

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 4010437/4020781
/4037124/4035273
Fax : 24044532/4024068 /4023516
Email : enquiry@mpcb.gov.in
Visit At : <http://mpcb.gov.in>



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: 04/02/2013

Consent No: BO/JD-PAMS/NK-12418/R/CC-1911

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 & 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. Megafine Pharma (P) Ltd.
Gat No. 201, Lakhmapur, Tal. Dindori,
Dist. Nashik

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: **31.12.2017**.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity in MT/A
1	Disodium Pamoate	61.5
2	Paliperidone	0.5
3	Pyrantel Tartrate Zeolex	20
4	Iloperidone	0.4
5	Bosentan Monohydrate	1
6	Pyrantel Pamoate	40
7	Sildanefil Citrate Intermediate(SIL-II)	15
8	Mirtazapine	2
9	Darifenacine Hydrobromide	0.2
10	Ammonium Benzene Sulphonate	15
11	Quetiapine Hemifumarate	4
12	Thiophene-2 Aldehyde(T2A)	25
13	Ziprasidone hydrochloride	0.25
14	Erythromycine Oxime Base(EOB)	2
15	3-Methyl Thiophene -2 Aldehyde(3MT2A)	15
16	2 Acetyl Thiophene(2AT)	1.5
17	Oxantal Pamoate	4
18	CL-7	3
19	Donepezil hydrochloride	0.5

20	Venlafaxine Hydrochloride	5
21	DFTA	20
22	Pamoic Acid	20
23	Amlodipine Maleate	1
24	N-Acetyl Piperazine (NAP)	1.5
25	Vildagliptin	0.5
26	Des. Venlafaxine Succinate	1
27	Diene crystalised	2
28	Cinacalcet Hydrochloride	0.1
29	Solifenacin Succinate	0.1
30	Morantel Citrate	25
31	Memantine Hydrochloride	0.5
32	1,2-Dimethyl 1,4,5,6-Tetrahydropyrimidine(THP)	50
33	Asenapine Maleate	0.2
34	NBPCHO	0.55
35	Prasugrel Hydrochloride	0.15

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **18.40M³**.
(ii) The daily quantity of sewage effluent from the factory shall not exceed **12.0M³**.

(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:

01	pH	6.0-8.5
02	Oil & Grease	10
03	BOD (3 days 27 °C)	100
04	Total Dissolved Solids	2100
05	Bioassy Test	90% survival of fish after first 96 hrs in 100% effluent
II Additional Parameters		
06	Arsenic	0.20
07	Cyanide	0.10
08	Phenolics (C ₆ H ₅ OH)	1.0
09	Sulphide (as S)	2.0
10	Phosphate(as P)	5.0
11	Suspended Solids	100
12	COD	250
13	Chloride	600
14	Sulphate	1000

- (iv) **Trade Effluent Disposal:** : The treated effluent should be recycled/ reused to maximum extent using forced evaporation system and remaining should be disposed on land for gardening within own premises only. 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 Of Waste	Quantity	UOM	Disposal
1	MS Drums/fibre drums	60.00	No/M	Sale to autho. party
2	HDPE bags	250.00	No/M	Sale to autho. party
3	Boiler Ash	800.00	Kg/Day	Sale to brick mfg.

(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 | ... | 15.00 CMD |
| (ii) | Water gets Polluted & Pollutants are Biodegradable | ... | 15.90 CMD |
| (iii) | Water gets Polluted, Pollutants are not Biodegradable & Toxic | ... | 0.00 CMD |
| (iv) | Industrial Cooling, spraying in mine pits or boiler feed | ... | 7.00CMD |

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:**

- i. Air pollution control system of adequate capacity should be provided to limit emissions and also to any other sources of emissions.
- ii. Sufficient capacity of wet scrubber / bag filter shall be provided to limit the emission
- iii. There shall not be any fugitive (secondary) emissions.

b. **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. 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.
- d. 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.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. 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

c. Standards for Stack Emissions:

SPM/TPM	Not to exceed	150 mg/Nm ³ .
SO ₂	Not to exceed	223.952 kg/day
HCL/ Acid mist	Not to exceed	35 mg/Nm ³
Cl ₂	Not to exceed	3 ppm
Nox	Not to exceed	35 ppm
NH ₃	Not to exceed	50 ppm

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	Briquettes	8.00	MT/day
2	Diesel	70.00	Ltr/hr

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Briquette/coal fired boiler	30.50
2	Theric Fluid Heater	24.00
3	Boiler No. 1	24.00
4	Scrubber (acidic) (3Nos)	18.00
5	Scrubber (Alkaline)(4Nos)	18.00
6	DG Set-1-380 KVA	3.00 above the roof
7	DG Set-2- 500 KVA	8.00 above the roof

- (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	5.2 Wastes/residue containing oil	0.50	MT/A	sale to autho. recycler
2	20.3 Distillation residues	2.58	MT/A	CHWTSDF
3	28.2 Spent catalyst / spent carbon	4.90	MT/A	CHWTSDF
4	28.2 Spent catalyst / spent carbon	0.15	MT/A	CHWTSDF
5	33.3 Discarded containers barrels / liners	5400.00	Nos/A	sale to autho reconditioner
6	33.3 Discarded containers barrels / liners	144.00	Nos/A	CHWTSDF
7	28.5 Spent organic solvents	2220.80	MT/A	sale to autho. recycler
8	34.3 Chemical sludge from waste water treatment	237.94	MT/A	CHWTSDF
9	35.1 Filters and filter mater which have organic liquid	2490.00	MT/A	CHWTSDF
10	5.2 Wastes/residue contain oil	0.10	MT/A	CHWTSDF

(ii) Treatment: - NIL

- a. Whenever due to any accident or gas leakage 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 Collector, Directorate of Industry, Safety and Health, Police Station, Fire Brigade, Directorate of Health Services, Department of Explosives, Board and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emission 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 organization as require under the law.
- a. 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.
- b. 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 2008.

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.
- ix. 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.
- xii. 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.

- xiii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- xiv. The applicant shall obtain Consent to Operate before Commercial Commencement of the production activity.
8. The industry shall comply the CREP guidelines for bulk drug and pharmaceutical industry.
9. This consent is issued pursuant to decision of Consent Committee meeting held on 15.02.2013 and with the approval of Honorable Chairman of the Board.
10. The industry shall submit the Bank Guarantee of Rs. 5/- Lakhs towards not to exceeding the production quantity beyond the consented limit to Regional Office, Nashik within 15 days from date of issue of this consent order.
11. The Capital investment of the industry is Rs. 43.59/- Crs. (existing) + increased by Rs. 15.17/- Crs. Total CI is Rs.58.76/- Crs.


(Rajeev Kumar Mital)
Member Secretary

To,
M/s. Megafine Pharma (P) Ltd.
Gat No. 201, Lakhmapur, Tal. Dindori,
Dist. Nashik

Copy to:

1. RO/SRO Nashik : They are directed to obtain BG of Rs. 5.0/- Lacs from the industry and ensure the compliance of consent conditions.
2. Cess/ CAO.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	560100	213905	02 Oct 2012	SBI Bank