

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

Red/L.S.I

Date: 07/02/2012

Consent No: BO/PAMS/R/EIC NO.PN-10022 -11/CC-198

Consent to Operate 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 / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

M/s Lupin Limited (BioTech Unit)
Gat No. 1156, Pirangut, Ghotwade,
Tal- Mulashi, Dist-Pune, Maharashtra

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to: 30/04/2013
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
Risk Group Classification : GROUP-II			
1	Granulocyte Colony Stimulating factor(GCSF)	5500.00	Gms/A
2	Parathyroid Hormone(TPH)	2750.00	Gms/A
3	Interleukin-2	2750.00	Gms/A
4	Interleukin-11	2750.00	Gms/A
5	R & D Products such as :		
	(A) Interfercn alpha 2b (IFN)		
	(B) Reteplase (tPA)		
	(C) Interleukin-1 receptor antagonist(IL-1 RA)		
	(D) GMCSF-Granulocyte macrophage colony stimulating factor		
	(E)Diproyl peptidase IV and VIII (DPPP)		
	(F) Platelet derived growth factor (PDGF)		
	(G) Epidermal Growth Factor (EGF)		
	(H) Human Growth Hormone (HGH)		
	(I) Enterokinase (EK)		
	Risk Group Classification : GROUP-II		
	(J) Tumor Necrosis Factor receptor (TNFR)		
	(K) Rituximab		
	(L) Trastuzumab		
	Total production quantity for the products at Sr. No 5 (A to L) above is 1000.00		Gms/A

3. CONDITIONS UNDER WATER ACT:

Handwritten signature

- (i) The daily quantity of trade effluent from the factory shall not exceed **30.00 M³**.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed **9.0 M³**.
(**Sewage effluent should be treated in ETP and recycled completely**)
- (iii) **Trade Effluent :**
Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment followed by R.O. & Multiple effect Evaporator so as to achieve ZERO discharge and maintain the same continuously. In case of any failure of the system industry shall voluntarily close down the production activity
- (iv) **Trade Effluent Disposal:** The treated effluent should be recycled /reused completely. In no case the treated effluent should be used on land for gardening / irrigation purpose. The industry should achieve ZERO discharge.
- (v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.
- (1) Suspended Solids Not to exceed 100 mg/l.
(2) BOD 3 days 27o C. Not to exceed 100 mg/l.
- (vi) **Sewage Effluent Disposal:** The treated domestic effluent should be treated in ETP and achieve ZERO discharge.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	Head cap's foot wear, Gloves, garments	50.00	Kg/day	Sale

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under

The daily water consumption for the following categories is as under:

- (i) Domestic purpose ... 10.00 CMD
- (ii) Water gets Polluted & Pollutants are Biodegradable ... 28.00 CMD
- (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic ... 00.00 CMD
- (iv) Industrial Cooling, spraying in mine pits or boiler feed ... 17.00CMD
- (v) Plantation / Gardening ... 55.00 CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. CONDITIONS UNDER AIR ACT :

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

a. Control Equipment:

- I. Adequate fume extraction system followed by dust collector of sufficient capacity shall be provided to all dust generating locations and operated properly.
- II. There shall not be any secondary (fugitive) emissions.

b. Standards for Emissions of Air Pollutants:

- | | | |
|----------------------|---------------|--------------------------|
| (i) SPM/TPM | Not to exceed | 150.0 mg/Nm ³ |
| (ii) SO ₂ | Not to exceed | 216.0 Kg/day |

6. Standards for Stack Emissions:

- (i) **The applicant shall observe the following fuel pattern:-**

Sr. No.	Type Of Fuel	Quantity	UOM
01	Furnace Oil	2400.00	Lit/Day
02	HSD (For Boiler)	960.00	Lit/Day
03	HSD (for DG Set)	320.00	Lit/Hrs

- (ii) **The applicant shall erect the chimney(s) of the following specifications:-**

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler-1 (2.5 TPH)	30.0
2	Boiler -2 (400 Kg/Hr-Standby)	Common Stack 21.0
3	Boiler -2 (400 Kg/Hr-Standby)	
4	D.G. Set (1010 KVA)	6.3
5	D.G. Set (285 KVA- 2 Nos)	3.3

* installed above the roof of bldg

- (iii) 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.
- (iv) 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.

(vi) Other Conditions:

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality Regularly.

7. 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. The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- d. 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.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. 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
- g. D.G. Set shall be operated only in case of power failure
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.

8. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDRY MOVEMENT) RULES, 2008:

- (i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
01	5.1 Used Oil	12.00	Kg/Day	Sale to Authorized party
02	5.2 Waste Oil	1.00	Kg/day	
03	28.3 Date Expired, discarded & specification products	As & when generated	---	CHWTSDF
04	20.2 Spent Solvents	900.00	Kg/Day	Sale to Authorized party
05	33.3 Discarded containers /liner Glass bottles	As & when generated	--	Authorized party after decontamination.
06	34.3 ETP sludge	78.00	Kg/day	CHWTSDF
07	34.3 RO reject solids from Evaporator	78.00	Kg/day (on dry basis)	CHWTSDF

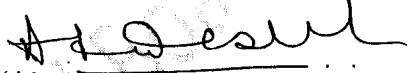
- (ii) Treatment: - NIL

9. Whenever due to any accident or gas leakage 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 Collector, Directorate of Industry, Safety and Health, Police Station, Fire Brigade, Directorate of Health Services, Department of Explosives, Board and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emission and ensure that the emissions do not cause any harm or nuisance in the surrounding. The industry should not restart the process without permission of the Board and other statutory organization as require under the law.

10. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste – 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 to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant 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 & conditions of this consent regarding pollution levels.
- v. The applicant shall not change or alter 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.
- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- vii. The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- viii. 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 pre the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- ix. As inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- ix. The applicant shall install a separate electric 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.
- Xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.

- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
11. This consent shall not be construed as any exemption from obtaining necessary No Objection Certificate from other Government agencies as may deemed fit necessary.
12. This consent is issued as per the decision taken in the meeting of the Consent Committee of the Board held on 19/01/2012 and approval of the Hon'ble Chairman of the Board.
13. The Capital investment of the industry is Rs 57.64 Crore
(Existing C.I. Rs 47.17 Cr + Increased CI Rs 10.47 Cr)


(Ajay A. Deshpande)
Joint Director (PAMS)

To,
M/s Lupin Limited (BioTech Unit)
Gat No. 1156, Pirangut, Ghotwade,
Tal- Mulashi, Dist-Pune, Maharashtra

Copy to :

RO, Raigad /SRO, Raigad II

-- They are directed to ensure the compliance of consent conditions.
CAO/Cess Branch/Master file.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	75100.00	380418	03 Mar 2011	CITI Bank
2	75000.00	380419	03 Mar 2011	CITI Bank
3	60000.00	748631	18 April 2011	CITI Bank
4	50000.00	114396	17 Nov 2011	CITI Bank