

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

Consent order No :- Formate 1.0/ BO/CAC-Cell/UANNo 0000001313/3rd CAC - 9254
Date- 19/07/2016

To,
M/s.Ferring Therapeutics Pvt.Ltd.
K-28/1, MIDC, Addl. Ambernath
Dist.Thane.

Subject: Renewal of combined consent and authorization under RED category.
Ref : 1. Earlier Consent granted vide No. Formate 1.0/BO/CAC-Cell/EIC No NM-5499-14/1st CAC-5081 dated 02.05.2015
2. Your application approved in CAC meeting held on 08.07.2016

Your application:CR1603000736
Dated:16.05.2016

For: Renewal of combined consent and authorization 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 & Biomedical waste (Management & Handling) Rules 1998 & amended is considered and the consent & Authorization 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 01.05.2016 upto 30.04.2017.
2. The actual capital investment of the industry is Rs.226.28 Cr. (As per C.A.Certificate submitted by industry)
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity
1	MESALAZINE (Active Pharmaceutical Ingredients (API))	300 TPA

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	141	As per Schedule -I	Zero discharge
2.	Domestic effluent	4	As per Schedule -I	

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 (2 nos)	2	As per Schedule -II
2.	Process stacks(2 nos)	2	As per Schedule -II

3.	DG set (750 KVA)	1	As per Schedule -II
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6. Conditions about Non Hazardous Wastes:

Sr. No.	Type	Qty & UOM	Treatment	Disposal
1	Waste paper	0.65 MT/A		Sale to authorized party
2	Corrugated Box	0.01 MT/A		Sale to authorized party
3	Broken Glasses/Non Contaminated Plastic	0.6 MT/A		Sale to authorized party
4	Used but decontaminated drums	0.06 MT/A		Sale to authorized party
5	Plastic decontaminated bags	3.2 MT/A		Sale to authorized party

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

Sr. No.	Type Of Waste	Category	Quantity	Treatment	Disposal
1	(spent activated carbon)	28.2	142MT/A		CHWTSDF
2	Spent organic solvents (isopropyl alcohol	28.5	300MT/A		CHWTSDF /AUTHORISED RECYCLER
3	Spent organic solvents distillate aniline	28.5	168 MT/A		CHWTSDF
4	Chemical sludge from waste water treatment	34.3	3085MT/A		CHWTSDF
5	Filters and filter material which have organic liquid	35.1	0.1MT/A		CHWTSDF
6	Discarded containers / barrels / liners	33.3	3MT/A		CHWTSDF
7	Off specification products	28.4	0.78MT/A		CHWTSDF

8	Used /spent oil	5.1	1.6MT/A	Authorized used oil recycler
9	waste residue containing oil	5.2	0.36MT/A	CHWTSDF
10	E-WASTE		1 MT/A	Sale to authorized dealers

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. Industry shall recycle the treated trade effluent 100% so as to achieve zero discharge.

For and on behalf of the
Maharashtra Pollution Control Board

(P.K.Mirashe)

Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	452560	16533	23.03.2016	HSBC
2	125000	HSBCN16166215825	14.06.2016	HSBC

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. CC/CAC desk- for record & website updation purposes.

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

- 1) A] As per your application, you have provided the MEE followed by ATDF for treatment of high COD stream of 49 CMD and Effluent Treatment Plant (ETP) followed by RO for treatment of low COD stream of 92 CMD
- B] The treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way for gardening/outside factory premises.
- 2) A] As per your consent application, you have provided septic tanks and soak pits.
- 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 soaked in a soak pit, which shall be got cleaned periodically.
- 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	261
2.	Domestic purpose	5
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	112
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0
5	Others such as agricultural, gardening etc.	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 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	Boiler - 3T	Stack	33	LDO	215 kg/Hr	1.8	185
2	Boiler - 3T	Stack	33	LDO	215 kg /Hr	1.8	185
3	Process stack	Acidic and alkaline Scrubber	10 each
4	D.G.Set (750 KVA)	Acoustic Enclosure	12	HSD	300 kg/hr on 100% load	1	144

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
Acid Mist	Not to exceed	35 mg/Nm ³
SO ₂ (from process)	Not to exceed	50 ppm
Hydrocarbon	Not to exceed	10 ppm

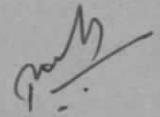
4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement well before its life come to an end or erection of new pollution control equipment.
5. The Board reserves its rights to 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).

[Handwritten Signature]

Schedule-III
Details of Bank Guarantees

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	Rs 5 lakhs*	Submitted	O & M OF PCS	30.04.2017	30.08.2017
2	C to R	Rs 10 lakhs*	Submitted	Towards achieving zero discharge	30.04.2017	30.08.2017
3	C to R	50000	Within 15 days from the date of issue of consent	To Segregate and Handle BMW as per Rule	30.04.2017	30.08.2017
4	C to R	25000	Within 15 days from the date of issue of consent	To Maintain records of BMW and submission of annual Report in Form - II before 31st January	30.04.2017	30.08.2017
5	C to R	25000	Within 15 days from the date of issue of consent	To Maintain records of BMW material received / delivered to authorized party CBMWTSDF (Transporter only)	30.04.2017	30.08.2017

*The above BGs of Rs 5 lakh and Rs 10 lakh shall be extended for a period upto 30.08.2017.



Schedule-IV

Terms & Conditions for compliance of Biomedical Waste Management

1. The "authorized Person" Sr. Manager - EHS, M/s.FERRING THERAPEUTICS PRIVATE LIMITED, K-28/1, M.I.D.C, Addl. Ambernath, Dist. THANE shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
2. The combined consent is granted for generation, storage, treatment, transportation and disposal of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below:

Sr. No.	Category	Description	Quantity not to exceed (MT/A)	Segregation Color coding	Treatment & Disposal
1	Cat-3	Microbiology & Biotechnology Waste	0.6	Yellow	CBMWTSDF
2	Cat-4	Waste Sharps	0.006	Blue / white translucent	CBMWTSDF
3	Cat-8	Liquid waste	0.6	Yellow	CBMWTSDF
4	Cat-10	Chemical waste	0.06	Yellow	CBMWTSDF

3. (i) BMW shall not be mixed with other wastes or reused or sold in any form.
- (ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-II prior to storage, treatment and disposal. The containers shall be labeled according to Schedule III of BMW Rules 1998.
- (iii) If a container containing BMW is to be transported from the premises where BMW is generated to any waste treatment facility outside the premises, the container shall, apart from the Label prescribed in Schedule III, also carry information prescribed in Schedule IV and shall be transported by authorized Transporter only.
- (iv) Notwithstanding anything contained in the Motor Vehicles Act, 1988 or Rules there under, BMW shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.
- (v) No untreated BMW shall be kept stored beyond a period of 48 hours.
- (vi) Necessary protective gear for the waste handlers shall be provided by the firm Authority.
- (vii) You shall ensure proper collection of mercury spillage arising mainly due to breakage of thermometers pressure gauges (Sphygmomanometers) other equipments used in health care facilities (HCFs) as well as its storage in

accordance with the Hazardous waste (Management & Handling) Rules (presently these Rules has to be read as 'Hazardous Waste (Management & Handling and Trans boundary Movement) Rules, 2008) and returning it to the instrument manufacturers apart from necessary taking steps to ensure that the spilled mercury does not become a part of bio-medical or other solid wastes generated from the HCFs.

- (viii) Authorized person shall obtain prior permission from MPCB for generation & disposal, if Bio-Medical waste quantity of category specified exceed the limits authorized at condition No. 2. Above
4. (i) You shall submit an Annual Report to the prescribed authority in Form-II by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.
- (ii) You shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of BMW in accordance with these Rules and any guidelines issued.
- (iii) All records shall be subject to inspection and verification by the prescribed authority at any time.
5. When any accident occurs at any institution or facility or any other site where BMW is handled or during transportation of such waste, the authorized person shall report the accident in Form III to the prescribed authority forthwith.
6. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

STANDARDS FOR WASTE AUTOCLAVING:

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste,

(I) When operating a gravity flow autoclave, medical waste shall be subjected to :

(i) a temperature of not less than 121 C° and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or

(ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or

(iii) a temperature of not less than 149 C° and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.

(II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following:

(i) a temperature of not less than 121 C° and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or

(ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;

(III) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicator indicates that the required temperature, pressure or residence time was not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(IV) Recording of operational parameters

Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

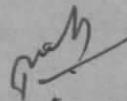
(V) Validation test

Spore testing :

The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Bacillus stearothermophilus* spores using vials or spore Strips; with at least 1×10^4 spores per millilitre. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121 C or a pressure less than 15 psi.

(VI) Routine Test

A chemical indicator strip/tape the changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved



Schedule-V

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/quarterly.
- 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 statement on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end, with the Environment Statement.
- 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.

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