

MAHARASHTRA POLLUTION CONTROL BOARD

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ORANGE/L.S.I (074)

Date: 02/01/2024

No:- Format1.0/RO/UAN No.MPCB-
CONSENT_AMMENDMENT-0000012213/CE/2401000006

To,
M/s. STERIBIO LIFESCIENCES PRIVATE LIMITED
Gat no. 148, Pune- Solapur National Highway,
Near Patas Toll Naka, Village- Patas,
Taluka- Daund, Dist. Pune- 412219



Your Service is Our Duty



Sub: Application for Grant of Consent to Establish.

- Ref:**
1. Your application for grant of Consent to Establish (UAN No. MPCB-CONSENT-0000167415)
 2. Consent to Establish granted by the Board vide no. Format1.0/RO/UAN No.0000167415/CE/2307000724, Dtd. 13/7/2023
 3. Application for Amendment in Consent vide no. MPCB-CONSENT_AMMENDMENT-0000012213, Dtd. 01/12/2023

Your application No.MPCB-CONSENT_AMMENDMENT-0000012213 Dated 01.12.2023

For: Grant of Consent to Establish under Section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization under Rule 6 and Rule 18(7) of the Hazardous & Other Wastes (Management & Transboundary Movement) Rules 2016 is considered and the consent is hereby granted subject to the following terms and conditions and as detailed in the schedule I, II, III & IV annexed to this order:

1. **The consent to establish is granted for a period up to commissioning of the unit or up to 5 year whichever is earlier.**
2. **The capital investment of the project is Rs.49.80 Crs. (As per C.A Certificate submitted by industry)**
3. **Consent is valid for the manufacture of:**

Sr No	Product	Maximum Quantity	UOM
Products			
1	Dextrose (5%) (500 ml product))	21500	No/D
2	Dextrose (5%) & Sodium Chloride (0.9%)(500 ml product)	21500	No/D
3	Sodium Chloride (0.9%) (500 ml product))	21500	No/D
4	Compound Sodium Lactate Inj (500 ml product)	5375	No/D
5	Ringer Solutions (500 ml product))	5375	No/D
6	Electrolyte-M (500 ml product))	2150	No/D

Sr No	Product	Maximum Quantity	UOM
7	Electrolyte-P (500 ml product))	2150	No/D
8	Electrolyte-G (500 ml product))	2150	No/D
9	Linezolid IV (500 ml product))	5375	No/D
10	Dextrose (10%) (500 ml product))	5375	No/D
11	Sodium Chloride (0.45%,0.33% %3%) (500 ml product))	5375	No/D
12	Dextrose (5%) & Sodium chloride (0.45%) (500 ml product)	3225	No/D
13	Mannitol (20%) (500 ml product)	3225	No/D
14	Tindazole (500 ml product)	3225	No/D
15	Dextrose (5%) (1000ml products)	1875	No/D
16	Dextrose (5%) & Sodium Chloride (0.9%)(1000 ml product)	1875	No/D
17	Sodium Chloride (0.45%,0.33% %3%) (1000 ml product)	2500	No/D
18	Dextrose (10%) (1000 ml product)	2500	No/D
19	Sodium Chloride (0.45%,0.33% %3%) (1000 ml product)	1875	No/D
20	Dextrose (5%) & Sodium chloride (0.45%) (1000 ml product)	1875	No/D
21	Sodium Chloride (0.9%) (100 ml Products)	20000	No/D
22	Ofloxacin (100 ml Products)	8000	No/D
23	Ciprofloxacin (0.2 %) (100ml Products)	4000	No/D
24	Metronidazole (0.5%)(100ml Products)	4000	No/D
25	Paracetamol (1.0%) (100 ml)	16000	No/D
26	Moxifloxacin 0.4% (100 ml)	8000	No/D
27	Levofloxacin 0.5% (100 ml)	4000	No/D
28	Linezolid IV 0.2% (100 ml product)	4000	No/D
29	Electrotype-P (100 ml product)	4000	No/D
30	Ornidazole 0.2 % (100ml product)	4000	No/D
31	Fluconazol 0.2 % (100 ml)	4000	No/D

(Only Mixing and Formulation activity)

4. **Conditions under Water (P&CP), 1974 Act for discharge of effluent:**

Sr No	Description	Permitted (in CMD)	Standards to	Disposal Path
1.	Trade effluent	29.5	As per Schedule -I	For Boiler and Chiller only
2.	Domestic effluent	29.5	As per Schedule - I	Flushing and gardening

5. **Conditions under Air (P& CP) Act, 1981 for air emissions:**

Sr No.	Stack No.	Description of stack / source	Number of Stack	Standards to be achieved
1	1	D.G. Set 1000 KVA	1	As per Schedule -II
2	2	Boiler	1	As per Schedule -II

6. **Non-Hazardous Wastes:**

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	STP Sludge	12	Kg/Day	Composting	Used as manure

7. **Conditions under Hazardous & Other Wastes (M & T M) Rules 2016 for Collection, Segregation, Storage, Transportation, Treatment and Disposal of hazardous waste:**

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
1	35.3 Chemical sludge from waste water treatment	12	Kg/Day	NA	CHWTSDF

Industry shall obtain membership of CHWTSDF before applying for consent to First operate.

8. **Conditions under Plastic Waste Management Rules, 2016 (Notification dtd. 18/03/2016):**

Sr No	Type of Waste	Quantity	UoM	Disposal Path
1	Plastic Bags	200.00	Kg/Day	Authorized Recycler

9. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding on the industry.
10. This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.
11. The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/Activity. (Establish)
12. . The applicant shall not use plastic and plastic packaging material, which are banned as per the provision of Maharashtra Plastic & Thermocol Products (Manufacture, Usage, Sale, Transport, and Handling & Storage) Notification 2018 and further amendments.
13. The applicant shall obtain necessary permission from the Directorate of Industrial Safety and Health (DISH), in case of store /handle/ process the Hazardous Chemicals.
14. The applicant shall not manufacture any product/activity, which comes under the purview of Environment Clearance as per EIA Notification, 2006 and their amendments.
15. The Capital investment of the industry is Rs. 49.80 Crores.
16. This consent is having overriding effect on the earlier granted consent to establish in the name of M/s. STERIBIO LIFESCIENCES PRIVATE LIMITED vide no. Format1.0/RO/UAN No.0000167415/CE/2307000724, Dtd. 13/07/2023

Received Consent fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	100000.00	MPCB-DR-18509	19/04/2023	RTGS

Copy to:

1. Regional Officer, MPCB, Pune and Sub-Regional Officer, MPCB, Pune I
 - They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Sion, Mumbai



SCHEDULE-I

Terms & conditions for compliance of Water Pollution Control:

1. A] As per your application, you have proposed to provide Effluent Treatment Plant (ETP) of designed capacity of 65.00 CMD consisting of for the treatment of 29.5 CMD of trade effluent.
- B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent:

Sr.No	Parameters	Limiting concentration not to exceed in mg/l, except for pH
(1)	pH	6.0 -8.5
(2)	BOD (3 days 27°C)	30
(3)	COD	250
(4)	TSS	100
(5)	Oil & Grease	10
(6)	TDS	2100
(7)	Chloride	600
(8)	Sulphate	1000

- C] The treated effluent shall be recycled for secondary purposes as for Boiler 15 CMD and Chiller 14.5 CMD after confirming above standards. In no case, effluent shall find its way for gardening / outside factory premises.
2. A] As per your application, you have provided Sewage Treatment Plant of designed capacity 30 CMD for the treatment of 29.5 CMD of sewage.
 - B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards.

Sr.No	Parameters	Standards (mg/l)	
1	Suspended Solids	Not to exceed	50
2	BOD 3 days 27°C	Not to exceed	30
3	COD	Not to exceed	100

- C] The treated sewage shall be recycled for secondary purposes i.e. Flushing 19.5 CMD and remaining 10 CMD shall be discharged on land for gardening within premise after confirming above standards. In no case, sewage shall find its way for gardening / outside factory premises.
3. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification there of & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or an extension or addition thereto.
 4. The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.

5. The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Act, 1974 and as amended, by installing water meters and other provisions as contained in the said act:

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	0.00
2.	Domestic purpose	35.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	35.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Gardening	0

6. The Applicant shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance/ CREP guidelines.

SCHEDULE-II

Terms & conditions for compliance of Air Pollution Control:

1. As per your application, you have proposed to provide the Air pollution control (APC) system and also to erect following stack (s) to observe the following fuel pattern:

Stack No.	Source	APC System provided/proposed	Stack Height(in mtr)	Type of Fuel	Sulphur Content(in %)	Pollutant	Standard
1	D.G. Set 1000 KVA	Acoustic Enclosure Stack	15.00	Diesel 125 Lit/Day	1.0	SO ₂	17.28 Kg/Day
2	Boiler	Stack Dust Collector	23.00	Coal 500 Kg/Hr	0.5	SO ₂	120.0 Kg/Day
						TPM	150.0 Mg/Nm ³

Industry shall provide the necessary air pollution control system with adequate stack height as above.

2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance / CREP guidelines.
3. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
4. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).

SCHEDULE-III

Details of Bank Guarantees:

Sr. No.	Consent(C2E/C2O/C2R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	Consent to Establish	Rs.3.0 Lakh	15 days	Compliance of consent conditions	COU	COU+4 months

** The above Bank Guarantee(s) shall be submitted by the applicant in favour of Regional Officer at the respective Regional Office within 15 days of the date of issue of Consent.

Existing BG obtained for above purpose if any may be extended for period of validity as above.

BG Forfeiture History

Srno.	Consent (C2E/C2O/C2R)	Amount of BG imposed	Submission Period	Purpose of BG	Amount of BG Forfeiture	Reason of BG Forfeiture
NA						

BG Return details

Srno.	Consent (C2E/C2O/C2R)	BG imposed	Purpose of BG	Amount of BG Returned
NA				

SCHEDULE-IV

General Conditions:

- The waste generator shall.-
 - take steps to minimize generation of plastic waste and segregate plastic waste at source in accordance with the Plastic Waste Management Rules, 2016 or as amended from time to time.
 - not litter the plastic waste and ensure segregated storage of waste at source and handover segregated waste to 'urban local body or gram panchayat or agencies appointed by them or registered waste pickers', registered recyclers or waste collection agencies;
- All institutional generators of plastic waste, shall segregate and store the waste generated by them in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time and handover segregated wastes to authorized waste processing or disposal facilities or deposition centers either on its own or through the authorized waste collection agency.
- All waste generators shall pay such user fee or charge as may be specified in the byelaws of the local bodies for plastic waste management such as waste collection or operation of the facility thereof, etc.;
- Every person responsible for organizing an event in open space, which involves service of food stuff in plastic or multilayered packaging shall segregate and manage the waste generated during such events in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time.
- The Energy source for lighting purpose shall preferably be LED based
- The PP shall harvest rainwater from roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial applications within the plant

7. Conditions for D.G. Set
 - a) Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
 - b) Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.
 - c) Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
 - d) Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
 - e) A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use.
 - f) D.G. Set shall be operated only in case of power failure.
 - g) The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
 - h) The applicant shall comply with the notification of MoEFCC, India on Environment (Protection) second Amendment Rules vide GSR 371(E) dated 17.05.2002 and its amendments regarding noise limit for generator sets run with diesel.
8. The applicant shall maintain good housekeeping.
9. The non-hazardous solid waste arising in the factory premises, sweepings, etc. be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal of solid waste.
10. The applicant shall not change or alter the quantity, quality, the rate of discharge, temperature or the mode of the effluent/emissions or hazardous wastes or control equipments provided for without previous written permission of the Board. The industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
11. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding upon you.
12. The industry shall submit quarterly statement in respect of industries obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can be downloaded from MPCB official site).
13. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
14. The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification No. B-29016/20/90/PCI-L dated. 18.11.2009 as amended.
15. This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.
16. The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.
17. You shall operate OCEMS installed for source emission round 'O' clock and transmit data online to CPCB and MPCB server. You shall also monitor effluent quality, stack emissions and ambient air quality monthly/quarterly. You shall conduct Dioxin Furan monitoring by third party NABL Accredited agency once in year and submit report to Sub Regional Officer.
18. You shall ensure collection, and segregation of BMW regularly to treat and dispose Off within 48 hrs from generation.

19. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.
20. The applicant shall provide an alternate electric power source sufficient to operate all pollution control facilities installed to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms and conditions of this consent.
21. The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the Hazardous and Other Wastes (M & TM) Rules 2016, which can be recycled /processed /reused /recovered and only waste which has to be incinerated shall go to incineration and waste which can be used for land filling and cannot be recycled/reprocessed etc. should go for that purpose, in order to reduce load on incineration and landfill site/environment.
22. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
23. You shall not Rent, Lend, Sell, Transfer or Close Down the facility or otherwise transport the Bio Medical waste for any other purpose without obtaining prior written permission of the MPC Board.
24. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of the collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes/sewers downstream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
25. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
26. The industry should not cause any nuisance in surrounding area.
27. The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB (A) during day time and 70 dB (A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.
28. You shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the facility premises.
29. The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.
30. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or an extension or addition thereto
31. The applicant shall install a separate meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
32. The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end.
33. The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions.

34. The firm shall submit to this office, the 30th day of September every year, the Environment Statement Report for the financial year ending 31st March in the prescribed FORM-V as per the provisions of Rule 14 of the Environment (Protection) (second Amendment) Rules, 1992.
35. You should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly. You shall conduct Dioxin Furan monitoring by third party NABL Accredited agency once in every year and submit report to Sub Regional Officer.
36. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).
37. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous waste to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
38. You shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.
39. You shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act, 1981 and Environmental Protection Act, 1986 and industry specific standard under EP Rules 1986 which are available on MPCB website (www.mpcb.gov.in).
40. You shall create the Environmental Cell by appointing an Environmental Engineer and Chemist for looking after day-to-day activities related to compliance of CCA.
41. You should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 , Bio Medical Waste Management Rules,2016 and submit the Annual Returns as per Rule 6(5) & 20(2) of Hazardous and Other Wastes (M & TM) Rules, 2016 for the preceding year in Form-IV by 30th June of every year
42. You should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 , Bio Medical Waste Management Rules,2016 and submit the Annual Returns as per Rule 6(5) & 20(2) of Hazardous and Other Wastes (M & TM) Rules, 2016 for the preceding year in Form-IV by 30th June of every year

This certificate is digitally & electronically signed.
