

MAHARASHTRA POLLUTION CONTROL BOARD

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Sion Circle, Sion (E),
Mumbai – 400 022

Orange/L.S.I

Consent No: BO/AST/O/EIC NO.PN-20759-14/CC-03998 Date:29/04/2014

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 & Transboundary Movement) Rules 2008

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

**M/s. Fresenius Kabi India Pvt. Ltd.
A-3, MIDC Ranjangaon,
Tal-Shirur, Dist-Pune**

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: 31/03/2018.
2. The Consent is valid for the Pharmaceuticals Products of various types of Intravenous fluid formulations - 1,41,000 Litrs / Day -

Sr. No.	Product Name
01	Haes- Steril- 8%
02	Haes- Steril- 6 %
03	Haes- Steril- 10%
04	Sodium Chloride Injections 0.9 % w/v. IP
05	Sodium Chloride Intravenous Infusion BP
06	Dextrose Injection 5.0 % w/v IP
07	Glucose Intravenous Infusion BP 50 g/l
08	Dextrose Injection 10.0 % w/v IP
09	Glucose Intravenous Infusion BP 100 g/l
10	Dextrose Injection 20.0 % w/v USP
11	Dextrose Injection 25.0% w/v IP
12	Dextrose Injection 50.0% w/v IP
13	Glucose Intravenous Infusion BP 500 g/l
14	0.9 % w/v Sodium Chloride & 5.0 % w/v Dextrose Injection IP
15	0.9 % w/v Sodium Chloride & 5.0 % w/v Glucose Intravenous Infusion BP
16	0.9 % w/v Sodium Chloride & 10.0 % w/v Glucose Intravenous Infusion BP
17	0.45 % w/v Sodium Chloride & 5.0 % w/v Dextrose Injection IP
18	0.33 % w/v Sodium Chloride & 5.0 % w/v Dextrose Injection IP
19	0.2 % w/v Sodium Chloride & 5.0 % w/v Dextrose Injection IP
20	0.18 % w/v Sodium Chloride & 4.0 % w/v Dextrose Injection IP

21	Compound Sodium Lactate Injection IP
22	Compound Sodium Lactate Intravenous Infusion BP
23	Sodium Lactate 1/6 th Molar IP
24	Mannitol Injection 20% w/v IP
25	Fresogyl (Metronidazole Injection IP 0.5 % w/v)
26	Metronidazole Injection 0.5% USP
27	Metronidazole Intravenous Infusion BP
28	Iveomezol D Injection (0.2 % w/v Metronidazole & 5% w/v Dextrose)
29	Fresoflox (Ciprofloxacin Injection IP)
30	Ciprofloxacin Injection USP
31	Iveolyte-P Injection (Multiple Electro & Dextrose Injection Type 3 USP)
32	Iveolyte-P Injection (Multiple Electro & Dextrose Injection Type 1 USP)
33	Iveolyte-G Injection
34	Iveolyte-E Injection
35	Glycine Irrigation Solution USP
36	Lactated Posassic Saline Injection (Darrow's Solution)
37	Lactated Posassic Saline Injection (Darrow's Solution-Half Strength)
38	Lactated Posassic Saline Injection with Glucose(Darrow's Solution-Half Strength)
39	Fluconazole Infusion 2 mg/ml
40	Ofloxacin Infusion
41	Normal Saline
42	Dextrose Saline
43	5% Dextrose Saline
44	Amino Acid
45	Cipro Aoxacin
46	Ringers Lactate

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 225.00 M³
(ii) The daily quantity of sewage effluent from the factory shall not exceed 39.00 M³.
(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 :-

Sr.no	Parameter		EP Standard	MPCB Standards
01	pH	Between	5.5 to 9.0	5.5 to 9.0
02	Suspended Solids	Not to exceed	100 mg/l	100 mg/l
03	BOD 3 days 27° C	Not to exceed	100 mg/l	100 mg/l
04	COD	Not to exceed	250 mg/l	250 mg/l
05	Oil & Grease	Not to exceed	10 mg/l	10 mg/l
06	Total Dissolved Solids	Not to exceed	2100mg/l	2100mg/l
07	Sulphates	Not to exceed	1000mg/l	1000mg/l
08	Chlorides	Not to exceed	600 mg/l	600 mg/l
09	Phenolic	Not to exceed	1.0 mg/l	1.0 mg/l
10	Sulfides	Not to exceed	2.0 mg/l	2.0 mg/l
11	Phosphates	Not to exceed	5.0 mg/l	5.0 mg/l

- (iv) **Trade Effluent Disposal:** The treated effluent should be reused in cooling & remaining discharge into CETP Ranjangaon through MIDC sewer system and on gardening in case of non-acceptability from CETP.

(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 27° 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 should be sued on land for gardening / plantation only.

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

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
01	Waste Packaging material	1000.00	Kg/m	By sale to authorized person
02	Glass Bottles	1000.00	Kg/m	By sale to authorized person
03	Plastic Scrap	6.00	MT/M	By sale to authorized dealers
04	Canteen Waste	500.00	Kg/M	Vermicomposting
05	Ash	60.00	MT/M	By Sale / Landfill

(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 | ... | 40.00 CMD |
| (ii) Industrial Processing | ... | 284.00CMD |
| (iii) Industrial Cooling | ... | 145.00CMD |
| (iv) Agriculture / Gardening | ... | ----- CMD |

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. Adequate air pollution system of sufficient capacity shall be provided to the all source of TPM/SPM to limit the emissions and operated properly.
- II. Scrubbing arrangements should be provided to boiler.
- III. There shall not be any secondary (fugitive) emissions.

b. Standards for Emissions of Air Pollutants:

- | | | |
|---------------------------------|---------------|--------------------------|
| (i) SPM/TPM | Not to exceed | 150.0 mg/Nm ³ |
| (ii) SO ₂ | Not to exceed | 2295.0 Kg/day |
| (iii) SO ₂ (Process) | Not to exceed | 50.0 PPM |

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

Sr. No.	Type Of Fuel	Quantity	UOM
01	HSD	2400	Litrs /Day/DG set
02	Agro Briquettes	20	MT/Day

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

Sr. No.	Chimney Attached To	Height in Mtrs.	APCS
01	Boiler I & II	35	Multi cyclone Dust collectors
02	D.G.Set (625 KVA 2 Nos)	6.45*	Stack

* Above the roof of the building

- (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.
 - 3) The DG set shall be operated in case of power failure only.
 - 4) The Industry should comply with Ozone Depletion Rules, 2000.
- C. 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.

6. 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
01	5.1 Used / Spent Oil	200.00	Ltrs/M	Sale to authorized Recycler
02	34.3 ETP Sludge	1500.00	kg/M	CHWTSDF Ranjangaon

(ii) Treatment: - NIL

7. 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.

8 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 per 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.
- x. 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.
- 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.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
09. **The board reserves the right to amend, revoke or add any conditions in this consent and same shall be binding on the applicant.**
10. **The industry shall also comply with the Industry specific standards notified under Environment Protection Act 1986.**
11. **This consent is issued as per the delegation of powers to HOD's vide Board Office Order No. 31 of 2013 dtd. 01/03/2013.**
12. **The applicant shall submit Bank Guarantee Rs. 5 lakh in favor of Regional Officer Pune valid up to 31.07.2018 towards compliance of consent conditions.**
13. **The Capital investment of the industry is Rs.87.66 Crores.**

P.K. Mirashe
27/4/14
(P.K.Mirashe)
Asst. Secretary (Tech)

To,
M/s. Fresenius Kabi India Pvt. Ltd
A-3, MIDC Ranjangaon,
Tal-Shirur, Dist-Pune

Copy to :

- 1) RO,Pune /SRO, Pune II. They are directed to ensure the compliance of consent conditions.
- 2) CAO/Cess Branch/Master file.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	353654.0	037146	03.02.2014	Bank of India
2	100.0	037145	06.02.2014	Bank of India
3	100.0	037113	06.02.2014	Bank of India

(Balance fees Rs. 103654 will be consider during next renewal of consent.)