

MAHARASHTRA POLLUTION CONTROL BOARD

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Kalpataru Point, 2nd, 3rd
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Mumbai-400022

ORANGE/L.S.I (O74)

Date: 26/03/2024

No:- Format1.0/CAC/UAN No.MPCB-
CONSENT_AMMENDMENT-0000010101/CR/2403000063

To,
M/s. Sandoz Private Limited
Plot No. 8-A/2, 8-B, MIDC T.T.C. Ind. Area,
Kalwe Block, Village, Digha Naka, Navi Mumbai,
Dist-Thane, Maharashtra 400708



Your Service is Our Duty



Sub: Grant of Amendment in Renewal of Consent to Operate under ORANGE/LSI

- Ref:**
1. Renewal of Consent to Operate accorded vide No. Format 1.0/CC/UAN No. MPCB-CONSENT-0000123256/CR/2203001190, dated 23/02/2022, which is valid upto 30/04/2026.
 2. Minutes of 32nd Consent Committee meeting (2023-24) held on 06/03/2024.

Your application No.MPCB-CONSENT_AMMENDMENT-0000010101 Dated 10.01.2023

For: grant 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 6 and Rule 18(7) 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 renewal is granted for a period up to 30/04/2026**
2. **The capital investment of the project is Rs.503.64 Crs. (As per C.A Certificate submitted by industry)**
3. **Consent is valid for the manufacture of:**

Sr No	Product	Maximum Quantity	UOM
Products			
1	Pharmaceuticals Formaulations such as Tablets and capsules	500	Million Nos./M

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	220	As per Schedule - I	CETP
2.	Domestic effluent	80	As per Schedule - I	CETP

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	1	As per Schedule -II
2	S-2	DG Set 1500KVA	1	As per Schedule -II
3	S-3	DG Set 1500KVA	1	As per Schedule -II
4	S-4	DG Set 1500KVA	1	As per Schedule -II
5	S-5	DG Set 1010KVA	1	As per Schedule -II
6	S-6	Fire Engine	1	As per Schedule -II
7	S7 to S-16	Process Vent (Scrubber)	10	As per Schedule -II

6. **Non-Hazardous Wastes:**

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	Packaging (waste)	300	MT/A	Scrap	Authorized waste handler
2	Non Packaging waste	250	MT/A	Scrap	Authorized waste handler

7. **Conditions under Hazardous & Other Wastes (M & T M) Rules 2016 for Collection, Segregation, Storage, Transportation, Treatment and Disposal of hazardous waste:**

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
1	3.3 Sludge and filters contaminated with oil	1	MT/A	Incineration	CHWTSDF
2	5.1 Used or spent oil	4	MT/A	Recycle	Sale to authorised party
3	5.2 Wastes or residues containing oil	2	MT/A	Incineration	CHWTSDF
4	28.1 Process Residue and wastes	20	MT/A	Incineration	CHWTSDF
5	28.5 Date-expired products	60	MT/A	Incineration	CHWTSDF
6	28.4 Off specification products	60	MT/A	Incineration	CHWTSDF
7	28.6 Spent organic solvents	20	MT/A	Incineration	CHWTSDF
8	33.1 Empty barrels /containers /liners contaminated with hazardous chemicals /wastes	35	MT/A	Recycle*	Sale to authorised party / CHWTSDF
9	Soot from Boiler stack	2	MT/A	Incineration	CHWTSDF
10	35.2 Spent ion exchange resin containing toxic metals	2	MT/A	Incineration	CHWTSDF

Sr No	Category No./ Type	Quantity	UoM	Treatment	Disposal
11	35.3 Chemical sludge from waste water treatment	20	MT/A	Landfill/ Incineration	CHWTSDf
12	35.4 Oil and grease skimming	1	MT/A	Incineration	CHWTSDf
13	33.2 Contaminated cotton rags or other cleaning materials	20	MT/A	Incineration	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. Conditions under E-Waste Management:

Sr No	Type of Waste	Quantity	UoM	Disposal Path
1	E-Waste	2.00	MT/A	Sale to Authorized recyclers/dismantler

9. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding on the industry.
10. This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.
11. The industry shall obtain necessary permission from the Directorate of Industrial Safety and Health (DISH).
12. The applicant shall not carry out any excess production or produce new products without Consent of the Board and without Environmental Clearance wherever it applicable.
13. The applicant shall properly collect, transport & regularly dispose-off the Hazardous Waste to CHWTSDf, in compliance of the Hazardous and other Waste (M & TH) Rule-2016 and keep proper manifest thereof.
14. Industry shall comply with direction issued to CETP, regarding installation of two-way SCADA, Auto-sampler, Non-Return Valve (NRV) with positive discharge to CETP chamber.
15. 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.
16. This consent is issued pursuant to the decision of the 32nd Consent Committee Meeting held on 06/03/2024
17. This consent is issued with overriding effect to earlier Renewal of Consent to Operate accorded vide No. Format 1.0/CC/UAN No. MPCB-CONSENT-0000123256/CR/2203001190, dated 23/02/2022, which is valid upto 30/04/2026.
18. The applicant shall make an application for renewal of consent 60 days prior to date of expiry of the consent.

Received Consent fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	2014560.00	MPCB-DR-8320	13/10/2021	NEFT

Copy to:

1. Regional Officer, MPCB, Navi Mumbai and Sub-Regional Officer, MPCB, Navi Mumbai
II
- 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 provided Effluent Treatment Plant (ETP) of designed capacity of 400.00 CMD consisting of for the treatment of 220 CMD of trade effluent.
- 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	Limiting concentration not to exceed in mg/l, except for pH
(1)	pH	5.5 to 8.5
(2)	Oil & Grease	10 mg/l
(3)	BOD (3 days 27°C)	30 mg/l
(4)	Total Suspended solids	100 mg/l
(5)	Total Dissolved solids	2100 mg/l
(6)	COD	250 mg/l
(7)	Chloride	600 mg/l
(8)	Sulphate	1000 mg/l

- C] The treated effluent 300 CMD (Industrial 220 CMD + Sewage 80 CMD) shall be discharged to CETP by achieving CETP outlet standards. In no case, treated effluent shall find its way outside factory premises.
2. A] As per your application, primary treated sewage connected to Effluent Treatment Plant for further treatment & disposal.
- B] Industry shall comply prescribed standards & disposal path as prescribed at Sr. No. 1 B & C of schedule I.
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 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	180.00
2.	Domestic purpose	80.00

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	200.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Gardening	60

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:

- As per your application, you have provided the Air pollution control (APC) system and erected following stack (s) to observe the following fuel pattern:

Stack No.	Source	APC System provided/proposed	Stack Height(in mtr)	Type of Fuel	Sulphur Content(in %)	Pollutant	Standard
S-1	Boiler	Stack	33.00	PNG 154 SCM/Day	-	TPM	50 Mg/Nm ³
				LDO 100 Ltr/Hr	1.8	SO2	86.40 Kg/Day
S-2	DG(Used in case of power failure)	Acoustic Enclosure	30.00	HSD 250 Ltr/Hr	1.0	TPM	50 Mg/Nm ³
						SO2	120 Kg/Day
S-3	DG(Used in case of power failure)	Acoustic Enclosure	30.00	HSD 250 Ltr/Hr	1.0	TPM	50 Mg/Nm ³
						SO2	120 Kg/Day
S-4	DG(Used in case of power failure)	Acoustic Enclosure	30.00	HSD 250 Ltr/Hr	1	TPM	50 Mg/Nm ³
						SO2	120 Kg/Day
S-5	DG(Used in case of power failure)	Acoustic Enclosure	16.00	HSD 170 Ltr/Hr	1	TPM	50 Mg/Nm ³
						SO2	34.80 Kg/Day
						TPM	-
S-6	Fire Engine	Stack	16.00	HSD 10 Ltr/Hr	1	TPM	50 Mg/Nm ³
						SO2	34.80 Kg/Day
S-7 To S-16	Scrubber-10 Nos.	Scrubber	11.00	-	-	HCL	35 Mg/Nm ³

- 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.
- 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.
- 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:

Sr. No.	Consent(C2E/C2O/C2R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to R	5.0 Lakh	Existing (To be extended)	Towards O&M of Pollution control system and compliance of consent conditions	30/4/2025	31/8/2025

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

Existing BG obtained for above purpose if any may be extended for period of validity as above.

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

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

SCHEDULE-IV

General Conditions:

1. Consumers or bulk consumers of electrical and electronic equipment listed in Schedule I shall ensure that e-waste generated by them is channelised through collection centre or dealer of authorised producer or dismantler or recycler or through the designated take back service provider of the producer to authorised dismantler or recycler
2. Bulk consumers of electrical and electronic equipment listed in Schedule I shall maintain records of e-waste generated by them in Form-2 and make such records available for scrutiny by the concerned State Pollution Control Board
3. Consumers or bulk consumers of electrical and electronic equipment listed in Schedule I shall ensure that such end-of-life electrical and electronic equipment are not admixed with e-waste containing radioactive material as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and rules made there under;
4. Bulk consumers of electrical and electronic equipment listed in Schedule I shall file annual returns in Form-3, to the concerned State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates. In case of the bulk consumer with multiple offices in a State, one annual return combining information from all the offices shall be filed to the concerned State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates.
5. Specific Conditions for storage, Handling and Disposal of Waste from Electrical & Electronic equipment (WEEE):

1. **Collection of WEEE** - The applicant must provide appropriate and dedicated vehicles duly identified as per the norms for transportation of Hazardous Waste. The applicant shall obtain all the required permits for transportation of WEEE from competent authority. The applicant shall ensure the safe transport of the WEEE without any spillage during transportation.

Storage for disassembled parts: The applicant must provide appropriate storage for disassembled spare parts from WEEE. Some spare parts (e.g. motors and compressors) will contain oil and/or other fluids. Such part must be appropriately segregated and stored in containers that are secured such that oil and other fluids cannot escape from them. These containers must be stored on an area with an area with an impermeable surface and a sealed drainage system.

2. **Storage for other components and residues:** Other components and residues arising from the treatment of WEEE will need to be contained following their removal for disposal or recovery. Where they contain hazardous substances they should be stored on impermeable surface and in appropriate containers or bays with weatherproof covering. Containers should be clearly labelled to identify their contents and must be secured so that liquids, including rain water cannot enter them. Components should be segregated having regard to their eventual destinations and the compatibility of the component types. All batteries should be handled and stored having regard to the potential fire risk associated with them.
3. **Balances :** WEEE Guidelines also requires that sites for handling of WEEE have "balances to measure the weight of the segregated waste". The objective is to ensure that a record of weights can be maintained of WEEE entering a facility and components and materials leaving each site (together with their destinations). The nature of the weighing equipment should be appropriate for the type and quantity of WEEE being processed.

4. Plastic, which cannot be recycled and is hazardous in nature, is recommended to be land filled in nearby CHWTSDf.
 5. Ferrous and nonferrous metal recycling facilities fall under the purview of existing environmental regulations for air, water, noise, land and soil pollution and generation of hazardous waste and the same should be followed.
 6. CFCS should be either reused or incinerated in common hazardous waste Incineration facilities at CHWTSDf.
 7. Waste Oil should be either reused or incinerated in common hazardous waste incineration facilities.
 8. PCB's containing capacitors shall be incinerated in common hazardous waste incineration facilities at CHWTSDf.
 9. Mercury recovery and lead recycling facilities from batteries fall under the Hazardous & Other Wastes (M & TM) Rules, 2016.
 10. Existing environmental regulations for air; water; noise, land and soil pollution and generation of hazardous waste and the same should be followed. In case Mercury or lead recovery is very low, they can be temporarily stored at e-waste recycling facility and later disposed in TSDF.
 11. The industry shall maintain records of the e-waste purchased, processed in Form-2 and shall file annual returns of its activities of previous year in Form-3 as per Rules 11(9) & 13(3)(vii) of the E-Waste(M) Rules, 2016; on or before 30th day of June of every year.
6. The Energy source for lighting purpose shall preferably be LED based
 7. 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
 8. 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 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.
 9. The applicant shall maintain good housekeeping.
 10. 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.

11. 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.
12. 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.
13. 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).
14. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
15. 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.
16. 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.
17. 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.
18. The PP shall provide personal protection equipment as per norms of Factory Act
19. Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
20. 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.
21. 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.
22. 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.
23. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
24. 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).

25. 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.
26. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
27. The industry should not cause any nuisance in surrounding area.
28. 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.
29. 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.
30. 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.
31. 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.
32. 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.
33. 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.
34. 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.
35. 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.
36. 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.
37. 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).

38. 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.

