1.5 KLM | Shall be sent to authorized solvent recovery units through M/s.Neovantage Innovation Park Private Limited. |
| 7 | Batteries | | 20 No's/ annum | Shall be sent back to suppliers on buy back basis. |
| 8 | Used Silica gel | 28.2 of Sch-I | 1 Kg/ month | Shall be sent to TSDF |
| 9 | Thermocol | | 100 Kg/ month | through M/s.Neovantage Innovation Park. |
| 10 | MS/Plastic Drums/ 500 g to 1000g plastic bottles | | 100 No's/ month | Shall be sent to Authorised Recyclers. |
| 11 | Expired Chemicals | | 100 Kg/ month | Shall be sent to TSDF through M/s. Neovantage Innovation Park. |
| 12 | E-Waste | | 100 Kg/ month | Shall be sent to Authorised Recyclers. |
| 13 | R & D Process residue & reject material | 28.1 of Sch-I | 200 Kg/ month | Shall be sent to TSDF/AFRF facilities/ cement units for co-processing through M/s.Neovantage Innovation Park. |

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

| Sl.No | Name of the Products/Line of Activity | |
|-------|---|--|
| 1. | Formulation R & D Services (No Commercial Production) | |

This combined order of Consent and Authorization is valid for a period ending with the 31.05.2034. 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.

JOINT CHIEF ENVIRONMENTAL ENGINEER

ON CON

Encl: Schedules A, B & C

To
M/s. Azurity Pharmaceuticals India LLP
(Formely M/s. Slayback Pharma India LLP)
Lab Suit No. E 201 & N 201/2, Plot No. 4,
Sy. Nos. 101 & 101/2& 340, 1st Floor, Building No.3600,
Neovantage Innovation Park Pvt Ltd, Genome Valley,
Lalgadimalakpet(V), Shameerpet (M), Medchal-Malkajgiri District
Email Id: nagaraju.karumuri@azurity.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 District for information and necessary action. 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 upto 31.05.2025. 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 31.05.2034.
- 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 Transboundary 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 | 5.0 KLD |
| 2. | Domestic | 2.4 KLD |
| | Total | 7.4 KLD |

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

- 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 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.

7. 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 µg/m³ |
|--------|---|--------------------|
| 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).

- 8. 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.
- 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 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. Neovantage Innovation Park Pvt. 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.Neovantage Innovation Park Pvt. 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, 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 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 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) Production details, RG-I records and Central Excise Returns.
 - b) Quantity of effluents generated.
 - c) Log Books for pollution control systems.
 - d) Daily solid waste generated and disposed.
- 20. The industry shall maintain good house keeping & maintain proper records for hazardous waste stated in the authorization.
- 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))

(Conditions of Authorization for occupier or operator handling hazardous wastes)

- 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 90 days as per the Hazardous & other wastes (Management and Transboundary Movement) Rules, 2016.
- 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.
- 5. The industry shall dispose Used Lead Acid Batteries to the manufacturers / dealers on buyback basis.
- 6. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.
- 7. The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board Office and concerned Regional Office.
- 8. The industry shall maintain good housekeeping & maintain proper records for Hazardous Wastes stated in Authorisation.
- 9. The industry shall maintain proper records for Hazardous Wastes stated in Authorisation in FORM-3 and file annual returns in Form- 4 Rules 6(5), 13(8), 16(6) and 20(2) as per of the Hazardous & other wastes (Management, Transboundary Movement) Rules, 2016.
- 10. 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.
- 11. The industry shall dispose the e-waste to authorized recyclers / re-processors only.

JOINT CHIEF ENVIRONMENTAL ENGINEER

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To

M/s. Azurity Pharmaceuticals India LLP (Formely M/s. Slayback Pharma India LLP) Lab Suit No. E 201 & N 201/2, Plot No. 4,

Sy. Nos. 101 & 101/2& 340, 1st Floor, Building No.3600, Neovantage Innovation Park Pvt Ltd, Genome Valley,

Lalgadimalakpet(V), Shameerpet (M), Medchal-Malkajgiri District.