

MAHARASHTRA POLLUTION CONTROL BOARD

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Consent order No :- Formate 1.0 BO/AST/ PN-174857-13/9th/CAC/ **7326**
Date-30.08.2013

To,
M/s. Lupin Limited (BioTech Unit)
Gat No. 1156,1156/1, village Ghotawade,
Taluka Mulshi, Dist. Pune,
State - Maharashtra.

Subject: Amendment to Consent to operate under RED category.

Reference : 1. Earlier Consent granted vide no. BO/PAMS/R/EIC NO.PN-10022-11/CC-198 dtd. 07.02.2012
2. Minutes of CAC meeting held on 05.08.2013

Your application

Dated: 30.03.2013

For: Renewal of consent along with expansion & change in product mix under Section 26 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 from 01.05.2013 to 30.04.2016
2. The actual capital investment of the industry is Rs. 85.03 Crs. (As per C.A. Certificate submitted by industry)
3. The Consent is valid for the manufacture of -

| Sr. No. | Product/By-Product Name | Maximum Quantity in gms/A |
|---------|--|---------------------------|
| 1 | Granulocyte Colony Stimulating Factor (GCSF) | 6276 |
| 2 | Parathyroid Hormone (PTH) | 312 |
| 3 | Interferon Alpha 2b (IFN) | 182 |
| 4 | Tumor Necrosis Factor Receptor (TNFR - Etanercept) | 10200 |
| 5 | Rituximab | 46800 |
| 6 | Trastuzumab | 63000 |
| | R & D Products such as : | |
| | (a) Ranibizumab | 1000 |
| | (b) Bevacizumab | |
| | (c) Adalimumab | |

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 | 37.0 (Including 7 CMD received from sister concern M/s. Lupin Ltd., Wakad) | As per Schedule -I | Recycle |
| 2. | Domestic effluent | 9.0 | As per Schedule -I | Recycle |

SRO Punell/I/R/L/30037000

[Signature]

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. | Boiler | 2 | As per Schedule -II |
| 2. | DG set | 3 | As per Schedule -II |

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

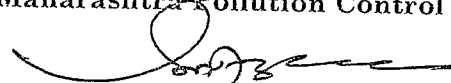
| Sr. No. | Type Of Waste | Category | Quantity | UOM | Treatment | Disposal |
|---------|---|----------|---------------------|-----------------------|-----------|--|
| 1 | Used Oil | 5.1 | 12 | Kg/Day | In House | Sale to Authorized party/CHWTSDF |
| 2 | Waste Oil | 5.2 | 1.0 | Kg/Day | In House | Sale to Authorized party/CHWTSDF |
| 3 | Date Expired discarded & off specification products | 28.3 | As & when generated | - | In House | CHWTSDF |
| 4 | Spent solvents | 20.2 | 900 | Kg/day | In House | Sale to Authorized party /CHWTSDF |
| 5 | Discarded containers/liners glass bottles | 33.3 | As & when generated | - | In House | Sale to Authorized party after decontamination / CHWTSDF |
| 6 | ETP Sludge | 34.3 | 78 | Kg/day | In House | CHWTSDF |
| 7 | RO reject solids from Evaporator | 34.3 | 78 | Kg/day (On dry basis) | In House | CHWTSDF |

7. 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. The consent is granted as per S. No. 6 in the Govt. order dated 13th July 2009 of RRZ policy for existing industries who have been granted MPCB consent are allowed modernization, expansion and or change in product mix provided there is reduction in pollution load.

For and on behalf of the
Maharashtra Pollution Control Board



(V. M. Motghare)
Member Secretary

Received Consent fee of -

| Sr. No. | Amount (Rs.) | DD. No. | Date | Drawn On |
|---------|--------------|---------|------------|-----------|
| 1. | 4,50,100/- | 010449 | 30.03.2013 | Citi Bank |

Copy to:

1. Regional Officer – MPCB, Pune and Sub-Regional Officer- Pune -II, 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.

Revolution Control Board

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

- 1) A] As per your application, you have provided the Effluent Treatment Plant (ETP) with the design capacity of 50 CMD.
B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve Zero Liquid Effluent discharge by using RO and MEE system and maintain the same continuously.
C] The treated effluent should be 100 % recycled/reused completely. In no case the treated effluent should be used on land for gardening/outside factory premises.
- 2) A] The domestic effluent (9 CMD) after septic tank shall be treated along with trade effluent.
B] The treated sewage shall be soaked in a soak pit, which shall be got cleaned periodically.
C] In case the treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at sr. no.1 B & C of schedule I shall be applicable.
- 3) 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 and extension or addition thereto.
- 4) 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.
- 3) 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 | 23.0 |
| 2. | Domestic purpose | 10.0 |
| 3. | Processing whereby water gets polluted & pollutants are easily biodegradable | 28.0 |
| 4. | Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic | 00.0 |

- 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.

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 proposed to erect / erected following stack (s) and to observe the following fuel pattern-

| Sr. No. | Stack Attached To | Height in Mtrs. | Type of Fuel | Quantity & DoM | S % | SO ₂ Kg/Day |
|---------|-------------------------|-----------------|--------------|----------------|------|------------------------|
| 1 | Boiler -1 (2.5 TPH) | 30 mtrs. | F.O | 100 Lit/Hr. | 4.5 | 216 |
| 2 | Boiler -2 (1.12 TPH) | (Combine stack) | | | | |
| 3 | D.G.Set -- 1 (1010 KVA) | 6.3 | HSD | 320 Lit/Hr. | 0.25 | 10.24 |
| 4 | D.G.Set -- 2 (285 KVA) | 3.3 | | | | |
| 5 | D.G.Set -- 3 (285 KVA) | 3.3 | | | | |

2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time.
3. 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 | 150 mg/Nm ³ |
|--------------------|---------------|------------------------|

4. 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.
5. 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).

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 |
|---------|----------------------|-------------------|-------------------|---------------|-------------------|---------------|
| N.A. | | | | | | |

Maharashtra Pollution Control Board

Schedule-IV

General Conditions:

- 1) The consent is granted as per S. No. 6 in the Govt. order dated 13th July 2009 of RRZ policy for existing industries who have been granted MPCB consent are allowed modernization, expansion and or change in product mix provided there is reduction in pollution load.
- 2) The proposed products are not covered in schedule of EIA notification dated 14th September 2006 and hence prior environmental clearance is not required. These products will be manufactured from yeast abstract using micro-organisms from Risk Group I and as per the notification Dated 20th September 2006 GSR 616(E) and the notification S.O. 1539(E) Dated 23rd August 2007, exemption under provisions (7 to 11) for permission from the expert authority is granted by MoEF.
- 3) 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.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) 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.
- 9) 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 30th June of every year.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- 12) 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).

- 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 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.
- 15) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 16) 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.
- 17) 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) 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.
 - c) 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.
 - 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
- 18) The industry should not cause any nuisance in surrounding area.
- 19) The industry 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.
- 20) The applicant shall maintain good housekeeping.
- 21) 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.
- 22) 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.
- 23) 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 industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.

- 24) The industry should monitor major stack emissions once a quarter and ambient air quality regularly.
- 25) The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises. Fugitive emission survey shall be done twice in a year (one for monitoring and other for checking after repair of leaks)
- 26) The industry shall submit quarterly statement in respect of industries obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can downloaded from MPCB official site).
- 27) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 28) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.

Madhya Pradesh Pollution Control Board