

MAHARASHTRA POLLUTION CONTROL BOARD

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ORANGE/L.S.I (O74)
No:- Format1.0/CC/UAN
No.0000013893/CO/2410000071

Date: 22/10/2024

To,
ALKEM LABORATORIES LTD
Plot No C-6/1 & C-6/2, MIDC Taloja
Tal Panvel, Dist Raigad.



Sub: Grant of Amendment in Consent to 1st Operate by amalgamation along with Renewal of Combined Consent to Operate and BMW Authorization under ORANGE/LSI.

- Ref:**
1. Consent to 1st Operate accorded vide No. Format1.0/AS(T)/UAN No. 0000133708/CO/2211001969, dated 24/11/2022, which was valid upto 30/09/2024.
 2. Renewal of Combined Consent & BMW authorization (CCA) accorded vide No. Format1.0/CAC/UAN No. 0000098217/CR-2108000576, dated 10/08/2021, which is valid upto 01/10/2025.
 3. Minutes of 8th Consent Committee meeting of 2024-2025 held on 09/09/2024.

Your application No.MPCB-SENT_AMMENDMENT-0000013893 Dated 26.06.2024

For: grant of Combined Consent to Operate and BMW 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 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 operate is granted for a period up to 30/09/2029**
2. **The capital investment of the project is Rs.205.3917 Crs. (CI (Pharma) is-Rs. 82 Crs + C.I. (112 bedded hospital) is - Rs. 123.3917 Crs)**
3. **Consent is valid for the manufacture of:**

Sr No	Product	Maximum Quantity	UOM
Products			
1	Pharmaceuticals R & D Activity	0	--NA--
2	(112 nos. of beds as per BNH certificate No. 4-14/2015/BA-BE/45 DGCI approval) For Clinical Research & Bioequivalence study.	0	--NA--

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	90	As per Schedule -I	At sister concern unit on Plot No C-17/7 MIDC Taloja for treatment & disposal
2.	Domestic effluent	45	As per Schedule - I	At sister concern unit on Plot No C-17/7 MIDC Taloja for treatment & disposal

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	0	0	0	As per Schedule -II

6. **Non-Hazardous Wastes:**

Sr No	Type of Waste	Quantity	UoM	Treatment	Disposal
1	Glass	500	Kg/M	Sale	Sale to authorized party
2	Metal scrap	2000	Kg/M	Sale	Sale to authorized party
3	Paper	250	Kg/M	Sale	Sale to authorized party

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	28.4 Off specification products	5	MT/A	Co-Processing through authorized pre-processor/Incineration	Other
2	28.5 Date-expired products	5	MT/A	Co-Processing through authorized pre-processor/Incineration	Other
3	29.4 Spent solvents	25	KL/A	Recycle*	Sale to authorised party / CHWTSDF
4	35.3 Chemical sludge from waste water treatment	3	MT/A	Landfill	CHWTSDF
5	5.1 Used or spent oil	1200	Ltr/A	Co-Processing through authorized pre-processor/Recycle*/Incineration	Co-Processing through authorized pre-processor/Sale to authorized party/CHWTSDF

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

8. **Conditions under Plastic Waste Management Rules, 2016 (Notification dtd. 18/03/2016):**

Sr No	Type of Waste	Quantity	UoM	Disposal Path
1	Plastic	300.00	Kg/M	Authorized Recycler

9. **Treatment and Disposal of Biomedical Waste generated to CBMWTSDf:**

Sr.No	Category	Type of Waste	Quantity not to exceed (Kg/M)	Segregation Color coding	Treatment & Disposal
1	Yellow	a) Soiled Waste	100.00	Yellow colored non- chlorinated plastic bags	CBMWTSDf
		b) Expired or Discarded Medicines	25.00		
		c) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	250.00		
		d) Microbiology Biotechnology and other clinical laboratory waste	250.00		
2	Red	Contaminated waste (Recyclable)	250.00	Red colored non chlorinated plastic bags or containers	CBMWTSDf
3	White (Translucent)	Waste sharps including Metals	200.00	Puncture proof, Leak proof, tamper proof container	CBMWTSDf
4	Blue	a) Glassware	30.00	Puncture proof & leak proof boxes or containers with blue colored marking.	CBMWTSDf

10. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding on the industry.
11. This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.
12. The industry shall obtain necessary permission from the Directorate of Industrial Safety and Health (DISH).
13. This consent is issued with overriding effect on earlier Consent to 1st Operate accorded vide No. Format1.0/AS(T)/UAN No. 0000133708/CO/2211001969, dated 24/11/2022, which was valid upto 30/09/2024 & Renewal of Combined Consent & BMW authorization (CCA) accorded vide No. Format1.0/CAC/UAN No. 0000098217/CR-2108000576, dated 10/08/2021, which is valid upto 01/10/2025.

14. This consent is issued pursuant to the decision of the 8th Consent Committee Meeting (2024-2025) held on 09/09/2024.
15. 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.
16. 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.
17. 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.
18. M/s. ALKEM LABORATORIES LTD Plot No C-6/1 & C-6/2, MIDC Talaja Tal Panvel, Dist Raigad and its sister concern unit M/s. ALKEM LABORATORIES LTD Plot No C-17/7, MIDC Talaja, Tal Panvel, Dist Raigad shall sign bi-lateral agreement for joint and severally responsibility for the use of ETP. If M/s. ALKEM LABORATORIES LTD Plot No C-17/7 fails to achieve the discharge standard prescribed in the consent, then M/s. ALKEM LABORATORIES LTD, Plot No C-6/1 & C-6/2, MIDC Talaja Tal Panvel, Dist Raigad should stop the manufacturing activity. In case of non-compliance, both units will be jointly & severally liable for the any legal action.
19. You shall adhere to the BMW Generation quantity and storage conditions as specified in Schedule-I of BMW Management Rules, 2016, as amended.
20. You shall segregate and handover BMW to BMW T&D CTF Mumbai Waste Management Ltd, Talaja, Navi Mumbai Strictly complying with the Provisions of Schedule-I and Maintain record of the same
21. The applicant shall make an application for renewal of consent 60 days prior to date of expiry of the consent.

This consent is issued on the basis of information/documents submitted by the Applicant/Project Proponent, if it has been observed that the information submitted by the Applicant/Project Proponent is false, misleading or fraudulent, the Board reserves its right to revoke the consent & further legal action will be initiated against the Applicant/Project Proponent.

Received Consent fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	625000.00	MPCB-DR-10932	23/03/2022	NEFT
2	2747644.69	MPCB-DR-29463	01/10/2024	NEFT

Copy to:

1. Regional Officer, MPCB, Navi Mumbai and Sub-Regional Officer, MPCB, Talaja
- 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) at at sister concern unit located on Plot No C-17/7 MIDC Talaja for treatment & disposal of effluent.
 - B] The Industry shall ensure connectivity online monitoring system to the MPCB server including separate energy meter for pollution control system.
 - C] The generated effluent shall be sent to sister concern unit located on Plot No C-17/7 MIDC Talaja for treatment & disposal. Industry shall comply with discharge standards prescribed in consent accorded vide No. Format1.0/RO/UAN No. MPCB-CONSENT_AMMENDMENT-000001429/CR/2408000035, dated 14/08/2024. In no case, effluent shall find its way outside factory premises.
 - D] M/s. ALKEM LABORATORIES LTD Plot No C-6/1 & C-6/2, MIDC Talaja Tal Panvel, Dist Raigad and its sister concern unit M/s. ALKEM LABORATORIES LTD Plot No C-17/7, MIDC Talaja, Tal Panvel, Dist Raigad shall sign bi-lateral agreement for joint and severally responsibility for the use of ETP. If M/s. ALKEM LABORATORIES LTD Plot No C-17/7 fails to achieve the discharge standard prescribed in the consent, then M/s. ALKEM LABORATORIES LTD, Plot No C-6/1 & C-6/2, MIDC Talaja Tal Panvel, Dist Raigad should stop the manufacturing activity. In case of non-compliance, both units will be jointly & severally liable for the any legal action.
2.
 - A] As per your application, you have provided Sewage Treatment Plant (STP) at at sister concern unit located on Plot No C-17/7 MIDC Talaja for treatment & disposal of Sewage.
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	20.00
2.	Domestic purpose	50.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	70.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
5.	Gardening	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.
7. All Health Care Facilities irrespective of the bed capacity shall install scientifically designed disinfection facilities before discharging the effluent into sewer line or reuse in the premises as stipulated under Schedule II (6) of Biomedical waste Management Rules, 2016



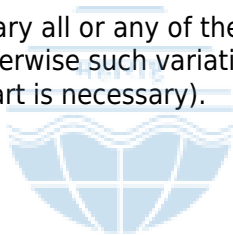
SCHEDULE-II

Terms & conditions for compliance of Air Pollution Control:

1. As per your application, you have provided the Air pollution control (APC) system and 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
S1	DG SET (1500 KVA)	Acoustic Enclosure	30.00	HSD 300 Kg/Hr	1	TPM	50 Mg/Nm ³
						SO ₂	48 Kg/Day
S2	DG SET (750 KVA)	Acoustic Enclosure	8.50	HSD 120 Kg/Hr	-	TPM	50 Mg/Nm ³
						SO ₂	19.2 Kg/Day

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).



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 O (existing to be extended)	Rs. 10 Lakh	15 days	Towards compliance of consent conditions.	30/09/2029	30/09/2030
2	CCA (existing to be extended)	Rs. 50,000/-	15 days	To Segregate and Handle BMW as per conditions of Authorization/BMW Rules	30/09/2029	30/09/2030
3	CCA (existing to be extended)	Rs. 50,000/-	15 days	Towards Operation and Maintenance of STP/ETP to achieve prescribed discharge standards	30/09/2029	30/09/2030
4	CCA (existing to be extended)	Rs. 25,000/-	15 days	To Maintain records of BMW and submission of Annual Report in Form -II before 31st January	30/09/2029	30/09/2030
5	CCA (existing to be extended)	Rs. 25,000/-	15 days	To maintain records of BMW handed over to CBMWTF	30/09/2029	30/09/2030

** 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. The waste generator shall.-
 - a) take steps to minimize generation of plastic waste and segregate plastic waste at source in accordance with the Plastic Waste Management Rules, 2016 or as amended from time to time.
 - b) not litter the plastic waste and ensure segregated storage of waste at source and handover segregated waste to urban local body or gram panchayat or agencies appointed by them or registered waste pickers', registered recyclers or waste collection agencies;
2. All institutional generators of plastic waste, shall segregate and store the waste generated by them in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time and handover segregated wastes to authorized waste processing or disposal facilities or deposition centers either on its own or through the authorized waste collection agency.
3. All waste generators shall pay such user fee or charge as may be specified in the byelaws of the local bodies for plastic waste management such as waste collection or operation of the facility thereof, etc.;
4. Every person responsible for organizing an event in open space, which involves service of food stuff in plastic or multilayered packaging shall segregate and manage the waste generated during such events in accordance with the Plastic Waste Management Rules, 2016 amendment from time to time.
5. The Energy source for lighting purpose shall preferably be LED based
6. 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
7. 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.
8. The applicant shall maintain good housekeeping.

9. 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.
10. 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.
11. The Board reserves the right to review, amend, suspend, revoke this consent and the same shall be binding upon you.
12. 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).
13. The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
14. 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.
15. This consent should not be construed as exemption from obtaining necessary NOC/ permission from any other Government authorities.
16. 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.
17. You shall ensure collection, and segregation of BMW regularly to treat and dispose Off within 48 hrs from generation.
18. 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.
19. 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.
20. 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.
21. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
22. You shall not Rent, Lend, Sell, Transfer or Close Down the facility or otherwise transport the Bio Medical waste for any other purpose without obtaining prior written permission of the MPC Board.

23. 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.
24. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
25. The industry should not cause any nuisance in surrounding area.
26. 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.
27. You shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the facility premises.
28. 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.
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. 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
30. 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.
31. 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.
32. 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.
33. 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.
34. 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).
35. 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.

36. You shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or 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.
37. You 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).
38. You shall create the Environmental Cell by appointing an Environmental Engineer and Chemist for looking after day-to-day activities related to compliance of CCA.
39. You should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 , Bio Medical Waste Management 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 in Form-IV by 30th June of every year
40. You shall handover Bio Medical waste only to MPCB Authorized Common Bio medical waste treatment and Disposal facility Mumbai Waste Management Ltd, Taloja, Navi Mumbai and maintain records thereof for 5 years.
41. You shall ensure segregation of Bio-Medical Waste in colour coded bags as per BMW Management Rules, 2016
42. You shall ensure use of colour coded bins and bags for segregation of BMW as required under BMW Management Rules 2016.
43. You shall not mix General/other Solid waste with Bio Medical Waste.
44. You shall pay the charges to authorized Common Bio Medical waste Treatment and Disposal facility for its services as agreed upon during the membership registration or as amended.
45. You shall comply and strictly abide with the conditions stipulated in BMW Management Rules, 2016 as amended time to time.
46. You are responsible to submit application for renewal of Combined Consent & Biomedical Waste authorization before 60 days of expiry

This certificate is digitally & electronically signed.
