



TELANGANA STATE POLLUTION CONTROL BOARD

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

CONSENT ORDER NO. 220823292428 DATED: 06/01/2022.

(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.

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. "**Ichor biologics pvt. limited ,MEDCHAL II,Shamirpet,Turkapally,Sy. No. 222P,NEAR ZENOTECH,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.220823292428 DATED: 06/01/2022.

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

Ichor biologics pvt. limited ,MEDCHAL II,Shamirpet,Turkapally,Sy. No. 222P,NEAR ZENOTECH,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 .January 06, 2022

MEMBER SECRETARY

To

The Managing Director,

M/s.ICHOR BIOLOGICS PVT. LIMITED,

MEDCHAL II,Shamirpet,Turkapally,Sy. No. 222P,NEAR ZENOTECH,500078,

Pin: 500078

Copy to :

SCHEDULE – A

SCHEDULE - B

1. Total Water Consumption shall not exceed : 16.00 KLD

S.No.	Purpose	Quantity
1	Process	10
2	Cooling water makeup	2
3	Domestic	2
4	Greenbelt	2

2. The Treated Effluent Dischrge/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.ICHOR BIOLOGICS PVT. LIMITED,
MEDCHAL II,Shamirpet,Turkapally,Sy. No. 222P,NEAR ZENOTECH,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,
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CONSENT & HW AUTHORIZATION ORDER - RED CATEGORY

Consent Order No: 729 -RR-II/TSPCB/ZOH/TS-iPASS/CFO/2022- 705 Date: 05.01.2022

(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. Ichor Biologics Pvt. Limited
(Formerly M/s. Hemarus Therapeutics Ltd.,)
(Formerly M/s. Credence Clinical Research Pvt. Ltd.,),
Sy.No.222P, 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 & Washings	8.0 KLD	After treatment in ETP, the treated waste water shall be used for on land for gardening within the factory 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 mg/lit.
2.	Domestic Effluents	2.0 KLD	Septic tank followed by soak pit	---

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow	Emission Standards
1.	Attached to oil fired boiler of capacity – 850 Kgs/hr	---	SPM – 115 mg/Nm ³ SO ₂ – 600 mg/Nm ³ . At 6% dry O ₂ , for solid fuel and 3% dry O ₂ for liquid fuel. NO _x – 600 mg/Nm ³ . At 6% dry O ₂ , for solid fuel and 3% dry O ₂ for liquid fuel.
2.	Attached to DG set of capacity – 400 KVA	----	SPM – 115 mg/Nm ³

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

M/s. Ichor Biologics Pvt. Limited (Formerly M/s. Hemarus Therapeutics Ltd.,) (Formerly M/s. Credence Clinical Research Pvt. Ltd.), Sy.No.222P, 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 and quantity of the Hazardous waste	Stream	Disposal option
1	Collection Tank Sludge (8 Kgs/day)	35.3 of Sch - I	Shall be lifted to M/s HWM Project (TSDF), Dundigal (V), Medchal for scientific disposal.
2	Waste oils (50 LPA)	5.1 of Sch-I	Shall be sent to authorized recyclers / re-processors of waste oil
3	Gloves & used vials (5.0 Kgs/day)	----	Shall be disposed to Common Bio-Medical Waste Treatment Facility i.e., M/s. G.J.Multiclave Pvt. Ltd.,

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 Product	Total capacity
	Thawing of plasma into following factors	
1	Blood clotting Factor -VIII	48 MIU/annum
2	Blood clotting Factor –IX	72 MIU/annum
3	Intravenous Immunoglobulin (IVIG)	960 Kgs/annum
4	Human Albumin	6000 Kgs/annum

This combined order of Consent & Hazardous Waste Authorization shall be valid for a period ending with the 30.11.2026. *The industry shall pay the consent fees annually from the financial year 2023-2024 to till the validity of the consent order i.e., upto 30.11.2026.*

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. Ichor Biologics Pvt. Limited
(Formerly M/s. Hemarus Therapeutics Ltd.,)
(Formerly M/s. Credence Clinical Research Pvt. Ltd.),
Sy.No.222P, Turkapally (V), Shameerpet (M),
Medchal-Malkajgiri District
Email Id: qa.head@ichor.in

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 & Air Acts) and Authorisation 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 Authorisation 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. 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. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8.
 - a) The industry shall carryout analysis of waste water discharges or emissions through chimneys, for the parameters mentioned in Schedule – B of this order at regular intervals.
 - b) The industry shall maintain following records to accessible to the Board, whenever required.
 1. Analysis reports of waste water/ emissions.
 2. Log book for operation of pollution control systems.
 3. Inspection book.
9. Separate power connection with energy meter shall be provided for the Pollution Control Equipment and record of power consumption and chemicals consumption for the operation of pollution control equipment shall be maintained separately.
10. 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.
11. 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.
12. 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.

13. 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.
14. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 shall be followed.
15. The occupier shall educate the workers and nearby public of possible accidents and remedial measures.
16. For any accident or spillage of hazardous wastes causing damage to the Environment, the occupier or the transporter as the case shall be held responsible.
17. In case of closure of industry, the un-used/not consumed raw materials falling under the category of Hazardous Chemicals and mentioned in Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment Rules, 2003 shall be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident. In case the above hazardous chemicals have lost their properties originally acquired, then they shall be treated as Hazardous Waste and they should be disposed off only to the authorized agencies of TSPCB in a safe manner.
18. Packaging, labeling and transportation of Hazardous Wastes shall be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling shall be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.
19. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter shall carry a Transport Emergency (TREM) card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.
20. Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes should be thoroughly detoxified before selling to agencies authorized by TSPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste Containers / container Liners should be maintained in the following way:
 - i . Number of containers received.
 - ii . Date and method of detoxification.
 - iii . Name of agencies to whom containers were sold with quantities.
 - iv . Transportation particulars.
21. No Hazardous Wastes shall be mixed with any other waste or shall be discharged to a common, other internal, external sewerage or other drainage system without prior approval of TSPCB.
22. If HDPE bags are used for storing Hazardous Wastes, it should be ensured that they are perfectly sealed mechanically or double hot sealed. If MS / HDPE bags or drums are used for Hazardous Wastes, these drums / bags should be ensured that they are perfectly sealed.
23. The person authorized shall not rent, lend, sell, transfer their industrial premises without obtaining prior permission of State Pollution Control Board.
24. Any Unauthorized change in personnel, equipment and working condition as mentioned in the application by the person authorized shall constitute a breach of this authorization.
25. The applicant shall put up two black boards of size 6 ft by 4 ft. at the main entrance to their plant. One board shall contain the specific CFE and CFO conditions, in sufficiently large font size so that it can be read easily from a distance of 10 ft to a normal eye, and other board shall carry, again in sufficiently large font size so as to be able to read from a distance of 10 ft, the latest Water, Air, Noise and solid waste monitoring data as well as the maximum vulnerable zone.
26. The applicant shall exhibit the Consent & HW Authorization order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.
27. 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.

28. The authorization issued under Hazardous and other wastes (Management and Transboundary Movement) Rules, 2016, shall comply with the provision of the Environment (Protection) act, 1986.
29. 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 of 7,08,750/- i.e., upto 30.11.2023. The industry shall pay the consent fees annually from the financial year 2023-2024 to till the validity of the consent order i.e., upto 30.11.2026.
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 mentioned below

S. No.	Consumption	Total quantity
1.	Process & Washings	10.0 KLD
2.	Cooling	2.0 KLD
3.	Domestic	2.0 KLD
4.	Gardening	2.0 KLD
	Total	16.0 KLD

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 (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.

8. The industry shall regularly operate the Effluent Treatment Plant and the treated waste water shall be used on land for irrigation within the premises duly meeting the prescribed standards.
9. The industry shall provide ducting connected to scrubber for the fume cup boards to control the fugitive emissions during the R&D activity.
10. The industry shall not discharge any waste water outside the factory premises.
11. The industry shall not dispose any solid waste outside the factory premises.
12. The industry shall not cause any air pollution / odour nuisance to the surrounding environment.
13. The industry shall collect Hazardous waste generated i.e., Collection Tank Sludge properly and shall lift the Hazardous waste to TSDF, Dundigal regularly. The industry shall segregate the bio medical waste properly and shall lift the bio-medical waste to the Combined Bio-medical Waste Treatment Facility (CBMWTF).
14. 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
15. 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,
 - b) Quantity of effluents generated and used for gardening.
 - c) Log Books for pollution control systems.
 - d) solid waste generated and disposed.
16. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
17. The industry shall take necessary measures to control fugitive emissions.
18. The industry shall comply with all the directions issued by the Board from time to time.
19. 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.
20. The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.
21. 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 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 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. Ichor Biologics Pvt. Limited
(Formerly M/s. Hemarus Therapeutics Ltd.,)
(Formerly M/s. Credence Clinical Research Pvt. Ltd.),
Sy.No.222P, Turkapally (V), Shameerpet (M),
Medchal-Malkajgiri District.

