MAHARASHATRA POLLUTION CONTROL BOARD Phone 4010437/4020781

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AHARASHTRA

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Red/L.S.I

Date:23/0//2013

Consent No:BO/JD-PAMS/TN-3874-12/E/CAC-795

Consent to Establish 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 / Renewal, of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Trans boundary 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 LTD,T-142, MIDC Tarapur, Sar. No. 30/10 30/11, 30/12, 30/13 & 64/7, Tal. Palghar, Dist. Thane,.

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 Establish is granted for a period up to: Commissioning of the Unit OR Five years whichever is earlier.
- 2. The Consent is valid for the manufacture of –

| Sr. No. | Product Name | Existing Product Qty. in MT/A as per consent Dt. 12.07.2012 | Addition / Deletion QTY. in MT/A | C. to E. for Proposed production Qty. MT/A |
|------------|-------------------------------|---|---|--|
| 1 | Rifa S, Rifa O & Rifampcin | | | |
| | | 300.00 | 0.00 | |
| 2 | Lovastatin | 120.00 | -76.00* | |
| 3 | Rifabutin | 3.00 | 0.00 | |
| 4 | Simvastatin | 96.00 | -46.00* | |
| 5 | Zolpidem tartarate | 1.00 | 0.00 | |
| 6 | Venlafaxin | 3.00 | -3.00 | |
| 7 | Sertralin | 55.00 | 0.00 | |
| 8 | Rifaximin | 25.00 | 8.00 | |
| 9 | Pentaprazole | 1.00 | 0.00 | 8 |
| 10 | Pyrazinamide | 225.00 | 25.00 | |
| 11 | Levitracitam | 350.00 | 10.00 | <u> </u> |

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| | Carvediol & Carvediol | 1 |] | 1 |
|---------|----------------------------------|---------|---------|-------|
| 12 | phospate | 1.00 | 0.00 | |
| 13 | Ethambutol | 5.00 | -0.50* | |
| 14 | Risperidone | 0.25 | 0.00 | |
| 15 | Amlodipine Besilate | 8.00 | 0.00 | |
| 16 | Azythromycin | 0.00 | 1.50 | 1.50 |
| 17 | Topiramate | 6.00 | -6.00 | |
| 18 | R& D batches | 5.00 | 0.00 | |
| 19 | Losartan pottasium | 36.00 | 14.00 | 14.00 |
| 20 | Lamivudine | 2.00 | 2.00 | 2.00 |
| 21 | Imipramine HCI | 1.00 | 0.50 | 0.50 |
| 22 | Imipramine Palmoate | 0.46 | 0.24 | 0.24 |
| 23 | Nabumetone | 5.00 | -5.00 | |
| 24 | Desloratidine | 1.00 | 0.00 | |
| | Fenofibrate / Choline | | | |
| 25 | Fenofabrate | 30.00 | 0.00 | |
| 26 | Omeprazole/Clindamycin | 1.20 | 0.30 | 0.30 |
| 27 | Levofloxacine | 30.00 | -20.00* | |
| 28 | Memantine | 0.50 | 0.00 | |
| 29 | Ziprasidone | 10.00 | -2.00* | |
| 30 | Valsartan | 65.00 | 15.00 | 15.00 |
| 31 | Quetiapine Fumarate | 30.00 | 15.00 | 15.00 |
| 32 | Sumatriptan Succinate | 2.00 | -1.50* | |
| 33 | Irbesartan | 25.00 | -5.00* | |
| 34 | Escitalopram Oxalate | 6.00 | -2.00* | |
| 35 | Abacavir | 0 | 4.70 | 4.7 |
| 36 | Efavirenz | 0 | 17.00 | 17 |
| 37 | Tenofavir | 0 | 8.00 | 8 |
| 38 | Emitricitabin | 0 | 10.00 | 10 |
| 39 | Ranolazine 🗙 🗹 | 0 | 35.00 | 35 |
| 40 | Gatifloxacine | 0 | 0.01 | 0.01 |
| 41 | Rabiprazole | 0 | 0.75 | 0.75 |
| * Thoma | Total | 1449.41 | · | |

* -There is addition / deletion of production quantity in existing consent granted by the Board vide letter dtd.12.07.2012.

[The industry should not exceed their existing consented total production quantity 1449.41 MT/A due to expansion activity.]

3. CONDITIONS UNDER WATER ACT:

(i) The daily quantity of trade effluent from the expansion activity shall be NIL.

(ii) The daily quantity of sewage effluent from the factory shall be NIL.

(iii) Trade Effluent : For existing industrial effluent-

Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment 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:

- (iv) Trade Effluent Disposal: NIL (from expansion activity.)
- (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 amound | | Ŭ |
| (-) | DOD 0 days 210 C. | Not to exceed | 100 | mg/l. |

(vi) Sewage Effluent Disposal: The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) Non-Hazardous Solid Wastes:

| Sr. No. | Type Waste | Quantity | UOM | Treatment | Disposal |
|---------|---------------|----------|-----|-----------|----------|
| | | NIL | | | |
| | | | | <u> </u> | |

(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: (As per existing consent)

| (i) Domestic purpose | 0.00 CMD |
|---------------------------------------|-----------|
| (ii) Water gets Polluted & | |
| Pollutants are Biodegradable | 00.00 CMD |
| (iii) Water gets Polluted, Pollutants | |
| are not Biodegradable & Toxic | 0.00 CMD |
| (iv) Industrial Cooling, spraying | |
| in mine pits or boiler feed | 00.00CMD |
| | |

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:

Industry shall provide air pollution control equipments of sufficient capacity to control the emissions.

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b. Standards for Stack Emissions:

The industry shall follow the norms of existing consent granted by the Board vide letter dtd.12.07.2012.

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

| | No. Type Of Fuel Quantity UOM |
|------------------|---|
| Th | NIL |
| 1 1 | ere is no addition in fuel consumption. |
| (ii) | The applicant shall erect the chimney(s) of the following specifications:- |
| | Sr. No. Chimney Attached To Heiseley M |
| | Sr. No. Chimney Attached To Height in Mtrs. NO ADDITIONAL CHIMNEY |
| (iii) | The applicant shall provide ports in the chimney/(s) and facilities such ladder, platform etc. for monitoring the air emissions and the same shall open for inspection to/and for use of the Board's Staff. The chimney(s) ven attached to various sources of emission shall be designated by numbe such as S-1, S-2, etc. and these shall be painted/ displayed to facilita 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 7 dB(A) during night time. Day time is reckoned in between 6 a.m. and 1 p.m. and night time is reckoned between 10 p.m. and 6 a.m. |
| (vi) | Other Conditions: |
| | The industry should not cause any nuisance in surrounding area. The industry should monitor stack emissions and ambient air quality Regularly. |
| | ITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & SBOUNDRY MOVEMENT) RULES, 2008: |
| (i) | The Industry shall handle hazardous wastes as specified below. |
| , , , | |
| Sr. | |
| Sr. | e industry shall not generate additional load of hazardous waste. |

7. 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.
- x. 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.

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xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

8. This is issued pursuant to decision of consent Appraisal committee meeting of the Board held on 08/01/2013.

- 9. The industry shall submit Bank Guarantee of Rs. 5/- Lakhs to Regional Office, Thane within 15 days towards the compliance of consent to establish conditions.
- 10. The industry shall not exceed their existing pollution load in terms of air, water and hazardous waste.
- 11. The industry shall recycle/reuse their treated industrial effluent to the maximum extent of 400 CMD.
- 12. The Capital investment of the industry is Rs. 526.65/-Crs (existing) and Rs 55.0/- Crs. (expansion).

(Rajeev Rumar Mital) Member Secretary

To, M/s. LUPIN LTD,T-142, MIDC Tarapur, Sar. No. 30/10 30/11, 30/12, 30/13 & 64/7, Tal. Palghar, Dist. Thane,.

Copy to: Regional Officer, MPCB, Thane/ Sub-Regional Officer, MPCB, Tarapurl- They are directed to obtain BG of Rs. 5/- Lakhs from the industry within 15 days to ensure the compliance of consent conditions.

3) Chief Accounts Officer, MPCB, Mumbai

Received Consent fee of -

| Sr. No. | Amount(Rs.) | DD. No. | Date | Drawn On |
|---------|-------------|---------|-------------|----------|
| 1 | 100100 | 993431 | 25 Oct 2012 | SBI Bank |
| · | S. | | | |