

MAHARASHTRA POLLUTION CONTROL BOARD REGIONAL OFFICE, PUNE

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"Your Service is Our Duty"

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Wakdevadi, Mumbai-Pune Road,
Pune - 411 003.

Red/S.S.I.

Consent order No: RO-PUNE/consent-2107000197 Date: 02/07/2021

To,
M/s. Lupin Healthcare Ltd (Lupin Diagnostics)
Varsha Court, Plot No 66, Survey No. 129
and 130/1+2, Anand Park, Aundh, Pune

Subject: Combined Consent to Establish and BMW Authorization under RED category to Health Care Establishment (HCE). Diagnostics Laboratory.

Your Application: MPCB- CONSENT- 0000113984 MPCB-BMW_AUTH- 0000034546

For: Combined Consent to Establish and BMW Authorization under Section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981, Authorization under Rule 5 of the Hazardous & Other Wastes (M & T M) Rules 2016 and Biomedical Waste Management Rules, 2016, as amended is considered and the consent is hereby granted subject to following terms and conditions and as detailed in the schedule I, II, III, IV & V annexed to this order:

1. The combined consent to Establish and BMW authorization is granted for a period Upto commissioning of the unit or five years whichever is earlier.
2. The actual capital investment of the Health Care Establishment is Rs. 164.00 Lakhs (As per undertaking certificate submitted by applicant)
3. The Combined Consent is valid for the Activity of -

Sr. No.	Activity	No of Samples
1	Diagnostics Lab (Non-Bedded)	30000 per Month

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

Sr. no.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	0.095	As per Schedule -I	Trade effluent shall be disinfected & drained to local body sewerage along with domestic effluent.
2.	Domestic effluent	2.40	As per Schedule -I	



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

Sr. No.	Description of stack/ source	Number Of Stack	Standards to be achieved
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6. Conditions under Hazardous & Other Wastes (M & T M) Rules, 2016 for treatment and disposal of hazardous waste:

Sr. No.	HW category	Type Of Waste	Quantity	UOM	Treatment	Disposal
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7. Non-Hazardous Solid Wastes:

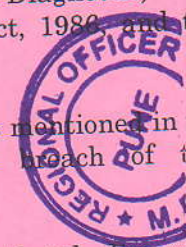
Sr. No.	Type Of Waste	Quantity	UOM	Treatment	Disposal
1	---	NA	Kg/M	--	NA

8. This Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the Diagnostic center.

9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government agencies.

10. This consent is issued subject to conditions mentioned below,

- i) The "authorized Person" of M/s. Lupin Healthcare Ltd(Lupin Diagnostic) shall comply with the provisions of the Environment (Protection) Act, 1986 and the Rules made there under.
- ii) Any unauthorized change in equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.
- iii) You shall submit details of Management and Handling of outdated, discarded, unused **Cytotoxic drugs** generated in the Cancer centers, research and health care in the format prescribed by CPCB which is available on www.cpcb.nic.in along with Annual Report to MPCB with a copy to CPCB before 31st January every year.
- iv) You shall manage the **Mercury Waste** in the HCE in environmentally sound manner (including storage, spilled collection, transportation and disposal) as per CPCB guidelines published on CPCB website www.cpcb.nic.in dated 07.09.2010 as detailed in document entitled "Environmentally Sound Management of Mercury Waste in Health Care Facilities".
- v) You shall ensure phase out of chlorinated plastic bags, glows and blood bags by HCEs within 02 years.
- vi) You shall establish Bar Code System within 01 year.



- vii) You shall insure that liquid waste is treated and disposed by all the occupier or operator of a CBWTF in accordance with the Water (P&CP) Act, 1974.
- viii) You shall maintain day to day basis and display the monthly record including Annual Report on its web site within 02 years from the date of publication of the Bio Medical Waste Management (Amendment), Rules, 2018.
- ix) You shall submit compliance of Bank guarantee conditions every six months to regional Officer, Pune for verification purpose.
- x) You shall apply for combine consent to operate & BMW Authorization before actual commissioning of the unit.

For and on behalf of the
Maharashtra Pollution Control Board

Nitin Shinde
(Nitin Shinde)
I/c Regional Officer, Pune

Received Consent/ Authorization fee of -

Sr. No.	Amount (Rs.)	Transaction No/DR.No.	Date
1.	15000.00	MPCB-DR-5993	17.05.2021
2.	2500.00	MPCB-DR-5994	17.05.2021

Copy to:

- 1) 1) Sub-Regional Officer, MPCB -P -I / P -II / P.C. / Satara / Solapur
- For Information & with instruction to Monitor the Necessary Compliance of the Condition stipulated in the Letter of Auhorization

Chief Accounts Officer, MPCB, Mumbai

Schedule-I
Terms & Conditions for compliance of Water Pollution Control

1) Trade Effluent :

A) The above should be replaced by:

"You shall provide wastewater disinfection system for disinfection of trade effluent. Trade effluent after disinfection and domestic sewage generated from the Diagnostic laboratory shall be discharged into the local body sewerage system."

- 2) 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.
- 3) The applicant 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.
- 4) 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 if applicable.

II) Conditions under Water (Prevention & Control of Pollution) CESS Act, 1977 as amended

The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 and as amended, by installing water meters, filing water cess returns in Form-I and other provisions as contained in the said act.

Sr. No.	Purpose for water consumed	Water Consumption quantity CMD
1.	Industrial Cooling, boiler feed etc.,	Nil
2.	Domestic purpose	3.0
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	0.095
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	Nil



Schedule-II
Terms & conditions for compliance of Air Pollution Control

1. As per your application, you have provided the Air pollution control (APC) system and also erected following stack (s) to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type Of Fuel	Qty.	UOM	S%	SO2 Kg/day
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2. The applicant shall operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Particulate matter	Not to exceed	NA
SO2	Not to exceed	NA

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).

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Maharashtra Pollution Control Board

Schedule-III

D) Terms & Conditions for compliance of Biomedical Waste Management

The "authorized Person" Administrator of M/s. Lupin Healthcare Ltd, (Lupin Diagnostic) shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.

1. The combined consent is granted for generation and disposal of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below:

Sr. No.	Category	Description	Quantity not to exceed (Kg/Month)	Segregation Colour coding	Treatment & Disposal
1	Yellow	Human Anatomical waste	150.0	Yellow	CBMWTDF
		Soiled Waste		Yellow	
		Expired or Discarded Medicines		Yellow	
		Clinical Laboratory waste		Yellow	
		Chemical Liquid waste	2865.0	Separate collection system disinfection & drain to local body sewerage.	After resource recovery, the chemicals liquid waste shall be pre-treated before mixing the other wastewater. The combine discharge shall confirm to discharge norms given in Schedule - III of BMW Rules.
		X-ray hypo solution (fixture)	120.0		
		Microbiology Biotechnology and other clinical laboratory waste			
2	Red	Solid Waste	120.0	Red.	Autoclaving followed by shredding CBMWTDF
4	Blue	Waste Sharps	90.0	Blue / white translucent	Disinfection (chemical treatment) autoclaving / mutilation / shredding to CBMWTDF

No onsite treatment of BMW is permitted. The above mentioned Bio medical Waste shall be sent to Common BMW Treatment & Disposal facility authorized by MPCB i.e. M/s. Passco Environmental Solutions Pvt. Ltd, Pune.

2. (i) BMW shall not be mixed with other wastes or reused or sold in any form.
- (ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-I prior to storage, treatment and disposal. The containers shall be labeled as specified in Schedule IV of BMW Management Rules, 2016.
- (iii) If a container containing BMW is to be transported from the premises where BMW is generated to any waste treatment facility outside the premises, the container shall, apart from the Label as provided in part 'A' of the Schedule IV along with

necessary information as specified in part 'B' prescribed of the Schedule IV and shall be transported by authorized Transporter only.

- (iv) The vehicles used for transportation of bio medical waste shall comply with the conditions if any stipulated by the Maharashtra Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the Rules made there under for transportation of such infectious waste.
 - (v) Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of 48 hours.
 - (vi) Necessary protective wear for the waste handlers shall be provided by the diagnostic center Authority.
 - (vii) Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilization to Log 6 or disinfection to Log 4, as per the World Health Organization guidelines before packing and sending to the common bio medical waste treatment facility.
 - (viii) You shall ensure proper collection of mercury spillage arising mainly due to breakage of thermometers pressure gauges (Sphygmomanometers) other equipments used in health care facilities (HCFs) as well as its storage in accordance with the Hazardous & Other wastes (Management & TM) Rules 2016 and returning it to the instrument manufacturers apart from necessary taking steps to ensure that the spilled mercury does not become a part of bio-medical or other solid wastes generated from the HCFs.
 - (ix) Authorized person shall obtain prior permission from MPCB for generation & disposal, if Bio-Medical waste quantity of category specified exceed the limits authorized at condition No. V. Above.
 - (x) Bar code & global positioning system shall be added by the Occupier and common bio medical waste treatment facility in one year time.
3. (i) You shall submit an Annual Report to the prescribed authority in Form-IV by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.
- (ii) You shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of BMW in accordance with these Rules and any guidelines issued.
- (iii) All records shall be subject to inspection and verification by the prescribed authority at any time.
4. When any accident occurs at any institution or facility or any other site where BMW is handled or during transportation of such waste, the authorized person shall report the accident in Form I to the prescribed authority forthwith.
 5. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.



Schedule-IV : Bank Guarantee (this will applicable when CTO will be issued)

Statement of conditions to be complied and Bank Guarantee imposed to ensure timely compliance to be observed by M/s. Lupin Healthcare Ltd .

Sr. No.	Activity / Condition to be Complied	Compliance Timeline (Months)	Bank Guarantee Amount
I (A)	Operation and Maintenance		
1	To Segregate and Handle BMW as per Rule	Continuous	10,000/-
I (B)	Records		
1	To Maintain records of BMW, generation, transportation, treatment & disposal and submission of Annual Report in Form -II before 31 st January every year.	Continuous	10,000/-
II	Performance		
1	To provide Separate BMW storage facility As per guidelines of CPCB.	Six	10,000/-

Note:

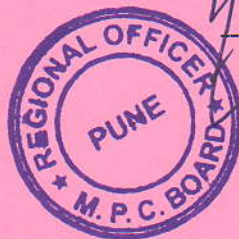
- (i) The above Bank Guarantees shall be submitted by the applicant at the Regional Office, M.P.C. Board, Pune within 15 days of the date of issue of Combined Consent and Authorization (CCA).
- (ii) The Bank Guarantee(s) shall be valid for for additional 4 months period after the validity of your granted Combined Consent and Authorization (CCA).



Schedule-V
General Conditions

- 1) 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.
- 2) The applicant should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 3) 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.
- 4) 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.
- 5) 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.
- 6) The firm shall submit to this office, the 30th day of September every year, the Environmental 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.
- 7) The Applicant shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the Hazardous & 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.
- 8) The Applicant should comply with the Hazardous & Other Wastes (M&TM) Rules 2016 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous & other Wastes (M & TM) Rules, 2016 for the preceding year April to March in Form-IV by 30th June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 10) **The applicant shall make an Combined Consent and Authorization (CCA) for renewal of the consent at least 120 days before the date of the expiry of the consent.**
- 11) Hospital shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act, 1981 and Environmental Protection Act, 1986 and Hospital specific standard under EP Rules 1986 which are available on MPCB website (www.mpcb.gov.in).
- 12) The Applicant shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent condition towards Environment Protection.
- 13) 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.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 15) 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.
- 16) 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) Applicant 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) Applicant 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 MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel.
- 17) The Applicant should not cause any nuisance in surrounding area.
 - 18) The Applicant 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 65 dB (A) during day time and 55 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.
 - 19) The applicant shall maintain good housekeeping.
 - 20) 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.
 - 21) 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.
- 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 Hospital will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 22) The Applicant shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
 - 23) The Applicant shall submit official e-mail address and any change will be duly informed to the MPCB.
 - 24) The Hospital shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.



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