

# MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

Consent order No :- Formate 1.0/ BO/CAC-Cell/ EIC No PN-18096-13/14thCAC/907  
Date-25/10/2013

To,  
M/s. Cipla Limited.  
Plot No D-07, MIDC Kurkumbh,  
Tq. Daund, Dist. Pune

Subject: Consent to Operate RED category.

Ref : 1. Earlier Consent granted vide no. BO/ZOPAMS/RO-ABAD/EIC-PN6240-10/R/CC24 dated 10/02/2011.  
2. Minutes of CAC meeting held on 05.10.2013

Your application CR1306000079

Dated: 29/05/2013

For: Renewal of consent

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 01/09/2013 to 30/04/2014
2. The actual capital investment of the industry is Rs. 265.48 Crs. (As per C.A. Certificate).
3. The Consent is valid for the manufacture of

| Sr. No. | Product / By-Product Name       | Maximum Quantity in MT/A  |
|---------|---------------------------------|---|
| I       | Bulk Drug (API)                 |   |
| A       | Anti-inflammatory               | 1 Celecoxib<br>2 Fluticascode Propionate<br>3 Meloxicam<br>4 Beclomethasone Dipropionate<br>5 Menthosone Furate<br>6 Budesonide<br>7 Loteprednol Etabonate                      |
| B       | Anti-Retrovirals/Anti-Bacterial | 1 Famiciclover<br>2 Lamivudine<br>3 Ciprofloxacin Hydrochloride<br>4 Norfloxacin<br>5 Fluconazole   |
| C       | Anti-Diabetic                   | 1 Pigolitazone Hydrochloride<br>2 Nateglinide   |
| D       | Anti-Psychotic                  | 1 Citalopram Hydrochloride<br>2 Paroxetine Hydrochloride<br>3 Sertaline Hydrochloride<br>4 Olanzapine<br>5 Quetiapine Fumerate<br>6 Ziprasidone Hydrochloride<br>7 Aripiprazole |

|                |                           |   |                               |
|----------------|---------------------------|---|-------------------------------|
| E              | Cardiac                   | 1 | Carvedilol                    |
|                |                           | 2 | Losartan Potassium            |
|                |                           | 3 | Clopidogril Bisulphate        |
|                |                           | 4 | Ramipril                      |
| F              | Bronchodialator           | 1 | Salbutamol Sulphate           |
|                |                           | 2 | Formoterol Fumarate           |
| G              | Anti-Emetic               | 1 | Ondencetron Hydrochloride     |
| H              | Bone Resorption Inhibitor | 1 | Pamidronic Acid/Disodium      |
|                |                           | 2 | Alendronate Sodium Trihydrate |
| I              | Anti-Parkinsonian         | 1 | Pramipexole Dihydrochloride   |
| J              | Sedative                  | 1 | Zolpiderm Tartrate            |
|                |                           | 2 | Rizatriptan Benzoate          |
| K              | Anti-Obesity              | 1 | Sibutramine Hydrochloride     |
| Total Capacity |                           |   | 160 MT/Year                   |

2] Formulations: The total equivalent weight of the formulation products manufacturing shall not to exceed 325 MT/year

| Sr. No. | Product / By-Product Name                       | Maximum Quantity in MT/A               |
|---------|---|--|
| 1       | Tablets as approved by FDA                      | Total quantity: 2000 Million Nos./Year |
| 2       | Capsules as approved by FDA                     | Total quantity: 170 Million Nos./Year, |
| 3       | Soft Gelatin products as approved by FDA        | Total quantity: 21.2 Million Nos./Year |
| 4       | Suppositories and Oral Paste as approved by FDA | Total quantity: 12 Million Nos./Year,  |
| 5       | Sachets as approved by FDA                      | Total quantity: 85 lac Nos./Year       |

Industry shall manufacture 12 products at a time on a campaign basis.

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    | 330                                   | As per Schedule -I       | 100% Recycle |
| 2.      | Domestic effluent | 70                                    | As per Schedule -I       | 100% Recycle |

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 & Thermopack           | 03              | As per Schedule -II      |
| 2.      | Process Stacks                | 23              | As per Schedule -II      |
| 3.      | DG set                        | 05              | As per Schedule -II      |

6. Conditions about Non Hazardous Wastes:

| Sr. no. | Type Of Waste   | Quantity & UoM | Treatment | Disposal                 |
|---------|---|----------------|-----------|--------------------------|
| 1       | Plastic Scrap, Glass scrap, Wooden Scrap, Metal Scrap | 250 MT/Year    | Nil       | Sale to authorized party |

7. 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 /spent oil                                     | 5.1      | 400      | Lit/M                     | —         | Sale to authorized reprocessor |
| 2       | Discarded containers barrels / liners               | 33.3     | 400.00   | Nos./M                    | —         | sale to authorized party       |
| 3       | Chemical sludge from waste water treatment          | 34.3     | 1500     | Kg/m                      | —         | CHWTSDF                        |
| 4       | Sludge from wet scrubbers                           | 36.1     | 5000     | Kg/M                      | —         | CHWTSDF                        |
| 5       | Sludge from MEE system                              | 36.1     | 30       | MT/M                      | —         | CHWTSDF                        |
| 6       | Spent solvents                                      | 20.2     | 150      | KL/M                      | —         | Sale to authorized reprocessor |
| 7       | Spent catalyst / spent carbon                       | 28.2     | 500      | Kg/m                      | —         | CHWTSDF                        |
| 8       | Date-expired, discarded and off-specification drugs | 28.3     | 5000     | Kg/M                      | —         | CHWTSDF                        |
| 9       | Spent organic solvents                              | 28.5     | 5000     | Lit/M                     | —         | Sale to authorized reprocessor |
| 10      | Spent mother liquor                                 | 28.4     | 750      | m3/dilution with water/ M | In-house  | MEE                            |

8. 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.

For and on behalf of the  
Maharashtra Pollution Control Board

( Rajeev Kumar Mital, IAS )  
Member Secretary

**Received Consent fee of -**

| Sr. No. | Amount(Rs.) | DD. No. | Date       | Drawn On  |
|---------|-------------|---------|------------|-----------|
| 1       | 26,54,900/- | 001136  | 15-05-2013 | HDFC Bank |
| 2       | 1,00,000/-  | 000020  | 21-06-2013 | HDFC Bank |

The balance fees of Rs 23,00,826 will be considered at the time of next renewal by the Board.

**Copy to:**

1. **Regional Officer - Pune and Sub-Regional Officer- Pune-I, MPCB, Pune.**  
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.**

Maharashtra Pollution Control Board

### Schedule-I

#### Terms & conditions for compliance of Water Pollution Control:

1) A] As per your application, you have provided the Combined Effluent Treatment Plant (ETP) with the design capacity of 400 CMD.

B] The Applicant shall operate the combined effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

| Sr No. | Parameters             | Standards prescribed by Board (If any)        |
|--------|------------------------|---|
|        |                        | Limiting Concentration in mg/l, except for pH |
| 01     | pH                     | 5.5 to 9.0                                    |
| 02     | Oil & Grease           | 10  |
| 03     | BOD (3 days 27oC)      | 30  |
| 04     | Total Dissolved Solids | 2100  |
| 05     | Mercury                | 0.01  |
| 06     | Arsenic                | 0.20  |
| 07     | Chromium (Hexavalent)  | 0.10  |
| 08     | Lead                   | 0.10  |
| 09     | Cyanide                | 0.10  |
| 10     | Phenolics (C6H5OH)     | 1.0   |
| 11     | Sulphide (as S)        | 2.0   |
| 12     | Phosphate(as P)        | 5.0   |
| 13     | Suspended Solids       | 100   |
| 14     | COD                    | 250   |
| 15     | Chloride               | 600   |
| 16     | Sulphate               | 1000  |

C) The treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way outside factory premises. The low COD effluent after biological treatment followed by Reverse Osmosis shall be recycled for utility and High COD effluent shall be treated in Multiple Effect Evaporator (MEE) and VTFD to get solid concentrate. The Solids generated will be sent to CHWTSDF. The treated effluent shall not be used on land for gardening. Only fresh water shall be used for gardening purpose.

D] The domestic effluent, the overflow of septic tank will be mixed along with trade effluent for further treatment as the industry is having Biological treatment system for the treatment of trade effluent and the septic tank will be cleaned periodically and to meet the standards as mentioned above at 1 [B].

B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards/ prescribed under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

- (1) Suspended Solids. Not to exceed 100 mg/l.
- (2) BOD 3 days 27oC. Not to exceed 100 mg/l.

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.

- 2) 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 or/ and extension or addition thereto.
- 3) 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.
- 4) 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                                       | 200                              |
| 2.      | Domestic purpose   | 82                               |
| 3.      | Processing whereby water gets polluted & pollutants are easily biodegradable                   | 315                              |
| 4.      | Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic | Nil                              |
| 5.      | Other such Agriculture/ Gardening  | 200                              |

- 5) 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/ Environmental Clearance / CREP guidelines.

**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 erected following stack (s) and to observe the following fuel pattern-

| Sr. No. | Stack Attached To    | APC System   | Height in Mtrs.   | Type of Fuel | Quantity & UoM | S % | SO <sub>2</sub> Kg/Day |
|---------|----------------------|--------------|---|--------------|----------------|-----|------------------------|
| 1       | Process Stacks (23)  | Wet Scrubber | 2.5,2.5,10,5.25,11,14.5,12,11.3,11,2,3.5,2.2,2.2,11.5,11.5,2.2,2.5,10.5,10.5,10.5,15,2.5,4.5. | --           | --             | --  | --                     |
| 2       | Thermopack           | Stack        | 30  | Furnace Oil  | 5.0 KL/Month   | 4.5 | 0.75                   |
| 3       | Boiler (2 nos)       | Stack        | Common chimney of 30  | Furnace Oil  | 4.5 KL/Day     | 4.5 | 16.58                  |
| 4       | D.G.Set (3x1250 KVA) | Stack        | 7.5 each  | Diesel       | 24.0 KL/Month  | 1   | 0.02                   |
| 5       | D.G.Set (1500 KVA)   | Stack        | 14.71   | Diesel       |                |     |                        |
| 6       | D.G.Set (750 KVA)    | Stack        | 5.5   | Diesel       |                |     |                        |

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 / Environmental Clearance / CREP guidelines.
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 <sup>3</sup> . |
| SO <sub>2</sub> from process | Not to exceed | 50 ppm                   |
| HCL                          | Not to exceed | 35 mg/Nm <sup>3</sup>    |
| NH <sub>3</sub>              | Not to exceed | 50 ppm                   |
| NOx                          | Not to exceed | 50 ppm                   |
| Halogen                      | Not to exceed | 0.3 ppm                  |

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).

Industry name, consent no & date

**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 |
|---------|----------------------|-------------------|-------------------|-----------------------------------|-------------------|---------------|
| 1       | C TO R               | Rs 5 lakhs        | Within 15 days    | O & M of pollution control system | 30.04.2014        | 31.08.2014    |

Maharashtra Pollution Control Board



#### Schedule-IV

##### General Conditions:

- 1) 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.
- 2) If the MIDC pipeline is broken/ overflowing chamber, in such cases industry shall not discharge their treated effluent into MIDC drain, it shall be sent to CETP by tanker.
- 3) Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 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
- 9) /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.
- 10) 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 30<sup>th</sup> June of every year.
- 11) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 12) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent (in case of Renewal of consent).
- 13) 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](http://www.mpcb.gov.in)).
- 14) 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.
- 15) 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.
- 16) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

- 17) 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.
- 18) 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
- 19) The industry should not cause any nuisance in surrounding area.
- 20) 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.
- 21) The applicant shall maintain good housekeeping.
- 22) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a statement on available open plot area, number of trees surviving as on 31<sup>st</sup> March of the year and number of trees planted by September end, with the Environment Statement.
- 23) 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.
- 24) 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.
- 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.
- 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 be 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.

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