

MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

Consent order No :- Formate I.0/ BO/CAC-Cell/ EIC No NK-19409-15/14th CAC/ 6593
Date- 18/05/2016

To,
Megafine Pharma (P) Ltd,
Gat No 201, Lakhampur,
Tal Dindori, Dist Nashik

Subject: Amendment in existing consent for change in product-mix and further renewal for two years under RED category.

Ref : 1. Earlier Consent granted vide no. BO/JD-PAMS/NK-12418/R/CC-1911 dtd 04.03.2013.

2. Your application approved in CAC meeting held on 02.02.2016.

Your application: CO1507000298

Dated: 20.06.2015

For: Amendment in existing consent for change in product-mix and further renewal for two years

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 date of issue of consent to 31.12.2019.
2. The actual capital investment of the industry is Rs.99.11 Crs. (As per C.A. Certificate submitted by industry)
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity in MT/A
1	Disodium Pamoate	13
2	Paliperidone	0.25
3	Pyrantel Taryrate/Zeolex	30
4	Ioperidone	0.2
5	Bosentan Monohydrate	1
6	Pyrantel Pamoate	56
7	Sildanefil Citrate Intermediate (SIL-III)	18
8	Mitrazapine	6
9	Darifenacine Hydrobromide	0.2
10	Ammonium Hemifumarate	22
11	Quetiapine Hemifumarate	20
12	Thiophene-2 Aldehyde (T2A)	10
13	Ziprasidone Hydrochloride	0.5
14	Zip-II	5
15	Oxantel Pamoate	7

16	Donepezil Hydrochloride	1
17	Venlafaxine Hydrochloride	20
18	DFTA III	25
19	Vildagliptine	0.5
20	Des. Venlafaxine Succinate	2
21	Diene Crystallised	1
22	Cinacalet Hydrochloride	0.5
23	TPP	2
24	Soifenacine Succinate	0.25
25	PTQ IV	1
26	Morantel Citrate	5
27	Memantine Hydrochloride	1
28	Asenapine Maleate	0.3
29	NBPCHO	1
30	Prasugrel Hydrochloride	0.25
31	Duloxetine Hydrochloride	3
32	Sildenafil Citrate Interd (MPC VII)	8
33	HMA (CMP)	15
34	Morantel Tartrate	15
35	Ambrisentan	0.2
36	Rivaroxaban	0.25
37	Lurasidone Hydrochloride	0.25
38	Apixaban	0.1
39	Vilazodone Hydrochloride	0.1
40	Ticagrelor	0.1
41	Ivabradine Hydrochloride	0.1
42	Mirabegron	0.1
43	Dabigatran	0.1
44	Brinzolamide	0.1
45	Riociguat	0.25
46	Macitentan	0.25
47	Vortioxetine	0.2
48	Teriflunoamide	2
49	CHP(Paliperidone)	5
50	MIC (Teriflunoamide)	10

51	BHC (Lurasidone)	10
52	HMC (Lurasidone)	5
53	PBT FB (Lurasidone)	8
54	GTR 03 (Ticagrelor)	0.25
55	DPA IV(Ambrisentan)	5
	Total	338.3

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	18.40	As per Schedule -I	Used in cooling towers
2.	Domestic effluent	12	As per Schedule -I	used in cooling tower (7 CMD) and remaining on land for gardening (5 CMD)

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.	IBR boiler	1	As per Schedule -II
2.	Thermic Fluid heater	1	As per Schedule -II
3.	Non IBR boiler	1	As per Schedule -II
4.	Process stack	7	As per Schedule -II
5.	DG sets (750 KVA X 2 nos)	2	As per Schedule -II

6. Non Hazardous solid Waste :

Sr. no.	Type of waste	Quantity	Disposal
1.	MS Drums/Fibre Drums	720 No/A	Sale to authorized party
2.	HDPE bags	3000 No/A	
3.	Boiler Ash	800 Kg/D	

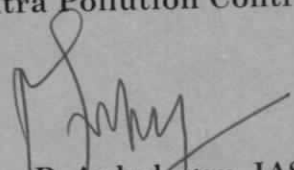
7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	Wastes/Residue containing oil	5.2	0.5	MT/A		Sale to authorized recycler
2	Distillation residue	20.3	2.58	MT/A		CHWTSDF
3	Spent	28.2	4.9	MT/A		CHWTSDF

	catalyst/spent carbon					
4	Spent catalyst/spent carbon	28.2	0.15	MT/A		CHWTSDF
5	Discarded containers/ barrels/liners	33.3	5400	Nos/A		Sale to authorized dealer
6	Discarded containers/ barrels/liners	33.3	144	Nos/A		CHWTSDF
7	Spent organic solvents	28.5	2220.8	MT/A		Sale to authorized party
8	Chemical sludge from waste water treatment	34.3	237.94	MT/A		CHWTSDF
9	Filters and filters material which have organic liquid	35.1	2490	MT/A		CHWTSDF
10	Wastes/residue containing oil	5.2	0.1	MT/A		CHWTSDF

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.
10. The consent is issued in accordance with MoEF, Govt of India circular dated December 14, 2006 stating that in cases of change of product-mix, changes in the quantities or the numbers of product may be allowed without E.C by the concerned SPCB provided such changes in the quantities of product are in the same category and are with the previously granted overall total limits.
11. This consent is granted on the basis of the proforma of no increase in pollution load submitted by the industry and certificate of "no increase in pollution load" dtd 14.10.2015 issued by ICT, Mumbai.
12. Industry shall install APCs such as wet scrubber/Bagfilters/ESP to the briquette fired boiler within a period of 3 months and shall submit BG of Rs 5 lakh towards the compliance of the same.
13. The consent is granted by overriding consent no BO/JD-PAMS/NK-12418/R/CC-1911 dtd 04.03.2013.

For and on behalf of the
Maharashtra Pollution Control Board

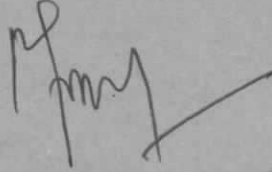

(Dr. P. Anbalagan, IAS)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	125100	464818	04.06.2015	SBI Bank
2	75000	299538	30.10.2015	SBI Bank
3	439484	776163	06.05.2016	SBI Bank
Previous consent fees				
1	560100	213905	02.10.2012	SBI Bank

Copy to:

1. Regional Officer -Nashik and Sub-Regional Officer-Nashik, MPCB: 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 ETP of 24 CMD with primary treatment followed by MEE

B] The Applicant shall operate the 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 - 9.0
02	Oil & Grease	10
03	BOD (3 days 27°C)	100
04	Total Dissolved Solids	2100
05	Suspended Solids	100
06	COD	250
07	Chloride	600
08	Sulphate	1000

C) The treated effluent shall be 100 % recycled in cooling towers.

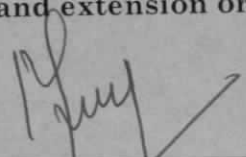
2) A] As per your consent application, you have provided the STP of capacity 48 CMD.

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	50	mg/l.
(2)	BOD 3 days 27°C.	Not to exceed	30	mg/l.
(2)	COD	Not to exceed	100	mg/l.

C] The treated sewage shall be used in cooling tower (7 CMD) and remaining on land for gardening (5 CMD).

3) 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.

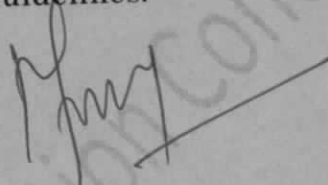


4) The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.

5) 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	78
2.	Domestic purpose	15
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	15.9
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0

6) 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.



Maharashtra Pollution Control Board

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 ₂ Kg/Day
1	IBR boiler	Stack with dust collectors	30.5	Bio - Briquette	8 MT/D	0.06	9.6
2	Thermic Fluid heater	Stack	24	Diesel	70 liter/Hr	1	33.6
3	Non IBR boiler	Stack	24				
4	DG Set 750 KVA	Stack	h + 3				
5	DG Set 750 KVA	Stack	h + 8				
6	Process stacks (3 nos)	Scrubber (acidic) 3 Nos	18 each	NA	NA	NA	NA
7	Process stacks (4 nos)	Scrubber (Alkaline) 4 Nos	18 each	NA	NA	NA	NA

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:

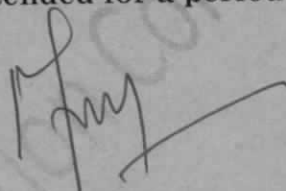
Particulate matter	Not to exceed	150 mg/Nm ³
HCL/Acid mist	Not to exceed	35 mg/Nm ³
CL ₂	Not to exceed	3 ppm
NO _x	Not to exceed	35 ppm
NH ₃	Not to exceed	50 ppm

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).

Schedule-III
Details of Bank Guarantees

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submissi on Period	Purpose of BG	Complian ce Period	Validity Date
1	C to R	Rs 10 lakh	Within 15 days from the date of issue of consent	O & M of PCS	31.12.2019	30.04.2020
2	C to R	Rs 5 lakh	Within 15 days from the date of issue of consent	Industry shall install APCs such as wet scrubbers/Bag filters/ESP to the briquettes fired boiler	31.08.2016	31.12.2016
3	C to R	Rs 5 lakh	Submitted *	Not to exceed the production quantity beyond the consented limit	31.12.2019	30.04.2020

*The existing BG of Rs 5 lakh towards not to exceed the production quantity beyond the consented limit shall be extended for a period upto 30.04.2020.



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) Industry should monitor effluent quality, stack emissions and ambient air quality monthly.
- 3) 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.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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/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.
- 8) 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 30th June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 10) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- 11) 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).
- 12) 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.
- 13) 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.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

- 15) 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.
- 16) 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.
 - 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.
 - The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel.
- 17) The industry should not cause any nuisance in surrounding area.
- 18) 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.
- 19) The applicant shall maintain good housekeeping.
- 20) 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.
- 21) 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.
- 22) 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.
- 23) 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.
- 24) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 25) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.