

MAHARASHATRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

RED/LSI

Consent No. BO/ZO-PAMS/EIC NO.TN-3281-11/Auto-Renewal/CC- **CAC-491**

Date: **12/07/2012**

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 Authorisation / Renewal of Authorisation 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,
T-142 M.I.D.C. Tarapur,
Sr. No.30/10, 30/11, 30/12, 30/13 & 64/7,
Via Boisar, Dist. Thane,

located in the area declared under the provisions of the Water Act, Air act and Authorisation 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 **-31.07.2013**.
2. The consent is valid for the manufacture of –

<u>Sr. No.</u>	<u>Product</u>	<u>Maximum Quantity</u> <u>(TPA)</u>
1.	Rifa S, Rifa O & Rifampcin	300.00
2.	Lovastatin	120.00
3.	Rifabutin	3.00
4.	Simvastatin	96.00
5.	Zolpidem tartarate	1.00
6.	Venlafaxin	3.00
7.	Sertraline	55.00
8.	Rifaximin	25.00
9.	Pentaprazole	1.00
10.	Pyrazinamide	225.00
11.	Levetiracetam	350.00
12.	Carvediol & Carvediol phosphate	1.00
13.	Ethambutol	5.00
14.	Risperidone	0.25
15.	Amlodipine Besilate	8.00
16.	Topiramate	6.00
17.	R & D batches	5.00
18.	Losartan pottasium	36.00
19.	Lamivudine	2.00
20.	Imipramine HCl	1.00
21.	Imipramine Palmoate	0.46
22.	Nabumetone	5.00
23.	Desloratidine	1.00

24	Fenofibrate / Choline Fenofibrate	30.00
25	Levofloxacin	30.00
26	Memantine	0.50
27	Clindamycin / Omeprazole	1.20
28	Ziprasidone	10.00
29	Valsartan	65.00
30	Quetiapine Fumarate	30.00
31	Sumatriptan Succinate	2.00
32	Irbesartan	25.00
33	Escitalopram Oxalate	6.00
TOTAL		1449.41

Total Production quantity shall not exceed 1449.75 TPA

Following by-products as a consequence of waste minimization efforts from spent solvent generated from Sertraline and recovery from effluent generated from AMP reaction of Rifampicin:

- Trans sertraline by product 500 kg/day.
- Piperazine diacetate by product 250 kg/day.

3. CONDITIONS UNDER WATER (PREVENTION & CONTROL OF POLLUTION) ACT, 1974:

- The daily quantity of trade effluent from the factory shall not exceed 1050.0 m³.
- The daily quantity of sewage effluent from the factory shall not exceed 95.0 m³.

(iii) Trade Effluent :

Treatment : The applicant shall provide comprehensive treatment system consisting of primary/secondary and/or tertiary treatment followed by Reverse Osmosis and Multiple Effect Evaporator as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards :

1	pH	Between	5.5 to 9.0
2	BOD 3 days 27 Deg. C.	Not to exceed	100 mg/l.
3	Oil & Grease	Not to exceed	10 mg/l
4	Suspended Solids	Not to exceed	100 mg/l.
5	COD	Not to exceed	250 mg/l.
6	TAN	Not to exceed	50 mg/l.
7	Sulphides	Not to exceed	2.0 mg/l
8	Phenolic Compounds	Not to exceed	1.0 mg/l.
9	Phosphates	Not to exceed	5.0 mg/l.

- Trade Effluent Disposal:** The treated effluent 400 CMD shall be recycled in the process and remaining 745 CMD shall be discharged into TEPS CETP (25MLD). In no case, the trade effluent shall find its way to local Nalla.

A register showing quantity of recycle of treated effluent in the process shall be maintained..

- Sewage Effluent Treatment and disposal:** The applicant shall mix the sewage effluent into the trade effluent and the same mixed effluent shall be treated in the comprehensive treatment system comprising of primary / secondary and /or tertiary treatment as mentioned above in condition no. 3(iii) and treated mixed effluent shall be disposed as mentioned above in condition no. 3(iv) so as to achieve the quality of treated effluent to the above standards.

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

S.No.	Type of waste	Quantity	Treatment	Disposal
1	Mycelia Waste	18.1 MT/day	Composting	Sale to Authorized Party
2	Bio-sludge (ETP)	5.82 MT/day	Composting	Sale to Authorized Party
3	Ash from Agro-waste Boiler	9.5 MT/day approx.	As manure/ brick manufacture	Sale to Authorized Party

(vii) **Other Conditions :**

1. The industry should monitor effluent quality regularly (quarterly).
 2. Industry shall comply with the guidelines issued by the Board for management and handling of Mycelium from Bulk drug industry.
 3. Industry shall adopt NADEP method of composting of Mycelium.
 4. Addition of water shall be made to maintain moisture content in the range of 50-60%, which helps in cooling the heap. A small addition of cowdung slurry helps as a seed for composting.
 5. Heaps of 1m breadth and suitable length shall be made for composting along with alternate layers of grass and fresh mycelia.
 6. Cowdung slurry shall be added for starting the composting process.
 7. Heaps shall be covered by jute bags and the moisture content shall be maintained between 50-60%.
 8. Holes shall be provided in the heap as well as turning of the heaps shall be done, which helps in aeration.
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 Rules there under. The daily water consumption for the following categories is as under:
- | | | | |
|-------|-----------------------|------|-----|
| (i) | Domestic | 120 | CMD |
| (ii) | Industrial Processing | 900 | CMD |
| (iii) | Industrial Cooling | 1100 | CMD |
| (iv) | Agriculture/Gardening | 150 | CMD |

The applicant shall regularly (quarterly) 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 (PREVENTION & CONTROL OF POLLUTION) ACT, 1981 :**

- (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 :**

1. Scrubbers of adequate capacity shall be provided to limit the process emissions .
2. Dust collector of adequate capacity shall be provided to limit the air emissions.

B) **Standards for Emissions of Air Pollutants :**

(i)	SPM/TPM	Not to exceed	150 mg/Nm ³ .
(ii)	SPM/TPM(Agro waste Boiler)	Not to exceed 500*	mg/Nm ³ .
(iii)	SO ₂	Not to exceed	4176 Kg/Day.
(iv)	SO ₂ (Process)	Not to exceed	50 ppm
(v)	HCl	Not to exceed	35 ppm
(vi)	Chlorine	Not to exceed	3 ppm

* As per CPCB General Standards (97/1) for Agro waste boiler- pulsating grate.

C) Emission Standards for VOC's (General) from process vents:

S. No.	Petrochemical Process / Compounds	Maximum Emission Limit (mg/Nm ³) dry basis
01	MA,PA, Phenol	20
02	Ethyl Benzene (EB), Styrene, Toluene, Xylene, Aromatics, EG, PG	100
03	Non-methane HC (paraffin), Acetone, Olefins	150

The industry should phase out the Ozone Depleting Substances (ODS) as per ODS Rules 2000 and should be informed to MPCB with in 3 months.

D) Conditions for D.G. set:

- Noise from the D.G.Set should be controlled by providing an acoustic enclosure or by the room acoustically.
- 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) should also be provided. The measurement of insertion will be done at three different points at 0.5 mtrs from acoustic enclosure/room and then average.
- The industry should take adequate measures for control of noise levels from its own sources at factory fence level in respect of noise to than 75dB (A) during day time & 70dB (A) during night time. Day time is reckoned between 6am to 10pm and night time is reckoned between 10pm to 6am.
- 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.
- Installation of DG Set much be strictly in compliance with recommendations of DG set manufacturer.
- 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.
- DG should be operated only in case of power failure or load shading.
- The applicant should not cause any nuisance in the surrounding area due to operation of D.G.Set

(ii) The applicant shall observe the following fuel pattern :

Sr. No.	Type of Fuel	Quantity
1.	Furnace Oil	45.03 MT/day
2.	HSD Only in emergency	6.23 TPD
3.	Agro Waste	1903 MT/Month

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

Sr. No.	Chimney attached to	Height in Mtrs.
1.	Boilers (12T/H & 10 T/H) 2 Nos.	57 (combined stack)
2.	Bolier	45
3.	Boiler Agro Waste (8 TPH)-2 Nos	30 (combine stack)
4.	Srubbers (19 Nos.)	
5.	Power G Set (2 x2.5MW)	48 each
6.	DG Sets (2x 2.5MW each)	30
7.	DG Sets (4x1.2.MW each)	6.9* each
8.	DG Sets (3x1.6.MW each)	8* each

*(above the height of the building where the DG set is installed).

- (iv) The applicant shall provide ports in the chimney(s) and facilitates 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.
- (v) The industry shall take adequate measures for control for 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. Daytime is reckoned in between 6 a.m. and 10 p.m. And nighttime is reckoned between 10 p.m. and 6 p.m.
- (vi) **Guidelines for Fugitive Emission Control:**
1. Fugitive emissions over reactors, formulations areas, centrifuges, chemical loading, transfer areas etc are yet to be collected through hoods & ducts by induced draft and controlled by-scrubber/dust collector.
 2. Usually scrubbers installed for channelized emissions are used for fugitive emissions to control also & sometimes dedicated scrubbers are provided. This practice may be permitted as long as tail gas concentrations are within prescribed limits.
 3. In addition, organic gaseous emissions (odour & toxic) be routed to activated carbon beds (adsorption) or to thermal oxidizer and for dust emissions cyclones/bag filters are to be provided.
 4. Emphasis to be given to solvent management/solvent loss prevention.
 5. Enclosures to chemical storage area, collection of emissions from loading of raw materials, in particulars, solvents through hoods and ducts by induced draft, and control by scrubber/dust collector or to be ensured.
 6. Vapor balancing, nitrogen blanketing ISO tanks etc. to be provided, besides special care needs to be taken for control in respect of odorous chemicals.
- (vii) 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.

6. **CONDITIONS UNDER HW (Management, Handling & Transboundary Movement) Rules 2008.**

- (i) The applicant shall handle hazardous wastes as specified below:

Sr. No.	Item No. of process generating H.W. As per Schedule-I	Types of Wastes	Quantity	Disposal
1.	20.3 / 36.4	Distillation Residue	2.4 MT/day	CHWTSDf/ (MWML) or to Authorized party
2.	28.2 / 35.3	Spent Carbon	0.51 MT/day	CHWTSDf/ (MWML) or to Authorized party
3.	5.1	Used / Spent Oil	0.025 MT/day	Sale to registered recycler or to CHWTSDf (MWML)
4.	5.2	Waste/Residue Containing Oil	0.02 MT/day	Sale of registered recycler or to CHWTSDf (MWML)
5.	28.1	Process Waste	3.7 MT/day	CHWTSDf (MWML)
6.	28.2	Spent Catalyst	0.367 MT/day	CHWTSDf (MWML) or to registered recycler
7.	28.3 / 28.4	Date Expired, discarded and off specification Products	As and when generated	To manufacturer for recycling or to CHWTSDf (MWML)
8.	20.2 / 28.5	Spent Solvent	370.42* MT/day	In house Distillation or CHWTSDf or sale to authorized party.

9.	33.3	Discarded containers / Barrels / Bags / Liners	As and when generated	Return to supplier after decontamination or sale to authorized party.
10.	33.1	Chemical containing residue from decontamination and disposal	As and when generated	CHWTSDf (MWML)
11.	---	Dried Solids from dryer (dry basis)	4.0	

*Quantity reduced by 4MT/day due to recovery of by-product Trans Setraline.

(ii) Treatment : ---

(iii) The authorization is hereby granted to operate a facility for collection, storage, transport and disposal of hazardous waste.

7. 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.

8. General Conditions :

1. The applicant shall-maintain good house keeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area/inhabitants.
2. 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.
3. 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.
4. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by the applicant to maintain compliance with the terms and conditions of abide by terms and conditions of this consent regarding pollution levels.
5. 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.
6. 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.
7. The applicant shall make an application for renewal of the consent at least 60 days before the date of expiry to the consent.
8. 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.
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 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.
11. 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 of 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.
12. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

13. 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.
9. The applicant shall comply with the conditions stipulated in Environmental Clearance granted by Government of Maharashtra, vide no EC (Lupin) – 2009/153/CR-167/TC. 1 dtd. 16/11/2010 and Environmental Clearance granted by Government of Maharashtra, vide no EC(Lupin)-2009/153/CR. 167/TC.1 dt. 04/01/2011.
10. If CETP does not operate efficiently and problem of pollution occurs, industry should voluntarily stop the production or total effluent should be reused.
11. Industry shall comply Corporate Responsibility for Environment Protection (CREP) Guidelines.
12. The consent is issued under scheme of auto renewal of consent based on self certification as per Board's OFFICE ORDER No. 6 OF 2012 vide letter No. MPCB/JD-PAMS/Autorenawal/B-654, dtd. 30.01.2012.
13. The industry shall carry out VOC monitoring on monthly basis.
14. This Board reserves the right to amend or add any conditions in this consent and the same shall be binding on the Applicant.
15. The capital investment of the industry is Total Rs.567.58/-Crs. (Existing Rs. 526.65/- Crs. + Rs. 40.93/-increased)

(Milind Mhaskar)
Member Secretary

M/s. Lupin Limited,
T-142 M.I.D.C. Tarapur,
Sr. No.30/10, 30/11, 30/12, 30/13 & 64/7, Via Boisar, Dist. Thane,

Copy to :

RO-Thane/SRO-Tarapur-I/CAO/Cess Branch/Master File

Received Consent fee of –

Amount	D.D.No.	Date	Drawn on
Rs. 1135160	991357	18.06.2012	State Bank of India
Rs. 81861	991356	18.06.2012	State Bank of India