

# MAHARASHTRA POLLUTION CONTROL BOARD

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## LETTER OF BIO-MEDICAL WASTE AUTHORISATION

[Authorisation for Generation, Collection, Reception, Segregation & Storage of Bio-Medical Wastes under Rule 7(4)]

No. MPCB/PSO/BMW/ Pune - 84

Dated: 15-10-2013

- I. File number of authorisation and date of issue
- II. **Lupin Ltd.(Biotech Unit)** is hereby granted an authorisation for generation, storage, treatment and disposal of biomedical waste on the premises situated at Gate no. 1156, Ghotawade, Taluka- Mulshi, Dist:- Pune.(email: praveenhans@lupinpharma.com)
- III. This authorisation is renewed w.e.f. 01.04.2013 and shall remain valid for a period up to shall be in force for a period up to 31.03.2016. An application shall be made by the occupier/operator for renewal 3 Months before expiry of earlier authorisation.
- IV. This authorisation is issued subject to compliance of the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Environment (Protection) Act, 1986.
- V. No of Beds: NIL (**Biotech Unit**)

### Terms and Conditions of authorisation

1. The "authorized Person" General Manager- Manufacturing of Lupin Ltd. (Biotech Unit), Mulshi, Pune shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorized by the prescribed authority i.e. Member Secretary, MPCB.
3. Any unauthorized change in equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorisation.
4. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility.

No. MPCB/PSO/BMW/ Pune - 84 Dated: 15-10-2013



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

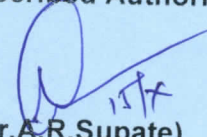
| Sr. No.  | Category | Description                        | Quantity not exceeding  | Segregation Colour coding | Treatment & Disposal                                      |
|--|----------|------------------------------------|-------------------------|---------------------------|---|
| 2  | Cat-3    | Microbiology & Biotechnology Waste | 600.0 Kg/M              | Yellow                    | Incineration  |
| 7  | Cat-8    | Liquid Waste                       | 630.0 m <sup>3</sup> /M | --                        | Disinfection by chemical treatment and discharge into ETP |
| No onsite treatment of BMW is permitted. The above mentioned Bio medical Waste shall be sent to Common BMW Treatment & Disposal facility authorised by MPCB i.e. M/s. Life Secure Enterprises, Talegaon. |          |                                    |                         |                           |   |

6. The liquid/solid waste generated from the treatment activity (from laboratory and washing, cleaning, housekeeping and disinfecting activities) shall be treated suitably by providing effluent treatment facility to conform the standards prescribed in Schedule V of said Rules and the Environment (Protection) Act, 1986.
7. (i) BMW shall be treated and disposed of in accordance with Schedule I; and in compliance with the standards prescribed in Schedule V of said Rules.  
(ii) You shall setup requisite BMW treatment facilities like incinerator, autoclave, shredder, etc., in accordance with the BMW rules. You shall disposed of the duly treated Plastic Wasteto authorized MPCB, recycler under Plastic Rules and incineration ash in secured land fill site at common H.W. treatment & disposal facility setup as per the Hazardous Waste (M & H) Rules, 1989 as amended and authorized by MPCB.
8. (i) BMW shall not be mixed with other wastes or reused, recycled or sold in any form.  
(ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-II prior to storage, treatment and disposal. The containers shall be labeled according to Schedule III.  
(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 prescribed in Schedule III, also carry information prescribed in Schedule IV and shall be transported by authorized Transporter only.  
(iv) Notwithstanding anything contained in the Motor Vehicles Act, 1988 or Rules there under, BMW shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.  
(v) No untreated BMW shall be kept stored beyond a period of 48 hours.  
(vi) Necessary protective gear for the waste handlers shall be provided by the firm authority.  
(vii) 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 waste (Management & Handling) Rules (presently these Rules has to be read as 'Hazardous Waste (Management & Handling and Transboundary Movement) Rules, 2008) 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.



9. (i) You shall submit an Annual Report to R.O.MPCB(HQ), Pune in Form-II 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 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.
10. 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 III to the prescribed authority forthwith.
11. This authorization is issued subject to condition as mentioned below,
- (i) To submit Bank Guarantee of Rs. 2.00 Lakhs towards compliance of condition mentioned at Annexure - A to Regional Office, Pune.
- (ii) You shall submit compliance of each Bank Guarantee conditions every six months to Regional Officer, Pune for verification purpose.
- (iii) You shall provide Annual report in Form -II duly certified by facility operator.
12. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

Sd/-  
**(Rajeev Kumar Mital)**  
**Member Secretary**  
**and**  
**Prescribed Authority**

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

To  
 Lupin Ltd.(Biotech unit)  
 Gate no. 1156, Ghotawade,  
 Taluka- Mulshi, Dist:- Pune  
 Authorization Fees Received:-

| Sr. No. | Amount | DD. No. | Date       | Drawn On |
|---------|--------|---------|------------|----------|
| 1       | 7600   | 704657  | 07.03.2013 | SBI      |

Copy to:-

1. Chief Accounts Officer, MPCB Board Mumbai – for information.
2. Regional Officer, MPCB, Pune- for information and necessary compliance of the condition mentioned in the authorization. He is also directed to ensure the timely compliance of condition No. 9, regarding Bank Guarantee and report to PSO.
3. Sub Regional Officer, MPCB , Pune -II – for information and n.a.

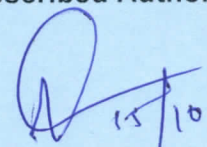


Annexure -A

Statement of conditions to be complied and Bank Guarantee imposed to ensure timely compliance to be observed by Lupin Limited (Biotech Unit), 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                   | 50,000                |
| 2                           | Operation and Maintenance of ETP to achieve prescribed discharged standards                               | Continuous                   | 50,000                |
| <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                   | 25,000                |
| 2                           | To maintain records of BMW material received /delivered to authorized party/ CBMWTSDF (Transporters only) | Continuous                   | 25,000                |
| <b>II</b>                   | <b>Performance</b>  |                              |                       |
| 1                           | To provide Separate BMW storage facility  | Six                          | 50,000                |
|                             |   | <b>Total,</b>                | <b>2,00,000/-</b>     |
| <b>Rupees Two Lakh only</b> |   |                              |                       |

Sd/-  
(Rajeev Kumar Mital)  
Member Secretary  
and  
Prescribed Authority

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