

# MAHARASHTRA POLLUTION CONTROL BOARD

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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: 01/4/2013

Consent No: BO/AST (T)/EIC.NO-RD-2515-13/R/CAC/02742

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

Cipla Ltd.  
Plot No-A-42, Khalapur  
MIDC Patalganga, Khalapur ,  
Dist-Raigad-410220  
Maharashtra, India

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: 31/04/2017.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	
1	Alfozosin Hydrochloride	<b>Total Production Quantity of all 59 products should not exceed 200 TPA</b>
2	Placitaxel/Docetaxel Trihydrate /Anhydrous	
3	Ropinirole HCl/Irinotecan Hydrochloride Trihydrate	
4	Rapaglinide/Desloratidine/Lecarnadipine	
5	Azelastin / Proparacaine HCl	
6	Miscellaneous Formulations	
7	Telmisartan/Irbesartan	
8	Guggelsterone /Gatifloxacin	
9	Stavudine /Zidovudine	
10	Glatiramer Acetate /Exemestane	
11	Brimonidine	
12	Nelfinavir / Moxifloxacin	
13	Dorzalomid Hydrochloride	
14	Efavirenz	
15	Imiquimod	
16	Valsartan/Azelastin/Abacavir	
17	Dutasteride	

18	Finasteride
19	Cetirizene Dihydrochloride
20	Tolteredine
21	Oxpentifyline/Piroxcam USP/Pefloxacin Mesylate
22	Ranitidine Hydrochloride/Base/Roxithromysin
23	Mirtazapine
24	Doxazosin Mesylate
25	Levo Salbutamol Sulphate
26	Perindropil Ebumine/Deferisivox
27	Ciprofloxacin HCL Monohydrate
28	Selegiline Hydrochloride/Brimonidine Tartarate
29	Ranolazine/ Ranolizine Dihydrochloride/ Levocetizine
30	Salmeterol Xinafoate
31	Ondansetron Hydrochloride Dihydrate
32	Valacyclovir Hydrochloride
33	Torsemide
34	Pregablin/Repiglinide
35	Dutasteride/Miratazapine/Rizatriptan Benzoate
36	Simvastatin
37	Tamsulusin Hydrochloride
38	Danazol
39	Terbutaline Sulphate/Terfenadine
40	Valgancyclovir/Varriconazole
41	Revastigmine
42	Bambuterol Hydrochloride/Trimetazidine Dihydrochloride
43	Artisunate/Artimether
44	Citalopram Hydrobromide
45	Levo Salbutamol Hydrochloride
46	Clarithromycin/Fluconazole/Praziquantel
47	Ciclesonide/Rimonabant
48	Sumatripton Succinate
49	Albuterol Sulphate
50	Escitalopram Oxalate
51	Olmesartan Medoxionil/ Limifantrine/Lamivudine
52	Leveteracetum
53	Adafovir
54	Bregnenolol/Troventol Hydrochloride
55	Saquinavir Mesylate/Tegasoride Maleate
56	Lorazepam
57	Terbutaline Sulphate
58	Terfenadine/ Atovaquone/ Zanamavin
59	Venlafaxin Hydrochloride

### 3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 140.00M3.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 20.00M3.

(iii) **Trade 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:

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	Bioassy Test	90% survival of fish after first 96 hrs in 100% effluent**	
8	Mercury	Not to exceed	0.01 mg/l.
9	Arsenic	Not to exceed	0.20 mg/l.
10	Chromium (Hexavalent)	Not to exceed	0.10 mg/l.
11	Lead	Not to exceed	0.10 mg/l.
12	Cyanide	Not to exceed	0.10 mg/l.
13	Phenolics (C6H5OH)	Not to exceed	1.0 mg/l.
14	Sulphide (as S)	Not to exceed	2.0 mg/l.
15	Phosphate(as P)	Not to exceed	5.0 mg/l.

(iv) **Trade Effluent Disposal:** The treated industrial effluent shall be segregated and reused back into process to maximum extent and remaining treated effluent shall be send to CETP for further treatment & disposal. There should not be any discharge of effluent 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 27o 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
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(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  | ... | 30.00 CMD  |
| (ii) Water gets Polluted & Pollutants are Biodegradable             | ... | 100.00 CMD |
| (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic | ... | 290.00 CMD |
| (iv) Industrial Cooling, spraying in mine pits or boiler feed       | ... | 0.00CMD    |

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 dust collector/Scrubber of sufficient capacity to control the emissions.

**Conditions for D.G. Set**

- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating 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) 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.
- 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.
- 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 must 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

- 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

**b. Standards for Emissions of Air Pollutants:**

- (i) SPM/TPM Not to exceed 150.0 mg/Nm<sup>3</sup>.  
(ii) SO<sub>2</sub> (for HSD as fuel) Not to exceed 60.0 kg/day.  
(iii) SO<sub>2</sub> (from process) Not to exceed 50.0 ppm.  
(iv) Acid Mist. Not to exceed 35.0 mg/Nm<sup>3</sup>

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	HSD	3000.00	Ltrs/day

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler-I	22.00
2	Boiler-II	22.00
3	D.G.Set (1000 KVA)	6.32
4	D.G.Set (1500 KVA)	7.75
5	D.G.Set (1500 KVA)	7.75
6	Scrubber	5.00
7	Scrubber	5.00
8	Scrubber	5.00

- (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.

**6. 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
1	5.1 Used /spent oil	4.00	MT/M	Sale to authorized party user / Preprocessor or shall be sent to CHWTSDF
2	28.1 Residues and wastes*	6.00	MT/M	CHWTSDF
3	28.2 Spent catalyst / spent carbon	6.00	MT/M	CHWTSDF
4	28.3 Date-expired, discarded and off-specification drugs	1.00	MT/M	CHWTSDF
5	28.4 Spent mother liquor	59.00	MT/M	Reuse / Recovered in your Plant/ CHWTSDF
6	28.5 Spent organic solvents	70.00	MT/M	Reuse / Recovered in your Plant/ CHWTSDF
7	34.4 Chemical sludge, oil and Grease skimming residues	24.00	MT/M	CHWTSDF

(ii) Treatment: - NIL

1. The authorization is hereby granted to operate a facility for collection, storage, transport & disposal of hazardous waste.
2. The industry should comply with the Hazardous Waste (M&H) Rules, 2003.
  - a. 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.
  - b. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.
  - c. It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Waste (Management & Handling) Rules, 1989 as amended on 2003 and shown & submitted to the Board as & when asked for.

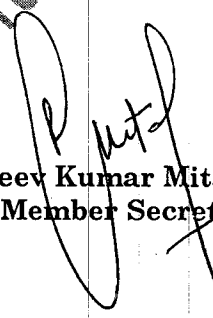
**7. Industry shall comply with following additional conditions:**

- 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 30<sup>th</sup> day of September every year, the Environmental Statement Report for the financial year ending 31<sup>st</sup> March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- ix. An 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.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

**8. If CETP does not work for achieving standards & problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.**

**9. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.**

10. The industry shall also comply with the Industry specific standards notified under Environment Protection Act.
11. This Board reserves the right to amend or add any conditions in this consent and the same shall be binding on the Applicant.
12. This Consent is issued pursuant to the decision of Consent Appraisal Committee meeting of 2013 held on 19/03/2013.
13. It was decided to grant renewal of consent on following conditions:-
  1. Industry shall submit Board Resolution towards increase in C.I. without prior permission of the MPC Board by 15/4.2013 and submit the Bank Guarantee of Rs. 2 Lakhs for compliance of this condition.
14. The Bank Guarantee of Rs. 2 Lakhs, valid upto consent period shall be submitted at Regional Office MPCB Raigad within 15 days period.
15. The Capital investment of the industry is Rs. 24400 lacs.

  
 (Rajeev Kumar Mital IAS)  
 Member Secretary

To,  
 Cipla Ltd.  
 Plot No-A-42, Khalapur,  
 MIDC Patalganga Khalapur,  
 Dist-Raigad-410220  
 Maharashtra, India

Copy for information to:-  
 Regional Officer MPCB Raigad.  
 Sub-Regional Officer MPCB, Raigad-I  
 Chief Account Officer MPCB Mumbai

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	100	046205	29 Nov 2012	Axis Bank
2	1222850	042696	04 Dec 2012	Axis Bank
3	1980500	042816	09 Jan 2013	Axis Bank