MAHARASHATRA POLLUTION CONTROL BOARD

Phone: 022-27576034

022-27572620 022-27562132

Fax : 022-2756

Email: roraigad@mpcb.gov.in

Visit At : http://mpcb.gov.in



Regional Office.

Raigad Bhavan,6th floor Sector - 11, C.B.D Belapur, Navi Mumbai - 400614

Orange/L.S.I.

Consent No: RO-Raigad/Consent/ 1902001023

Date: 21-02-2019

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 2016

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

CONSENT is hereby granted to

M/s. Kopran Ltd., Village- Savroli, Tal-Khalapur Dist-Raigad.

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: 31/12/2024

2. The Consent is valid for the manufacture of -Pharmaceuticals Formulations (Tablets & Capsules & Dry Syrup) based on average monthly consumption of the following Bulk Drugs)

Sr. No.	Product Name	Maximum Quantity	UOM
1	Albendazole	42.0	Kgs/M
2	Amlodipine	2.0	Kgs/M
3	Amoxycilin Trihydrate	6670.0	Kgs/M
4	Ampicillin Trihyrdate	2085.0	Kgs/M
5	Atenolol	835.0	Kgs/M
6	Atotvastain	500.0	Kgs/M
7	Azithromycin	50.0	Kgs/M
8	Bamuterol	3.0	Kgs/M
9	Bromohxime Hydrochloride	3.0	Kgs/M
10	Carvediol	9.0	Kgs/M
11	Ciprofloxacin	100.0	Kgs/M
12	Cisaprode Monohydrate	9.0	Kgs/M
13	Clarithromycin	250.0	Kgs/M
14	Cloxaciline Sodium	1670.0	Kgs/M
15	Dicloflenace Sodium	320.0	Kgs/M
16	Dilitazem Hydrochloride	21.0	Kgs/M
17	Enalaprit Maleate	2.0 Pollu	Kgs/M
18	Ephedrine Hydrochloride	1000.0	Kgs/M
19	Famotidine	17.0 g Regio	nal 5 Kgs/M

Raigad

20	Finasteride	9.0	TZ /N/I
		2.0	Kgs/M
21	Furazolidole	85.0	Kgs/M
22	Ibuprofen	1750.0	Kgs/M
23	Ketotifen Femerate Acid	2.0	Kgs/M
24	Lomofloxacin	167.0	Kgs/M
25	Loratadine	2.0	Kgs/M
26	Losartan Potassium	5.0	Kgs/M
27	Metformine Hydrochloride	1000.0	Kgs/M
28	Metronidazole	50.0	Kgs/M
29	Norfloxacin	320.0	Kgs/M
30	Paracetamol	542.0	Kgs/M
31	Pseudo Ephedrine	4.0	Kgs/M
	Hydrochloride	包括。1000年2月1日4日	
32	Pyrazinamide	320.0	Kgs/M
33	Pyridoxine Hydrochloride	10.0	Kgs/M
34	Rantidine Hydrochloride	50.0	Kgs/M
35	Roxithromycin	55.0	Kgs/M
36	Salbuttamole Sulphate	67.0	Kgs/M
37	Saparfloxacin	17.0	Kgs/M
38	Simvastain	200.0	Kgs/M
39	Sulphamethaxazole	167.0	Kgs/M
40	Terbinafine	42.0	Kgs/M
41	Terfenadine	34.0	Kgs/M
42	Theophyline	2250.0	Kgs/M
43	Tinidazole	1850.0	Kgs/M
44	Tramadol	13.0	Kgs/M
45	Trimethoprime	34.0	Kgs/M
46	Zopiclone	2.0	Kgs/M
A STATE OF THE PARTY OF THE PAR			

(Only for formulation activity only)

3. CONDITIONS UNDER WATER ACT:

- i) The daily quantity of trade effluent from the factory shall not exceed 6.0 M3/Day
- (ii) The daily quantity of sewage effluent from the factory shall not exceed.5.0M3.

(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:

0.1	pН	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 degree C	Not to exceed	100 mg/l.
5	COD	Not to exceed	250 mg/l.
6	TDS	Not to exceed	2100 mg/l.
7	T. Ammonical Nitrogen	Not to exceed	50 mg/l

(iv) Trade Effluent Disposal: The treated effluent shall be used on land for gardening/Irrigation only, excess if any shall be sent to CETP (Patalganga). In no case the treated effluent shall find its way directly or indirectly to the stream.

(v) Sewage Effluent Treatment: The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the

Raigad.

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 270 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, shall be used on land for gardening / plantation only.

(vii) Non-Hazardous Solid Wastes:

Sr. No	Type of Waste	Quantity	UOM	Treatment	Disposal
J. J. W.		-NA-			

(viii) Other Conditions:

1) Industry should monitor effluent quality regularly.

2) The green belt afforestation shall be done minimum up to 33% of the open available land.

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

5.0 CMD

(ii) Water gets Polluted &

Pollutants are Biodegradable

6.00 CMD

(iii) Water gets Polluted, Pollutants

are not Biodegradable & Toxic

0.00CMD

(iv) Industrial Cooling, spraying

in mine pits or boiler feed

10.00 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:

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:

SPM/TPM (i)

Not to exceed

150 mg/Nm³

SO2 (ii)

Not to exceed

31.2 Kg/day

A) Control Equipment:

I. Industry shall provide and operate dust collector of sufficient capacity shall be provided to mixing, packing and any other source to limit particulate emissions.

II. There shall not be any secondary (fugitive) emissions.

6. 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.

Raigad

- 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 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.
- d. Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper sitting 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.

7. Standards for Stack Emissions:

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	Diesel.	65.0	Lit./Hrs.

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	D.G. Set(750.0KVA)	11.0

- (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.

(v) 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 & TRANSBOUNDRY MOVEMENT) RULES, 2016:

(i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	28.3- Date Expired	100.0	Kg/Year	CHWTSDF
	Medicine			
2	33.3- Discarded Barrels &	7000.0	Nos./Year	Send back
	drums			supplier/CHWTSDF
3	5.1 Spent Oil	200.0	Liter/Year	Sale to
But street			Pollullon	MPCB authorized 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 2016.
- 9. 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.

10. Industry shall comply with following general conditions:

- 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 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 & 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 pre 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.

Officer Raigad.

- xi. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory
- 11. The Board reserves the right of review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
- 12. The consent should not be construed as any exemption from obtaining necessary NOC/permission from other Govt. agencies as may deemed fit necessary.
- 13. Industry shall obtain and submit NOC of Central Ground Water Authority (CGWA) within a period of 3 months else this consent stands automatically cancelled.
- 14. Industry shall submit Bank Guarantee of Rs.50,000/- (Rupees Fifty Thousand only) in favor of Regional Officer, Raigad, within 15 days period towards compliance of consent conditions.
- 15. The Capital investment of the industry is Rs. 50.86 Crs.

Regional Officer Raigad.

FOR ON THE BEHALF OF MPCB BOARD

Regional Officer, Raigad.

To, M/s. Kopran Ltd., Village- Savroli, Tal-Khalapur Dist-Raigad.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	500000.00	7618847	31.12.2018	State Bank Of India

^{*}Industry has paid consent fees of Rs.5,00,000/-(Rupees Five Lakh) along with application out of which Rs.3,15,000/-deducted towards renewal of consent and increase in C.I. and remaining amount of Rs.1,85,000/- will be adjusted in next renewal of consent.

Copy to:

Sub Regional Officer, MPC Board, Raigad-I

-He is directed to ensure compliance of consent conditions.