

MAHARASHTRA POLLUTION CONTROL BOARD

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Red/L.S.I EIC no. NK-8087-11

Date: 22/Dec /2011

Consent No: MPCBHQ/Nashik/AST/Operate(amend)/CC- 93

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 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 & TM) Rules respectively].

CONSENT is hereby granted to

Megafine Pharma (P) Ltd.
Gat No. 201, Lakhmapur, Tal. Dindori,
Dist. Nashik,
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:31/12/2012.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
1	Disodium Pamoate	61.5	MT/A
2	Ammonium Benzenesulphonate	15	MT/A
3	Quetiapine Hemifumarate	4	MT/A
4	Ziprasidone hydrochloride	0.25	MT/A
5	Solifenacin Succinate	0.1	MT/A
6	Pyrantel Pamoate	40	MT/A
7	Sildenafil Citrate Intermediate(SIL-II)	15	MT/A
8	Donepezil hydrochloride	0.5	MT/A
9	Diene crystallized	2	MT/A
10	Asenapine Maleate	0.2	MT/A
11	N- Acetyl Piperazine (NAP)	1.5	MT/A
12	NBPCHO	0.55	MT/A
13	DFTA	20	MT/A
14	Thiophene-2 Aldehyde (T2A)	25	MT/A
15	Amlodipine Maleate	1	MT/A

16	Memantine Hydrochloride	0.5	MT/A
17	3-Methyl Thiophene-2 Aldehyde (3MT2A)	15	MT/A
18	Desvenlafaxine Succinate	1	MT/A
19	Oxantal Pamoate	4	MT/A
20	Paliperidone	0.5	MT/A
21	Pyrantel Tartrate Zeolex	20	MT/A
22	Bosentan Monohydrate	1	MT/A
23	Pamoic Acid	20	MT/A
24	1,2-Dimethyl 1,4,5,6-Tetrahydropyrimidine (THP)	50	MT/A
25	Morantel Citrate	25	MT/A
26	Mirtazapine	2	MT/A
27	CL-7	3	MT/A
28	Venlafaxine Hydrochloride	5	MT/A
29	Erythromycine Oxime Base (EOB)	2	MT/A
30	2 Acetyl Thiophene (2AT)	1.5	MT/A
31	Vildagliptin	0.5	MT/A
32	Cinacalcet Hydrochloride	0.1	MT/A
33	Darifenacin Hydrobromide	0.2	MT/A
34	Prasugrel Hydrochloride	0.15	MT/A
35	Iioperidone	0.4	MT/A

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 **12.00M³**.

(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	5.5 to 9.0
2	Oil & Grease	Not to exceed	10 mg/l
3	Suspended Solids	Not to exceed	100 mg/l.
4	BOD 3 days 27 deg C	Not to exceed	100 mg/l.
5	COD	Not to exceed	250 mg/l.
6	T.D.S.	Not to exceed	2100 mg/l
7	Sulphates	Not to exceed	500 mg/l
8	Chlorides	Not to exceed	500 mg/l
9	% Sodium	Not to exceed	60 mg/l
10	Phenolic Compound	Not to exceed	5 mg/l

(iv) **Trade Effluent Disposal:** The treated effluent shall be recycled/ reused to the maximum extent using forced evaporation system and remaining shall be used on land for gardening in own 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 used on land for gardening / plantation only.

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

Sr. No.	Type Of Waste	Quantity	UOM	Treatme nt	Disposal
1	MS Drums/Fibre drums	60.00	No/M		Sale to authorized party
2	HDPE bags	250.00	No/M		Sale to authorized party
3	Boiler ash	800.00	Kg/Day		sale to brick manufacturer

(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	...	0.00 CMD
(iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic	...	15.90 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:**

- 1) Bag filter/ wet scrubber of adequate capacity should be provided to boiler and all other sources of TPM/SPM and operated and maintained properly so as to achieve prescribed standards.
- 2) Air pollution control equipments of sufficient capacity shall be provided to limit the emissions.

b. Standards for Emissions of Air Pollutants :

(i)	SPM/TPM	Not to exceed	150	mg/Nm ³
(ii)	SO ₂	Not to exceed	223.952	kg/day
(iii)	HCl/Acid mist (process)	Not to exceed	35	mg/Nm ³
(iv)	Cl ₂	Not to exceed	3	ppm
(v)	Nox	Not to exceed	35	ppm

6. 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
- D.G. Set shall be operated only in case of power failure
- The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set

7. Standards for Stack Emissions:

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	Bagasse /saw dust	8	MT/day
2	Diesel	150.00	Lit/hr
3	Furnace Oil	72.00	Kg/hr

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Briquete/coal fired boiler	30.50
2	Thermic fluid heater	24.00
3	Boiler	24.00
4	Scrubber(acidic) (3 Nos.)	18.00 each
5	Scrubber(Alkaline) (4 Nos.)	18.00 each
6	DG 1 (380 KVA)	3.00 *
7	DG 2 (500 KVA)	8.00*

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

- (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.

8. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDARY 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 authorised recycler
2	33.3 Discarded containers / barrels / liners	5400.00	Nos./A	sale to authorised recycler
3	33.3 Discarded containers / barrels / liners	144.00	Nos./A	CHWTSDF
4	34.3 Chemical sludge from waste water treatment	237.94	MT /A	CHWTSDF
5	35.1 Filters and filter material which have organic liquid	2490.00	Nos./A	CHWTSDF
6	5.2 Wastes/residue containing oil	0.10	MT /A	CHWTSDF
7	20.3 Distillation residues	2.58	MT /A	CHWTSDF
8	28.2 Spent catalyst / spent carbon	0.15	MT/A	CHWTSDF
9	28.2 Spent catalyst / spent carbon	4.90	MT/A	CHWTSDF
10	28.5 Spent organic solvents	2220.80	MT/A	sale to authorised recycler

- (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.

7. 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.
8. **General Conditions :**
- a. 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.
 - b. 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.
 - c. 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.
 - d. 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.
 - e. 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.
 - f. 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.
 - g. 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.
 - h. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
 - i. 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.
 - j. 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.
 - k. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
 - l. 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 applicant shall make an application for renewal of the consent at least 60 days before the date of expiry to the consent.**
10. The consent shall not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
11. This Board reserves the right to amend, revoke or add any conditions in this consent and same shall be binding on the applicant.

12. As per point no.6 of RRZ policy dtd. 13.07.2009, modernization, expansion, and/or change in product-mix is allowed subject to no increase in pollution load. Industry has submitted pollution load assessment certificate dated 02.07.2011 of ICT, Mumbai.
13. As per the para no.1 of MoEF circular dtd. 14.12.2006 (clarification regarding EIA clearance for change in product-mix), Changes in the quantities or numbers of products may be allowed without prior Environmental Clearance by the concerned State Pollution Control Board provided such changes in the quantities of products are in the same category and are within the previously granted overall total limits.
14. This consent is issued with an overriding effect to the previous consent issued by the Board vide no. BO/RO-Nashik/PCI-I/EICno.NK-943-07/Amend/CC-45 dated 29/10/2009.
15. This consent is issued pursuant to decision of Consent Committee Meeting held on 17.12.2011 of the Board.
16. Industry shall comply the CREP guidelines for bulk drug and pharmaceutical industry.
17. The total Capital Investment is ` 43.59/- crores.

For and on behalf of the
Maharashtra Pollution Control Board


(Milind Mhaskar, IAS)
Member Secretary

To,
Megafine Pharma (P) Ltd.
Gat No. 201, Lakhmapur, Tal. Dindori, Dist. Nashik
Maharashtra-India

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	50000	693320	27 Jan 2011	SBI
2	1,00,000	875629	16 Dec 2011	SBI