

MAHARASHTRA POLLUTION CONTROL BOARD

| | | |
|--|---|--|
| Tel: 24010437/24020781/24014701 |  | Kalpataru Point, 2 nd - 4 th Floor |
| Fax: 24024068 / 24023515 | | Opp. Cine Planet Cinema, |
| Website: http://mpcb.gov.in | | Near Sion Circle, Sion (E) |
| E-mail: pci2@mpcb.gov.in | | Mumbai-400 022. |

RED/LSI

Consent No. BO/JD PAMS/ RO Kalyan/EIC NO KN-4998-11/O/CC-186 Date: 04/01/2012

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 Authorization/Renewal of Authorization under Rule 5 of the Hazardous Waste (Management, Handling & Transboundary Movement) Rules 2008 and Amendment Rules, CONSENT is hereby granted to

M/s. Perrigo API India Pvt. Ltd.
N-39/39-1, MIDC Anand Nagar,
Ambarnath, Dist. Thane.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(MH & TM) 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: 30/09/2013.
2. The Consent is valid for the manufacture of -

| Sr. No. | Product | Maximum Quantity |
|---------|--------------------------|------------------|
| 1. | Pentoxifylline | 110 MT/ A |
| 2. | Fenofibrate | 45 MT/ A |
| 3. | Ammonium Lactate | 10 MT/ A |
| 4. | Cilostazol | 11 MT/A |
| 5. | Modafinil | 6 MT/A |
| 6. | Cetirizine Hydrochloride | 20 MT/A |
| 7. | Ompirazole Magnesium | 10 MT/A |

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **35.0 M³**.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed **4.0 M³**.

(iii) Trade Effluent:

Treatment: The applicant shall operate 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 :

| | | | |
|----|------------------------|---------------|------------|
| 1) | pH | Between | 6.5 to 8.5 |
| 2) | Suspended Solids | Not to exceed | 100 mg/l. |
| 3) | BOD 3 days 27 deg.0 | Not to exceed | 100 mg/l |
| 4) | COD | Not to exceed | 250 mg/l. |
| 5) | Oil & Grease | Not to exceed | 10 mg/l. |
| 6) | Total Dissolved Solids | Not to exceed | 2100 mg/l. |
| 7) | Sulphates | Not to exceed | 1000 mg/l. |
| 8) | Chlorides | Not to exceed | 600 mg/l. |
| 9) | T.A.N. | Not to exceed | 50 mg/l. |

- (iv) **Trade Effluent Disposal**: The treated trade effluent shall be 100% recycled in the process till CETP is commissioned at Ambarnath. In no case, trade effluent shall find its way outside factory premises.

(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 27°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 purpose within own premises.

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

--NA--

(viii) **Other conditions :** The industry shall monitor effluent quality regularly.

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:

| | |
|---|---------|
| Domestic | 5.0 CMD |
| Industrial processing generating Bio-Degradable waste water | 50 CMD |
| Industrial processing generating Non-Bio-Degradable waste water | Nil |
| Industrial Boiler/Cooling etc. | 35 CMD |
| Any other and gardening. | 10 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 which is also available on MPCB website at <http://mpcb.mah.nic.in/images/cessform1.pdf>.

5. CONDITIONS UNDER AIR ACT :

(i) The applicant shall operate 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:

- Scrubber of adequate capacity shall be provided to limit the process emissions.
- 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) | SO ₂ | Not to exceed | 270 | Kg/day |
| (iii) | HCl (process) | Not to exceed | 35 | mg/Nm ³ |

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

| Sr. No. | Type of Fuel | Quantity |
|---------|--------------|------------|
| 1 | Furnace Oil | 125 L/hr. |
| 2 | HSD | 104 Kg/hr. |

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

| Sr. No. | Type of Fuel | Height in meters |
|---------|------------------|------------------|
| 1 | Boiler | 36 |
| 2 | DG Set (82.5KVA) | 2.0* |
| 3 | DG Set (500 KVA) | 4.4* |

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

Conditions for D.G. Set :

1. Noise from D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
 2. 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 provide. The measurement of insertion loss will be done at different points at 0.5 metres from acoustic enclosure/room and the average.
 3. 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 75 dB (A) during day time and 70 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.
 4. Industry should make efforts to bring down noise level due to D.G. set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
 5. Installation of D.G. set must be strictly in compliance with recommendations of D.G. set manufacturer.
 6. A proper routine and preventive maintenance procedure for D.G. set should be set and followed in consultation with the D.G. manufacturer which would help to prevent noise levels of D.G. set from deteriorating with use.
 7. D.G. set shall be operated only in case of power failure.
 8. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. set.
- (iv) 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.
- (v) 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.

6. CONDITIONS UNDER HW (M,H &TM) RULES, 2008 :

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

| Sr. No. | Item No. of process generating HW as per Schedule-I | Type of Waste | Quantity | Disposal |
|---------|---|-------------------------|----------------|--|
| 1. | 5.1 | Used/Spent Oil | 16.7 Lit/Month | Sale to authorized recyclers or reprocessors |
| 2. | 28.1 | Residues/Wastes | 300Kg/M | CHWTSDF |
| 3. | 28.1 | Forced evaporated salts | | |
| 4. | 28.1 | Other mixed salts | | |
| 5. | 28.2 | Spent carbon | | |

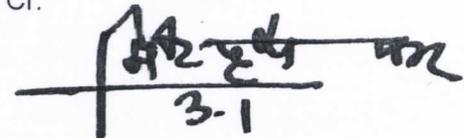
| | | | | |
|-----|------|---|---------------|--------------------------------|
| 6. | 28.2 | Off Specification Products | | |
| 7. | 28.4 | Spent Mother Liquor | | Sale to Authorized Reprocessor |
| 8. | 28.5 | Spent Organic Solvent | | Sale to Authorised Reprocessor |
| 9. | 28.5 | Distillation Bottoms | | Sale to Authorised Reprocessor |
| 10. | 33.3 | Discarded containers/barrels/liners contaminated with hazardous chemicals | 300 Nos/Month | Sale to authorized reprocessor |
| 11. | 34.3 | Chemical sludge from waste water treatment plant | 75kg/M | CHWTSDF |

7. Whenever due to any accident or release of gases 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 and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emissions 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 organizations as require under the law.

8. **General Conditions:**

- b. 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.
- c. 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.
- d. 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.
- e. 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 the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms and conditions of this consent regarding pollution levels.
- f. 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 equipment provided for without previous written permission of the Board.
- g. 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.
- h. The applicant shall make an application for renewal of the consent at least 60 days before the date of expiry to the consent.
- i. 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.

- j. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
 - k. 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.
 - l. 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 down stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
 - m. Neither storm water nor discharge from other premises shall be allowed to mix with effluents from the factory.
 - n. 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 industry shall comply with the conditions as stipulated in Environmental Clearance granted by MoEF, GOI vide no. F. No. J-11011/244/2005-IA II (I) Dated 29th May 2006.
 10. The consent granted has an overriding effect to the earlier consent granted by Board vide No. BO/ZO PAMS/RO KN/EIC No KN-4091-10/CC-11 Dated 28/01/2011.
 11. This consent is issued pursuant to the decision of Consent Committee meeting held on 04.11. 2011 of the Board.
 12. The consent is granted for the product mix changes proposed within the earlier consent production limit of 212 TPA, in the same product category, as per MoEF circular no. J-11013/41/2006-IA-II(I) Dt. 14th December, 2006.
 13. The capital investment of the industry is Rs. 53.41 Cr.


 3-1

(Milind Mhaiskar, IAS)
Member Secretary

To,
M/s. Perrigo API India Ltd.
N-39/39-1, MIDC Anand Nagar,
Ambernath, Dist. Thane.

Copy to: RO-Kalyan SRO-Kalyan-II :- They are directed to check & monitor the adequacy and performance of ETP within two months of issue of the consent.

Copy to: CAO/Cess Branch / Master File

Received Consent fee of –

| Amount (Rs.) | D.D. No. | Date | Drawn on |
|--------------|----------|------------|--|
| 1,50,100 | 214209 | 04/03/2011 | HSBC Bank |
| 50,000 | 630742 | 18/10/2011 | Hong Kong & Shanghai Banking corporation |