

MAHARASHTRA POLLUTION CONTROL BOARD

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RED/L.S.I (R58)
No:- Format1.0/CAC/UAN
No.0000190997/CE/2403000249

Date: 03/03/2024

To,
Lupin Limited (Research Park)
46A/47A, Village- Nande,
Tal. - Mulshi, Dist. - Pune.



Sub: Consent to Establish for Expansion with BMW Authorization, under RED category.

- Ref:**
1. Earlier 1st Consent to Operate vide No:- Format1.0/CAC/UAN No.0000163246/CR/2306001504 dated 21.06.2023 valid up to 30.04.2028.
 2. Minutes of 21st CAC meeting dated 07.02.2024.

Your application No.MPCB-CONSENT-0000190997 Dated 18.12.2023

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.105.35 Crs. (As per undertaking submitted by pp Existing CI is-Rs. 105.35 Crs.)**
3. **Consent is valid for the manufacture of:**

Sr No	Product	Maximum Quantity	UOM
Products			
1	Installation of Plant & Machinery, Lab Equipment & Glassware, Fire-Fighting system, Computer Appliances & system, Furniture & Fixtures, Electrical & Eletronics Instrument etc at M/s. Lupin Ltd (Research Park)-Village-Nande,Tal.-Mulshi, Dist.-Pune site shifted from Sister concern of M/s. Lupin Ltd. (Biotechnology Testing & Analytical Facility) -Ganga Silicon Square, Wakad, Pune & part of the labs from M/s. Lupin Bioresearch center, 146/2/1B, Sai Trinity, Unit-1,2,3,4,5,6 (East wing), 6 (West wing), Pashan, Haveli Pune	0	--NA--

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	7	As per Schedule-I	Recycle 100% to achieve ZLD
2.	Domestic effluent	9	As per Schedule-I	Recycle 100% to achieve ZLD

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	NA	Existing stacks	0	As per Schedule -II

6. **Non-Hazardous Wastes:**

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	Canteen waste	3	MT/M	NA	For Piggeries/Cattle feed by vendor
2	Broken Glass, Aluminium foil, wooden scrap, Corrugated box, Thermocol, cable etc	60	MT/M	Sale	Sale to authorized recycler.

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	28.1 Process Residue and wastes	100	Kg/M	Recycle/ Coprocessing	Co-process shall be routed thorough pre-processing at CHWTSDF
2	28.4 Off specification products	400	Kg/M	Recycle/ Coprocessing	Co-process shall be routed thorough pre-processing at CHWTSDF
3	33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	100	Kg/M	Recycle/ Coprocessing	Co-process shall be routed thorough pre-processing at CHWTSDF
4	28.6 Spent organic solvents	550	Ltr/M	Recycle/Incineration	Send to authorized reprocerser / CHWTSDF.

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
5	Lab Chemicals (Pyrophoric)	1	MT/M	Incineration/ Coprocessing	Co-process shall be routed thorough pre-processing at CHWTSDf, MWML, Talioja
6	Lab Chemicals (Non-pyrophoric)	1	MT/M	Incineration/ Coprocessing	Co-process shall be routed thorough pre-processing at CHWTSDf, MEPL, Ranjagaon

8. Treatment and Disposal of Biomedical Waste generated to CBMWTSDF:

Sr.No	Category	Type of Waste	Quantity not to exceed (Kg/M)	Segregation Color coding	Treatment & Disposal
1	Yellow	a) Soiled Waste	1.00	Yellow colored non-chlorinated plastic bags or containers	CBMWTF / (f) Chemical Liquid Waste will be Disinfected followed by treatment in ETP.
		b) Expired or Discarded Medicines	1.00		
		c) Chemical Waste	100.00		
		d) Chemical Liquid Waste	78000.00		
		e) Microbiology Biotechnology and other clinical laboratory waste	500.00		
2	Red	Contaminated waste (Recyclable)	800.00	Red colored non-chlorinated plastic bags or containers	CBMWTF
3	White (Translucent)	Waste sharps including Metals	30.00	Puncture proof, Leak proof, tamper proof container	CBMWTF

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. This consent is issued pursuant to the decision of the 21st Consent Appraisal Committee Meeting held on 07/02/2024.
12. Industry shall install online continuous monitoring system as per CPCB guidelines & data to be transmitted directly from Data Logger to Board server .

13. The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/Activity. (Establish)
14. Industry shall submit Bank Guarantee of Rs. 25 lakh towards compliance of consent conditions.
15. The consent issued for grant of Combined Consent to Establish & Authorization under BMW Rule for Installation of Plant & Machinery, Lab Equipment & Glassware, Fire-Fighting system, Computer Appliances & system, Furniture & Fixtures, Electrical & Electronics Instrument etc at M/s. Lupin Ltd (Research Park)-Village-Nande, Tal.-Mulshi, Dist.-Pune site shifted from Sister concern of M/s. Lupin Ltd. (Biotechnology Testing & Analytical Facility) –Ganga Silicon Square, Wakad, Pune & part of the labs from M/s. Lupin Bioresearch center, 146/2/1B, Sai Trinity, Unit-1,2,3,4,5,6 (East wing), 6 (West wing), Pashan, Haveli Pune-411021

Received Consent fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	210700.00	MPCB-DR-23270	02/01/2024	RTGS
2	2500.00	TXN2401001010	05/01/2024	Online Payment

Copy to:

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

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 550.00 CMD consisting of Primary (Neutralization tank, Equalization tank, Flash mixer, Primary Clarifier/Primary Settling Tank), Secondary (Activated sludge process), Advanced treatment (Reverse osmosis, Multi effective evaporator) for the treatment of 7 CMD of trade effluent.
B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent and recycle the entire treated effluent into the process for various purposes such as for cooling, process & Scrubbing with metering system so as to achieve Zero Liquid Discharge. There shall be no discharge on land or outside factory premises.
C] The Industry shall ensure connectivity online monitoring system to the MPCB server including separate energy meter for pollution control system.
D] The treated effluent shall be recycled for secondary purposes to the maximum extent and remaining shall be discharged on land for gardening within premise after confirming above standards. In no case, effluent shall find its way for gardening / outside factory premises.
2. A] As per your application, primary treated sewage connected to Effluent Treatment Plant for further treatment & disposal.
B] Industry shall comply prescribed standards & disposal path as prescribed at Sr. No. 1B of schedule I.
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	10.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	10.00
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:

Not Applicable

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	C to E (Exp.)	2500000	15 days	Towards compliance of consent conditions.	upto C to1stO	upto C to1stO

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:

1. The Energy source for lighting purpose shall preferably be LED based
2. 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
3. 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.
4. The applicant shall maintain good housekeeping.
 5. 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.
 6. 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.
 7. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding upon you.
 8. 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 downloaded from MPCB official site).
 9. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
 10. 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.
 11. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
 12. 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.
 13. 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.
 14. You shall ensure collection, and segregation of BMW regularly to treat and dispose Off within 48 hrs from generation.
 15. 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.
 16. 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.
 17. 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.
 18. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.

19. 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.
20. 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.
21. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
22. The industry should not cause any nuisance in surrounding area.
23. 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.
24. 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.
25. 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.
26. 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
27. 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.
28. 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.
29. 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.
30. 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.
31. You should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.

32. 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).
33. 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.
34. 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.
35. 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).
36. 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.
37. 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.

