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LETTER OF BIO-MEDICAL WASTE AUTHORISATION

[Authorisation for Generation, Storage, Treatment & Disposal of Bio-Medical Wastes under Rule 7(4) of BMW (M & H) Rules 1998]

No. MPCB/PSO/BMW/ Pune - 79

Dated: 19.08.2013

- I. File number of authorisation and date of issue
- II. **Lupin Ltd.(Research Park)** is hereby granted an authorisation for generation, storage, treatment and disposal of biomedical waste on the premises situated at 46/47 A, Mulshi, Nande, 46/47 A, Nande Village, Tal:- Mulshi, Dist:- Pune.
- III. This authorisation shall be in force for a period up to 26.10.2014. 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 (Research Park)

Terms and Conditions of authorisation

1. The "authorized Person" Sr. Vice President of Lupin Ltd. (Research Park), 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.

*Recd
P. Reddy
19/08/2013*

No. MPCB/PSO/BMW/ Pune - 79 Dated: 19.08.2013

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 Kg/M	Segregation Colour coding	Treatment & Disposal
1	Cat-2	Animal waste	750.0	Yellow	Incineration
2	Cat-3	Microbiology & Biotechnology Waste	25.0	Yellow	Incineration
3	Cat-4	Waste Sharps	3.0	White / Blue Translucent	Disinfection by chemical treatment, autoclaving , shredding and handed over to MPCB authorized metal recyclers.
4	Cat-5	Discarded Medicines and Cytotoxic drugs	5.0	Yellow	Incineration
5	Cat-6	Soiled Waste	4.0	Yellow	Incineration
6	Cat-7	Solid Waste	2.0	Red	Disinfection by chemical treatment, autoclaving , shredding and handed over to MPCB authorized plastic recyclers.
7	Cat-8	Liquid Waste	3.0	Plastic Container	Disinfection by chemical treatment and discharge into ETP
8	Cat-9	Incineration Ash	As per Actual	Black	Send to CHWTSDF authorized by MPCB

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. **Standards for waste autoclaving:**
The autoclave should be dedicated for the purposes of disinfecting and treating bio- medical waste,
- (I) When operating a gravity flow autoclave, medical waste shall be Subjected to:
- (i) a temperature of not less than 121 C° and pressure of 15 pounds per Square inch (psi) for an autoclave residence time of not less than 60 minutes; or
- (ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes;
- or
- (iii) a temperature of not less than 149 C° and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
- (II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following.
- (i) a temperature of not less than 121 C° and a pressure of 15 psi for an autoclave residence time of not less than 45 minutes; or

(ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes; or

(III) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicates that the required temperature, pressure or residence time was not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(IV) *Recording of operational parameters*:- Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(V) *Validation test: Spore testing*. - The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Bacillus stearothermophilus* spores using vials or spore strips, with at least 1×10^4 spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121 C° or a pressure, less than 15 psi.

(VI) *Routine Test*.—A chemical indicator strip/tape that changes color when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved.

10. The liquid / solid waste generated from the treatment activity (from laboratory and washing, cleaning, housekeeping and disinfecting activities) shall be treated suitably to conform to the standards prescribed in Schedule V of said Rules and the Environment (Protection) Act, 1986.

10.1 Standards for LIQUID waste :

The effluent generated should conform to the following limits

PARAMETERS	PERMISSIBLE LIMITED
PH	6.5- 9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l.
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent

These limits are applicable to those hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

10.4 The Applicant shall erect the Chimney (s) of the following specifications

S.No	Chimney attached to	Height above roof level shall be
1	Power generating set	H + 2 KVA

10.5 The Applicant shall provide ports in the chimney 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 chimneys shall be numbered as S-1, S-2 etc and these shall be painted / displayed to facilitate identification.

10.6 Conditions for Power Generating Sets (Diesel):-

1. Noise from Power Generating Sets shall be controlled by providing acoustic enclosure or by treating the room acoustically.
 2. Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/acoustic treatment of the room shall 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 shall be done at different points at 0.5 meters from acoustic enclosure/room and then average.
 3. The Applicant should make efforts to bring down noise level to DG Set., outside the premises, with ambient noise requirements by proper siting and control measures.
 4. Installation of DG Set must be strictly in compliance recommendations of DG set manufacturer.
 5. A proper routine and preventive maintenance procedure for Set shall be set and followed in consultation with the manufacturers, which would help to prevent noise levels of Sets from deteriorating with use.
 6. The DG set shall be operated only in case of power failure applicant shall make arrangement for regular electrical power
 7. The Applicant shall not cause any nuisance in the surround area due to operation of DG sets
 8. In case of problems, the D.G. set shall not be operated un set back to satisfactory position.
11. (i) You shall submit an Annual Report to MPCB(HQ), MUMBAI 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.
12. 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.

13. This authorization is issued subject to special condition as mentioned below,
- (i) To submit Bank Guarantee of Rs. 5.50 Lakhs towards compliance of condition mentioned at Annexure – A valid upto 26.10.2014 to Regional Officer, Pune.
- (ii) As stated in letter dated 13.05.2013 industry during the revamping of existing incinerator (i.e. from August- 2013 to October- 2014) shall dispose of BMW generated through authorized BMW transporter at CBMWTSDF, Talegaon with advance information to RO, MPCB, Pune and shall maintain records accordingly.
- (iii) Transportation, Treatment and Disposal at common facility shall confirm the regulatory requirements, as applicable.
14. This authorization has an overriding effect over the earlier authorization grant by Board vide letter No. MPCB/JD(PAMS)/BMW/Pune-74, dated 11.02.2013
15. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

Sd/-
(V.M. Motghare)
Member Secretary
And
Prescribed Authority

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

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

Authorization Fees Received:-

Sr. No.	Amount	DD. No.	Date	Drawn On
1	25000	931674	18 Sep 2012	Citi Bank

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 (Research Park), Pune

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	50,000
2	To conduct and meet sterilization validation test and temperature test for Autoclave	Continuous	25,000
I (B)	Records		
1	To Maintain records of BMW and submission of Annual Report in Form -II before 31 st January	Continuous	25,000
2	To maintain records of BMW material received /delivered to authorized party/ CBMWTSDF (Transporters only)	Continuous	25,000
II	Performance		
1	To provide Separate BMW storage facility	Six	50,000
2	To Provide / revamp of existing incinerator	upto October - 2014	3,75,000/-
		Total,	5,50,000/-
Rupees Five Lakh Fifty Thousand only			

Sd/-
(V.M.Motghare)
Member Secretary
and
Prescribed Authority

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