

# MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 4010437/4020781  
/4037124/4035273  
Fax : 24044532/4024068 /4023516  
Email : enquiry@mpcb.gov.in  
Visit At : <http://mpcb.gov.in>



Kalpataru Point, 3rd & 4th floor, Sion- Matunga  
Scheme Road No. 8, Opp. Cine Planet Cinema, Near  
Sion Circle, Sion (E),  
Mumbai - 400 022

Consent order No :- Formate1.0/ BO/CAC-Cell/EIC No PN-23010-14/23rd CAC/ 1770

Date- ~~14~~ 13/02/2015

To,  
M/s Lupin Ltd (Biotech Division),  
Gat No 1156 & 1156/1, Village-Ghotawade,  
Tal-Mulshi, Dist-Pune  
Maharashtra-411042

Subject: Consent to establish for expansion under RED category.

Ref : 1. Existing Consent granted vide no. Formate1.0/BO/AST/PN-174857-13/9th/CAC/7326 dtd 30.08.2013

2. Your application approved in CAC meeting held on 21.01.2015.

Your application: CE1410000137

Dated:26.09.2014

For: Consent to establish for expansion

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 5 of the Hazardous Wastes (M, H & T M) Rules 2008 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 is granted for a period up to: Commissioning of the unit or 5 years whichever is earlier.
2. The proposed capital investment of the industry is Rs.21.50 Crs. (As per Undertaking submitted by industry). The total capital investment of the industry is Rs 106.53 crs. (Existing = Rs 85.03 Crs + Proposed = Rs 21.50 Crs).
3. The Consent is valid for the manufacture of -

| Sr. No. | Product Name                     | Maximum Quantity |
|---------|----------------------------------|------------------|
|         | Formulation                      |                  |
| 1       | Pre Filled Syringe (upto 1.0 ml) | 750000 Nos/A     |
| 2       | Cartridge (3.0 ml)               | 500000 Nos/A     |
| 3       | (Vials (10.0 ml)                 | 500000 Nos/A     |

Industry has proposed to reduce the existing production of 1)Parathyroid Hormone (PTH) by 31.2 gms/A; 2)Interferon Alpha 2b (IFN) by 18.2 gms/A; 3)Rituximab by 4680 gms/A ; 4) Trastuzumab by 6300 gms/A and 5)Granulocyte Colony Stimulating factor ( GCSF) by 627.6 gm/A and proposed the above formulation products.

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 |
|---------|-------------------|---|-------------------|-------|--------------------------|----------|
|         |                   | Existing  | C to E (Proposed) | Total |                          |          |
| 1.      | Trade effluent    | 37 ( Including 7 CMD received from sister concern M/s Lupin Ltd, Wakad) | -1.7              | 35.3  | N.A                      | N.A      |
| 2.      | Domestic effluent | 9   | 1.25              | 10.25 | As per Schedule -I       | Recycle  |

The existing trade effluent of 37 CMD shall be reduced by 1.7 CMD after the proposed expansion. Therefore there will be reduction in total effluent (trade + domestic) reduction from 46 CMD to 45.55 CMD i.e 0.45 CMD after the proposed expansion.

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

There shall not be any increase in air emissions due to proposed expansion. Existing utilities shall be used.

6. Conditions about Non Hazardous Wastes:

| Sr. no. | Type Of Waste  | Quantity & UoM | Treatment | Disposal                   |
|---------|--|----------------|-----------|----------------------------|
| 1       | Solid Waste(Nonhazardous like Head caps, foot wear, gloves, Garments, Thermocol corrugated boxes , Boiler soot etc.) | 50.0-Kg/day    | --        | Sold to authorized parties |

7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

There shall not be any increase in Hazardous Wastes due to proposed expansion.

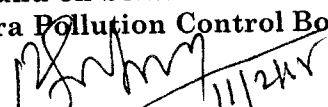
8. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.

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

10. Industry shall comply para 6 of RRZ notification, 2009 and submit BG of Rs 5 lakhs for the compliance of the same.

11. The consent is granted on the basis of no increase in pollution load certificate issued by ICT, Mumbai dated 21.11.2014.

For and on behalf of the  
Maharashtra Pollution Control Board

  
(Dr. P. Anbalagan, IAS)  
Member Secretary

Received Consent fee of -

| Sr. No. | Amount(Rs.) | DD. No. | Date       | Drawn On |
|---------|-------------|---------|------------|----------|
| 1       | 50100       | 569502  | 25.09.2014 | SBI Bank |

Copy to:

1. Regional Officer -Pune and Sub-Regional Officer-Pune -2 MPCB, They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. CC/CAC desk- for record & website updation purposes.



Maharashtra Pollution Control Board

**Schedule-I**

**Terms & conditions for compliance of Water Pollution Control:**

- 1) A] As per your consent application, the domestic effluent after septic tank shall be treated along with trade effluent in ETP of capacity 50 CMD followed by RO and MEE system.  
  
B] The treated effluent shall be recycled 100 % to achieve zero discharge. In no case, the treated effluent shall be used on land for gardening/outside factory premises.
- 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/and extension or addition thereto.
- 3) 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.
- 4) 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, spraying in mine pits or boiler feed                                       | 6.2                              |
| 2.      | Domestic purpose   | 1.25                             |
| 3.      | Processing whereby water gets polluted & pollutants are easily biodegradable                   | -4.55 *                          |
| 4.      | Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic | 0                                |

\*The existing water consumption for "Processing whereby water gets polluted & pollutants are easily biodegradable" shall be reduced by 4.55 CMD after proposed expansion.

- 5) 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 is not applicable**

**Schedule-III  
Details of Bank Guarantees**

| Sr. No. | Consent (C to E/O/R) | Amt of BG Imposed | Submission Period                                | Purpose of BG  | Compliance Period | Validity Date |
|---------|----------------------|-------------------|--|--|-------------------|---------------|
| 1       | C to E               | Rs 5 lakhs        | Within 15 days from the date of issue of consent | Industry shall comply para 6 of RRZ notification, 2009 | 30.12.2019        | 30.04.2020    |

*MR*

Maharashtra Pollution Control Board

## Schedule-IV

### 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) Industry 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 30<sup>th</sup> day of September every year, 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.
- 7) The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW(MH&TM) Rules 2008, 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 industry should comply with the Hazardous Waste (M,H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Waste (M,H & TM) Rules, 2008 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 applicant.
- 10) **The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/ Activity.**
- 11) Industry 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)).
- 12) The industry should comply with the Hazardous Waste (M, H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Wastes (M,H &TM) Rules, 2008 for the preceding year April to March in Form-IV by 30<sup>th</sup> June of every year.
- 13) The industry shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent condition towards Environment Protection.
- 14) 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