# **MAHARASHTRA POLLUTION CONTROL BOARD**

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Kalpataru Point, 2nd and 4th floor, Opp. Cine Planet Cinema, Near Sion Circle, Sion (E), Mumbai-400022

Date: 03/07/2022

RED/L.S.I (R58) No:- Format1.0/CC/UAN No.0000117803/CE/2207000141

To, KOPRAN RESEARCH LABORATORIES LTD. PLOT NO. K- 4/4,MIDC MAHAD TAL.- MAHAD, DIST- RAIGAD.



#### Sub: Grant of Consent to Establish (Expansion) under Red/LSI category.

- Ref: 1. Exisitng Consent to Operate granted by the Board vide No. Format 1.0/BO/ AST/UAN No. 00000071587/R/CC-1906001351, Date. 26.06.2019 valid upto 31.05.2024.
  - 2. Minutes of the 2nd Consent Committee meeting held on 23.05.2022.

Your application No.MPCB-CONSENT-0000117803 Dated 13.07.2021

For: Grant of Consent to Establish under Section 25 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 6 of the Hazardous & Other Wastes (Management & Transboundary Movement) Rules 2016 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 to establish is granted for a period up to commissioning of the unit or up to 5 year whichever is earlier.
- The capital investment of the project is Rs.9.94 Crs. (As per undertaking submitted by pp Existing Cl is-Rs. 49.28 Crs + Expansion/Increase in C.I. Rs. 9.94 Crs = The total C.I will be Rs. 59.22 Crs after expansion.)
- 3. Consent is valid for the manufacture of:

Sr No	Product	Maximum Quantity	UOM
Prod	ucts		
1	Atenolol	60	MT/A
2	Amlodiphine	30	MT/A
3	Metoprolol succinate	15	MT/A
4	Metoprolol tartate	15	MT/A
5	Azithromycin	55	MT/A
6	Roxithromycin	5	MT/A
7	Omeprazole	14	MT/A
8	Clarithromycin	30	MT/A
9	Esomeprazole magnesium	4	MT/A

Sr No	Product	Maximum Quantity	ИОМ
10	Venlafaxine	3	MT/A
11	Duloxetine	3	MT/A
12	Ceftriaxone	20	MT/A
13	Cefotaxime	30	MT/A
14	Cefepime	34	MT/A
15	Meropenem	30	MT/A
16	Doripenem	4	MT/A
17	Imipenem	4	MT/A
18	Ertapenem	4	MT/A
19	Feropenem	6	MT/A
20	Biapenem	2	MT/A
21	Tebipenem	4	MT/A
22	Pregabalin	30	MT/A
23	Lymecycline	3	MT/A
24	Nitroxoline	33	MT/A
25	Ticagrelor	6	MT/A
26	Canagliflozi, –	2	MT/A
27	Dapagliflozin	2	MT/A
28	Empagliflozin 🗧	2	MT/A
29	Rivaroxaban	3	MT/A
30	Apixaban	3	MT/A
31	Apixaban	3	MT/A
32	Apixaban	3	MT/A

# 4. Conditions under Water (P&CP), 1974 Act for discharge of effluent:

Sr No	Description	Permitted (in CMD)	Standards to	Disposal Path
1.	Trade effluent	76	As per Schedule-I	Recycle 100% to achieve ZLD
2.	Domestic effluent	3.0	As per Schedule-I	On land for gardening

# 5. Conditions under Air (P& CP) Act, 1981 for air emissions:

Sr No.	Stack No.	Description of stack / source	Number of Stack	Standards to be achieved
1	S-1	Boiler ( 6 TPH)	1	As per Schedule -II
2	S-2	Boiler 4.5 TPH (Standby)	1	As per Schedule -II
3	S-3	D.G. Set (1750 KVA)	1	As per Schedule -II
4	S-4 to S-7	Process Rector Vents	4	As per Schedule -II

# 6. Non-Hazardous Wastes:

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	Dry Garbage	20	Kg/Day	Municipal Council	Municipal Council
2	Wet Garbage	15	Kg/Day	Composting	Used as mannure
3	Ash	2	MT/Day	Sale	Sale to Brick Manufacturer

# 7. Conditions under Hazardous & Other Wastes (M & T M) Rules 2016 for treatment and disposal of hazardous waste:

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal	
1	5.1 Used or spent oil	0.6	MT/A	Recycle*	Sale to authorised party / CHWTSDF	
2	28.1 Process Residue and wastes	0.2	MT/A	Incineration	CHWTSDF	
3	20.3 Distillation residues	38.5	MT/A	Incineration	CHWTSDF	
4	35.3 Chemical sludge from waste water treatment	80	MT/A	Landfill after treatment	CHWTSDF	
5	28.3 Spent carbon	193.7	MT/A	Incineration	CHWTSDF	
6	33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	महार 5.5	MT/A	Recycle*	Sale to authorised party / CHWTSDF	
7	33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	5230	Nos./Y	Recycle*	Sale to authorised party / CHWTSDF	
8	37.3 MEE Salts	730	MT/A	Landfill after treatment	CHWTSDF	
9	28.1 - Poly Aluminum Chloride	4.0	KL/A	Recycle*	Sale to authorised party / CHWTSDF	
10	28.1 - Spent Acetic Acid	3.0	KL/A	Recycle*	Sale to authorised party / CHWTSDF	
11	28.6 Spent organic solvents	3.0	KL/A	Recycle*	Sale to authorised party / CHWTSDF	
12	28.3 - Spent Acid	4.0	KL/A	Recycle*	Sale to authorised party / CHWTSDF	

\* Industry shall ensure disposal of Hazardous Waste to the Actual user having permissions under Rule 9 of Hazardous and other Waste (M & TM) Rules, 2016.

8. The Board reserves the right to review, amend, suspend, revoke 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 applicant should not take any effective steps for implementation of the project before obtaining Environmental Clearance as per EIA Notification 2006 and amendments thereto. As per Para 2 of EIA notification dated- 14.09.2006, the effective steps include starting of any construction work or preparation of land by the project management. However as clarified by the MoEF vide office memorandum no. J-1103/41/2006-IA.II(I); Dated- 19/08/2010, fencing of the site to protect it from getting encroached and construction of temporary shed(s) for the guard(s) & acquisition of land not be treated as an effective step.
- 11. The industry shall obtain necessary permission from the Directorate of Industrial Safety and Health (DISH).
- 12. Industry shall install online continuous monitoring system as per CPCB guidelines & data to be transmitted directly from Data Logger to Board server.
- 13. This Consent is issued without prejudice to the order passed as may be passed by the Hon'ble NGT, in the matter O.A. No. 1038/2018.
- 14. Industry shall comply the Boards Circular dtd. 05.02.2020 for use of cleaner fuel.
- 15. Industry shall comply with direction issued to CETP on 22.01.2021, regarding installation of two-way SCADA, Auto-sampler, Non-Return Valve (NRV) with positive discharge to CETP chamber.
- 16. The industry shall dispose the by-products as Hazardous waste and shall comply the provisions of Hazardous & Other Wastes (M & TM) Rules,2016.
- 17. The Industry shall provide adequate effluent treatment systems so as to achieve Zero Liquid Discharge for the effluent generated in expansion activity.
- 18. Industry shall submit detailed water harvesting plan within 01 month period.
- 19. Industry shall develop green belt on 40% of the total plot area of the unit. Industry shall also develop greenbelt outside the project premises such as avenue plantation, plantation in vacant areas, social forestry etc.
- 20. This consent is issued pursuant to the decision of the 2nd Consent Committee Meeting held on 23.05.2022.
- 21. The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/Activity.

## **Received Consent fee of -**

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	25000.00	MPCB-DR-7921	17/09/2021	NEFT

#### Copy to:

- 1. Regional Officer, MPCB, Raigad and Sub-Regional Officer, MPCB, Mahad
- They are directed to ensure the compliance of the consent conditions.
- 2. Chief Accounts Officer, MPCB, Sion, Mumbai

#### **SCHEDULE-I**

## Terms & conditions for compliance of Water Pollution Control:

1. A] As per your application, you have proposed to segregate trade effluent into weak stream & strong stream and provide Effluent Treatment Plant (ETP) comprising of:

**i) Strong COD/TDS stream of 26 CMD -** Treatment system comprising of Primary (Collection tank, Neutralization tank, Equalization tank, Flash mixer, Primary Clarifier/Primary Settling Tank, Primary after stmt), Stripper, Multi effect evaporator (3 stage) with design capacity of 50 CMD followed by ATFD. The MEE condensate is treated in weak stream ETP.

**ii) Weak COD/TDS stream of 50 CMD -** Treatment system comprising of Primary (Collection tank, Neutralization tank, Equalization tank, Flash mixer, Primary Clarifier/Primary Settling Tank), Secondary (Activated sludge process), Tertiary (Pressure sand filter, Activated carbon filter), Advance treatment (Reverse osmosis, Of capacity 80 CMD & RO Permeate shall be recycled/ resued and RO reject shall be sent to MEE.).

- B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent and recycle the entire treated effluent into the process for various purposes such as for cooling, process & Scrubbing with metering system so as to achieve Zero Liquid Discharge. There shall be no discharge on land or outside factory premises.
- C] Industry shall install online monitoring system i.e. IP Camera and flow meter to ensure the Zero Liquid Discharge and it connectivity to the MPCB server. Industry shall also install separate energy meter to the pollution control devices.
- D] Industry shall also install separate energy meter to the pollution control devices.
- 2. A] As per your application, you have provided Septic Tank followed by Soak pit for the treatment of 3.0 CMD of sewage.
  - B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards.

S	ir.No	Parameters	Standards (mg/l)	
	1	Suspended Solids	Not to exceed	50
	2	BOD 3 days 27°C	Not to exceed	30

- C] The treated sewage shall be recycled for secondary purposes to the maximum extent and remaining shall be discharged on land for gardening within premise after confirming above standards. In no case, sewage shall find its way for gardening / outside 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 there of & 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 an 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) Act, 1974 and as amended, by installing water meters 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	82.00
2.	Domestic purpose	5.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	80.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Gardening	30.0

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.



#### **SCHEDULE-II** Terms & conditions for compliance of Air Pollution Control:

1. As per your application, you have proposed to provide the Air pollution control (APC) system and also to erect following stack (s) to observe the following fuel pattern:

Stack No.	Source	APC System provided/pro posed	Stack Height(in mtr)	Type of Fuel	Sulphur Content(in %)	Pollutant	Standard
S-1	Boiler	Fabric Bag Filter	32.00	Briquette 541.66	0.06	TPM	50 Mg/Nm <sup>3</sup>
51	Doner	Multi Cyclone	52.00	Kg/Hr	0.00	SO2	15.6 Kg/Day
S-2	Boiler 4.5 TPH	Stack	32.00	LDO 250	1.8	TPM	50 Mg/Nm³
5-2	(Standby)	Stack	52.00	Ltr/Hr	1.0	SO2	72 Kg/Day
S-3	D.G.Set	Acoustic Enclosure	12.00	HSD 210	1	TPM	50 Mg/Nm <sup>3</sup>
3-3	D.G.Set	Stack	12.00	Ltr/Hr	I	SO2	33.6 Kg/Day
S-4	Nitroxoline Plant Process	Caustic	12.00			Acid Mist	35 Mg/Nm³
5-4	Vent	Scrubber	12.00	-	-	SO2 (process)	50 PPM
S-5	Apixaban Process Vent	Acidic Scrubber	12.00	-	-	NH3	30 Mg/Nm³
S-6	Rivaroxaban Process Vent	Scrubber	12.00		-	Acid Mist	35 Mg/Nm <sup>3</sup>
S-7	Empagliflozin	Scrubber	12.00	-	_	Acid Mist	35 Mg/Nm <sup>3</sup>
	Process Vent					SO2	-

(D.G Set stack height shall be above roof of Building)

- 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 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.
- 4. 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).
- 5. Solvent Management shall be carried out as follows:
  - a. Reactors shall be connected to Water / Chilled Water /Brine Condenser system.
  - b. Reactors and solvent handling pumps shall have mechanical seals to prevent the leakages.
  - c. The condensers shall be provided with adequate Heat transfer area (HTA) and residence time so as to achieve more than 97% overall recovery
  - d. Solvents shall be stored in a separate space specified with all safety measures.
  - e. Proper earthing shall be provided in all the equipment's, wherever solvent handling is done.
  - f. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
  - g. All the solvent storage tanks shall be connected with vent condensers with Water / chilled water / Brine circulation.

- h. Fugitive emissions shall be controlled at 99.95% with effective chillers.
- i. Solvent transfer shall be through pump.
- j. Metering and control of quantities of active ingredients to minimize wastes.
- k. Use of automatic filling to minimize spillage.
- I. Use of close feed system into batch reactors.
- m. Venting equipment through vapour recovery system.

# **SCHEDULE-III** Details of Bank Guarantees:

Sr. No	Consent (C2E/ C2O /C2R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to E	Rs.5.0 Lakh	15 Days	Towards Compliance of consent conditions	CoU	31.05.2022

The above Bank Guarantee(s) shall be submitted by the applicant in favour of Regional Officer at the respective Regional Office within 15 days from the date of issue of Consent.

#### **BG Forfeiture History**

Srno.	Consent (C2E/C2O/C2R)	Amount of BG imposed	Submission Period	Purpose of BG	Amount of BG Forfeiture	Reason of BG Forfeiture	
	NA						
BG Return details							
				4.5.6			

Srno. Consent (C2E/C2O/C2R) BG imposed Purpose of BG Amount of BG Returned
NA

# SCHEDULE-IV

#### **General Conditions:**

- 1. The Energy source for lighting purpose shall preferably be LED based
- 2. The PP shall harvest rainwater from roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial applications within the plant
- 3. 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 sitting 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 MoEFCC, India on Environment (Protection) second Amendment Rules vide GSR 371(E) dated 17.05.2002 and its amendments regarding noise limit for generator sets run with diesel.
- 4. The applicant shall maintain good housekeeping.
- 5. 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.
- 6. 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.
- 7. 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.
- 8. 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).
- 9. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 10. The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification No. B-29016/20/90/PCI-L dated. 18.11.2009 as amended.
- 11. 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 an extension or addition thereto.

- 12. 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.
- 13. The PP shall provide personal protection equipment as per norms of Factory Act
- 14. Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 15. 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.
- 16. 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.
- 17. The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the Hazardous and Other Wastes (M & TM) Rules 2016, 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.
- 18. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 19. 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).
- 20. 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.
- 21. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 22. The industry should not cause any nuisance in surrounding area.
- 23. 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.
- 24. The industry shall create the Environmental Cell by appointing an Environmental Engineer, Chemist and Agriculture expert for looking after day to day activities related to Environment and irrigation field where treated effluent is used for irrigation.
- 25. 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.

- 26. The industry should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 and submit the Annual Returns as per Rule 6(5) & 20(2) of Hazardous and Other Wastes (M & TM) Rules, 2016 for the preceding year April to March in Form-IV by 30th June of every year.
- 27. 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.
- 28. 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.
- 29. 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.
- 30. The firm shall submit to this office, the 30th day of September every year, the Environment 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.
- 31. 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.
- 32. 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).
- 33. 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.

This certificate is digitally & electronically signed.