

MAHARASHTRA POLLUTION CONTROL BOARD

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RED/MSI

Consent order No:-Format 1.0/AST/RO-KNEIC No. KN-6740-15/R/CC- 13950

Date- 02/10/2015

To,

M/s. Pioneer Agro Industries,
(Pharmaceuticals Division),
Plot No. 6, 7, 8, 20 & 24, MIDC,
Post- Kulgaon, Badlapur,
Dist. Thane.

Subject: Consent to Renewal RED category.

Ref : 1. Earlier consent to operate is granted vide No. BO/ RO-Kalyan/PCI-II/
EIC-KN-3354-10/R/CC-175 dtd. 04.08.2010.

Your application: CR1503000456

Date: 04.03.2015

For Renewal of 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 (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 31.12.2014 to 31.12.2017
2. The total capital investment of the industry is Rs. 4.98 Cr. (Existing was Rs. 3.83 Cr.) (As per C. A Certificate submitted by industry)
3. The Consent is valid for the manufacturing of -

Sr. No.	Product Name	Maximum Quantity MT/M
1	Methadone HCL	0.800
2	Oxycodone HCL	0.025
3	Levomethadone HCL	0.100
4	Pentazocine HCL	0.500
5	Buprenorphine HCL	0.050
6	Naltrexone HCL	0.020
7	Naloxone HCL	0.020
8	Nalbutene	0.020
9	Nalbuphine	0.020
10	Apomorphine and its salts	0.100
11	Quinfamide	0.100
12	Ropivacaine HCL	0.250
13	Bupivacaine HCL	0.400
14	Mepivacaine HCL	0.250
15	Articaine HCL	0.250
16	Ketamine HCL	0.750
17	Oxybutynin Chloride	0.050
18	Noradrenaline/Epinephrine and its salts	0.025
19	Adrenaline/ Epinephrine and its salts	0.050

20	Pholcodine	0.030
21	Morphine Derivatives	0.025
22	Morphine Analogues	0.025
23	Neostigmine HCL	0.100
24	Tizanidine HCL	0.500
25	Buflomedil HCL	0.200
26	Methyl Phenidate HCL	0.200
27	Synephrin	1.000
28	Nimetazepam	0.500
29	Diphenoxylate HCL	0.100
30	Other Bulk Drugs	3.540

(Production of above Bulk Drugs shall not be exceeding 10 MT/M quantities).

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	20	As per Schedule -I	CETP
2.	Domestic effluent	8.0	As per Schedule -I	Septic tank & Soak pit

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-I	Common stack	As per Schedule -II
2.	Boiler-II		As per Schedule -II
3.	Thermic Fluid Heater		As per Schedule -II
4.	Process Reactor 3 nos	3	As per Schedule -II
5.	DG set 320 KVA 2 nos	2	As per Schedule -II

6. Conditions about Non Hazardous Wastes: NA

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

Sr. No.	Category & Type Of Waste	Sch.I	Quantity	Treatment	Disposal
1	Residues & Wastes	28.1	MT/A	CHWTSDF
2	Spent Carbon	28.2	MT/A	CHWTSDF
3	Date-expired, discarded and off specification drugs/ medicines	28.3	MT/A	CHWTSDF
4	Spent mother liquor	28.4	MT/A	CHWTSDF
5	Spent Organic solvents (Recovered)	28.5	MT/A	Sale for recovery to authorized party
6	Flue gas cleaning residues	34.1	MT/A	CHWTSDF
7	Chemical sludge, oil & grease, skimming residues from ETP	34.3	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 industry shall also comply with the Industry specific standards notified under Environment Protection Act.
11. This consent is issued as per the delegation of powers to HOD's vide Board Office Order No. 31/2013 dtd, 01.03.2013.

For and on behalf of the
Maharashtra Pollution Control Board

(P. K. Mirashe)
(Assistant Secretary (Tech.))

Received Consent fee of -

Sr. No.	Amount (Rs.)	DD. No.	Date	Drawn On
1	45,000/-	636102	09.02.2015	Corporation Bank

Copy to:

1. Regional Officer -Kalyan and Sub-Regional Officer, Kalyan-II, MPCB, - They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. Website updating purposes.

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

- 1) A] As per your application, you have provided the Effluent Treatment Plant (ETP) of Capacity 40 CMD, comprising Primary, secondary and Tertiary treatment systems.
- 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
	I. Compulsory Parameters	Limiting Concentration in mg/l, except for pH
01	pH	5.5 to 8.5
02	Suspended Solids	100
03	BOD 3 days 27 deg.0	100
04	COD	250
05	Oil & Grease	10
06	TDS	2100
07	Sulphates	1000
08	Chlorides	600

- C] The applicant shall recycle treated effluent to the maximum extent and remaining treated effluent shall be sent to CETP. There shall not be any discharge outside the factory premises.
- 2) A] As per your consent application, you have provided soak pit as a treatment for sewage.
- 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 27°C. | Not to exceed | 100 | mg/l. |
- C] The treated sewage shall be used on land for gardening/plantation only in the factory premises.
- 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	40
2.	Domestic purpose	10
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	30
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are	NIL

	toxic	
5.	For Agriculture/gardening	10

- 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.

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 proposed to erect 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	Boiler-I	Common Stack	30	LDO	720 Lit/D	1.8	25.92
2	Boiler-II						
3	Thermic Fluid Heater						
4	Process Reactor	Ammonia Scrubber	13
5	Process Reactor	HCL Scrubber	13
6	DG set 320 KVA 2 Nos	Stack	3.5*	HSD

* Above the roof

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.
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	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 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

Bank Guarantee History: Fresh and Existing BG's

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	5 Lakh	15 days	Towards O & M of Pollution Control Systems and compliance of consent conditions	31.12.2017	30.04.2018

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.
- 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/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.
- 9) 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.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Activity.
- 12) 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).
- 13) 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.
- 14) 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.
- 15) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

- 16) 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.
- 17) 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
- 18) The industry should not cause any nuisance in surrounding area.
- 19) 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.
- 20) The applicant shall maintain good housekeeping.
- 21) 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.
- 22) 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.
- 23) 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.
- 24) 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.
- 25) 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 downloaded from MPCB official site).
- 26) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 27) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.

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