

# MAHARASHTRA POLLUTION CONTROL BOARD

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Near Sion Circle, Sion (E)  
Mumbai - 400 022

Red/LSI

Consent No: Format 1.0/BO/PSO/HOD- 1810001705

Date: 29/10/2018.

To,  
Lupin Bioresearch Center  
Sai Trinity Unit 1,2,3,4,5,6 (East Wing)  
& 6 (West Wing), Survey No.146/2/1B,Pashan,  
Pune - 411021  
Email: [ravisekharkasibhatta@lupin.com](mailto:ravisekharkasibhatta@lupin.com)

**Sub : Combined Consent to Operate & BMW Authorization under RED Category to Health Care Establishment (HCE).**

**Ref :** 1. Your BMW Authorization & Consent application submitted to MPCB, HQ, Sion, Mumbai on 13/06/2018.  
2. Report submitted by SRO Pune-I  
3. Documents uploaded on webportal

## Combined Consent to Operate

under Section 25/26 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 Wastes (M, H & T M) Rules 2008 and Biomedical Waste Management Rules 2016 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 conditional combined consent to operate is granted for a period from 04.06.2018 to 04.06.2021
2. The capital investment of the HCE is Rs.99.08 Crore.  
(As per C. A. Certificate submitted)

3. The Consent is valid for the Activity of -

| Sr. No. | Activity               | Beds              |
|---------|------------------------|-------------------|
| 1       | Hospital               |                   |
|         | a) Beds                | 58 Nos.           |
|         | b) Total Plot Area     | 7100.00 sq. mtrs. |
|         | c) Total Built up Area | 5126.04 sq. mtrs  |

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 | 5.0                                   | As per Schedule -I       | Provide storage tank for effluent for 20 CMD and to be transported by |

M/s. Lupin Bioresearch Centre, Pune



|    |                   |      |                    |  |
|----|-------------------|------|--------------------|--|
|    |                   |      |                    | transporter authorized by MPCB for treatment at M/s. Lupin Limited (Research Park) at 46A/47A, village-Nande, Tal. Mulshi, Dist. Pune as per terms of Consent issued vide Format 1.0/BO/CAC-Cell/EIC No.PN-27554-15/15 <sup>th</sup> CAC-6343, dt-13.05.2016 |
| 2. | Domestic effluent | 11.0 | As per Schedule -I | PMC drainage   |

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

| Sr. no. | Description of stack / source | Number of Stack | Standards to be achieved |
|---------|-------------------------------|-----------------|--------------------------|
| 1.      | D.G. Set (320.0 KVA )         | 1 No.           | As per Schedule - II     |

6. Non-Hazardous Solid Wastes:

| Sr. No. | Type of Waste   | Quantity      | Treatment | Disposal   |
|---------|---|---------------|-----------|--|
| 1       | Canteen Waste   | As per Actual | N.A.      | Piggeries  |
| 2       | wooden, Aluminum foil, Corrugated box, Thermocol, MS metal scrap                    | As per Actual | N.A.      | Sale to authorized Recycler  |
| 3       | Broken glass, Plastic Paper, Poly Bags, Plastic Waste, gloves & Empty glass bottles | As per Actual | N.A.      | Sale to authorized Recycler after disinfection and decontamination |

7. Hazardous Solid Wastes:

| Sr. No. | Type of Waste & Cat.No.       | Quantity | Treatment | Disposal                                 |
|---------|-------------------------------|----------|-----------|--|
| 1       | Spent Organic Solvents - 28.5 | 400 Kg/M | N.A.      | Sale to authorized Reprocessors/ CHWTSDF |

8. This Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government agencies.
9. This consent is issued subject to conditions mentioned below,
- The "authorized Person" M/s. Lupin Bioresearch Center, Pashan, Pune shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
  - Any unauthorized change in equipment or working conditions as mentioned in the

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- iii) If the built up area exceeds more than 20,000 sq. mtrs. and if the hospital is commissioned after 14.09.2006, the project proponent shall comply EIA Notification 14.09.2006 by obtaining Environment Clearance.
- iv) 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](http://www.cpcb.nic.in) alongwith Annual Report to MPCB with a copy to CPCB before 31<sup>st</sup> 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](http://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, gloves and blood bags by HCEs within two years;
- (vi) You shall establish Bar code system within one year.
- (vii) You shall ensure that the liquid waste is treated and disposed by all the occupier or operator of a CBWTF in accordance with the Water Act, 1974;
- (viii) You shall maintain day to day basis and display the monthly record including Annual report on its website within two years from the date of notification.
- (ix) As per the report of SRO- Pune-I Bank Guarantee of Rs. 25,000/- is eligible for release for provision of separate BMW storage facility as per earlier BG condition.
- (x) You shall submit separate Bank Guarantee of Rs. 75,000/- towards compliance of condition mentioned at Annexure – IV to Regional Office, Pune within 30 days.
- (xi) You shall submit compliance of Bank Guarantee conditions every six months to Regional Officer, Pune for verification purpose.
- (xii) You shall submit application for renewal of Combined Consent and Biomedical Waste authorization before 120 days along with appropriate fees.

**For and on behalf of the  
Maharashtra Pollution Control Board**



(Dr. A.R. Supate)  
Principal Scientific Officer

Received Consent / Authorization fee of –

| Sr. No. | Amount (₹) | Dr no.  | Date       |
|---------|------------|---------|------------|
| 1       | 375000.00  | 7606496 | 26.03.2018 |
| 2       | 50000.00   | 7606704 | 05.04.2018 |
| 3       | 50000.00   | 7616121 | 19.10.2018 |

Copy to:

Regional Officer – MPCB , Pune and Sub –Regional Officer – Pune-I, MPCB – They are directed to ensure the compliance of the CCA conditions.

M/s. Lupin Bioresearch Centre, Pune



### Schedule-I

#### I) Terms & Conditions for compliance of Water Pollution Control

- 1) A] For Trade Effluent disposal you shall provide storage tank for effluent for 20 CMD and to be transported by transporter authorized by MPCB for treatment at M/s. Lupin Limited (Research Park) at 46A/47A, village- Nande, Tal. Mulshi, Dist. Pune as per terms of Consent issued vide Format 1.0/BO/CAC- Cell/EIC No.PN-27554-15/15<sup>th</sup> CAC-6343, dt-13.05.2016. For Domestic effluent you shall achieve general standard as notified under Environment (Protection) Act, 1986 and discharge into PMC drainage.

| Sr. No. | Parameters             | Discharge Standards applicable                         |
|---------|------------------------|--|
|         |                        | <b>Limiting Concentration in mg/l, except for pH</b>   |
| 01      | pH                     | 6.5-9.0  |
| 02      | Oil & Grease           | 10   |
| 03      | BOD (3 days 27°C )     | 30   |
| 05      | COD                    | 250  |
| 06      | Total Suspended Solids | 100  |
| 08      | Bio-Assay test         | 90 % survival of fish after 96 hours in 100 % effluent |

- 2) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waste water & the system for the disposal of effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps for expansion / modify or establish any modification to treatment and disposal system or an extension or addition thereto.
- 3) You 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) You shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time.

#### II) Water Consumption

| Sr. No. | Purpose for water consumed   | Water Consumption quantity CMD |
|---------|--|--------------------------------|
| 1.      | Industrial Cooling and boiler feed etc.,   | ---                            |
| 2.      | Domestic purpose   | 12.0                           |
| 3.      | Processing whereby water gets polluted & pollutants are easily biodegradable                   | 5.0                            |
| 4.      | Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic | ---                            |
| 5       | Other such as agriculture, gardening, etc.   | ---                            |



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## Schedule-II

### Terms & conditions for compliance of Air Pollution Control

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

| Sr. No. | Stack Attached to    | Height in meter | Type of Fuel | Quantity lit/hr |
|---------|----------------------|-----------------|--------------|-----------------|
| 1       | D.G. Set (320.0 KVA) | 5.0             | Diesel       | 92.5            |

2. The applicant shall provide stack height of 5.0 mtrs 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 | 150 mg/Nm <sup>3</sup> |
|--------------------|---------------|------------------------|

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).
5. Conditions for D.G. Set
- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
  - 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.
  - 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.
  - Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
  - 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.
  - D.G. Set shall be operated only in case of power failure.
  - The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
  - The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel.

### Schedule-III

#### Treatment and Disposal of Biomedical Waste generated from Hospital to CBMWTSDF

The authorisation is granted for generation and disposal of Bio-Medical Waste (BMW) to CBMWTSDF in waste categories and quantities listed here in below :

| Sr. No. | Category            | Type of Waste   | Quantity not to exceed (Kg/M) | Segregation Colour coding  | Treatment & Disposal  |
|---------|---------------------|---|-------------------------------|--|---|
| 1       | Yellow              | a) Human Anatomical waste   | --                            | Yellow coloured non- chlorinated plastic bags                              | 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 Solution, CBMWTSDF, Pune. |
|         |                     | b) Animal Anatomical Waste  | --                            |  |   |
|         |                     | c) Soiled Waste   | 1500.0                        |  |   |
|         |                     | d) Expired or Discarded Medicines   | 5.0                           |  |   |
|         |                     | e) Chemical Waste   | --                            | Separate collection system leading to effluent treatment system            |   |
|         |                     | f) Chemical Liquid Waste  | --                            |  |   |
|         |                     | g) Discarded linen, mattresses, beddings contaminated with blood or body fluid. | --                            | Yellow coloured non- chlorinated plastic bags or suitable packing material |   |
|         |                     | h) Microbiology Biotechnology and other clinical laboratory waste               | --                            | Autoclave safe plastic bags or containers                                  |   |
| 2       | Red                 | Contaminated waste (Recyclable)   | 1500.0                        | Red coloured non chlorinated plastic bags or containers                    |   |
| 3       | White (Translucent) | Waste sharps including Metals   | 120.0                         | Puncture proof, Leak proof, tamper proof container                         |   |
| 4       | Blue                | a) Glassware  | --                            | Cardboard boxes with Blue colored marking                                  |   |
|         |                     | b) Metallic body implants   | --                            |  |   |





**Schedule-IV : Bank Guarantees**

Statement of conditions to be complied and Bank Guarantee imposed to ensure timely compliance to be observed by M/s. Lupin Bioresearch Center, Pashan, Pune

| Sr. No.                           | Activity / Condition to be Complied  | Compliance Timeline (Months) | Bank Guarantee Amount |
|-----------------------------------|--|------------------------------|-----------------------|
| <b>I (A)</b>                      | <b>Operation and Maintenance</b>   |                              |                       |
| 1                                 | To Segregate and Handle BMW as per Rule  | Continuous                   | 25,000/-              |
| 2                                 | Operation and Maintenance of combined waste water treatment plant to achieve prescribed discharged standards | Continuous                   | 25,000/-              |
| <b>I (B)</b>                      | <b>Records</b>   |                              |                       |
| 1                                 | To Maintain records of BMW and submission of Annual Report in Form -II before 31 <sup>st</sup> January       | Continuous                   | 15,000/-              |
| 2                                 | To maintain records of BMW material delivered to CBMWTSDF  | Continuous                   | 10,000/-              |
|                                   |  | Total                        | 75,000/-              |
| Rupees Seventy Five Thousand only |  |                              |                       |

**Note : You shall submit the B.G. valid for additional 4 month period after the validity of your granted CCA.**



**Schedule-V**  
**General Conditions**

**The following general conditions shall apply as per the type of the industry**

- 1) You 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) You should monitor effluent quality, stack emissions, noise and ambient air quality quarterly.
- 3) You 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) You 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) You shall submit, the Environmental Statement Report for the financial year ending 31<sup>st</sup> March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992 to Regional Office, Pune, the 30<sup>th</sup> day of September every year.
- 7) You shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW (MH&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) You shall comply with the Hazardous Waste (M, H & TM) Rules, 2016 and submit the Annual Returns to RO- Pune as per Rule 5(6) & 22(2) of Hazardous Waste (M, H & TM) Rules, 2016 for the preceding year April to March in Form-IV by 30<sup>th</sup> June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the HCE.
- 10) 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](http://www.mpcb.gov.in)).
- 11) You shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent & authorization condition towards Environment Protection.

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- 12) 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.
- 13) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the HCE.
- 14) You 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.
- 15) You should not cause any nuisance in surrounding area.
- 16) You 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.
- 17) You shall maintain good housekeeping.
- 18) You shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement to Regional Office Pune by 30th September every year on available open plot area, number of trees surviving as on 31<sup>st</sup> March of the year and number of trees planted by September end.
- 19) 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.
- 20) You 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. You will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 21) You shall submit Six Monthly statement in respect of obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can be downloaded from MPCB official site).
- 22) You shall submit official e-mail address and any change will be duly informed to the MPCB, forthwith.
- 23) You shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended
- 24) You shall observe provisions of E-waste (Management and Handling) Rules 2011 and Battery Waste (Management and Handling) Rules 2001, as amended.

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