

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: 24010706/24010437
Fax: 24023516
Website: <http://mpcb.gov.in>
Email: cac-cell@mpcb.gov.in



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

RED/M.S.I

Date: 04/11/2022

No:- Format1.0/CC/UAN No.0000136695/CO/2211000316

To,
MACLEODS PHARMACEUTICALS LTD.
PLOT NO.95, ROAD NO.16, OPP. SUNCITY HOTEL, MAROL MIDC,
ANDHERI EAST
ANDHERI,
Mumbai Suburban-400093
Email: drashish@macleodspharma.com
Contact No.: 9867023914



Your Service is Our
Duty

Combined Consent to 1st Operate and BMW Authorization (CCA) under the provisions of Water (P & CP) Act, 1974, Air (P & CP) Act, 1981 and Bio-Medical Waste Management Rules, 2016 as amended and Hazardous Waste (M & TM) Rules, 2016.

- Ref:**
1. Bio-Medical Waste Authorization granted by the Board vide no.MPCB/SROM-II/BMW/Autho-368/MU-5521-14 dated 28.01.2014, MPCB/SROM-II/BMW/Autho-369/MU-5520-14 dated 28.01.2014, MPCB/SROM-II/BMW/Autho-223 dated 31.10.2015
 2. Your application for Combine Consent and Bio-Medical Waste Authorization dated 18/04/2022
 3. Minutes of 11th CC meeting held on 01.08.2022
 4. Your reply vide mail dated 29.08.2022,30.08.2022

After examining the proposal, The Maharashtra Pollution Control Board hereby grant 1st operate Combined Consent and BMW Authorization to HCE under Section 25/26 of the Water (P&CP) Act, 1974, Section 21 of the Air (P&CP) Act, 1981 and Bio-Medical Waste Management Rules, 2016, and Authorization under Rule 5 of the Hazardous Wastes (Management & Transboundary Movement) Rules, 2016 respectively, under Environment (Protection) Act, 1986, subject to terms and conditions as specified below and in the **Schedules(I-IV) and Annexures (I-II)** enclosed in this order.

1. This CCA shall be in force for a period From **13-01-2020** To **13-01-2025**
2. The capital investment of the HCF is **₹1803.00** Lakhs (As per C.A Certificate Submitted by HCF)
3. HCF Area: - Plot Area 1000.00 M² with Built-up area 1389.40 M².
4. **Activities Included**
 - a Research & Development Activity
Clinical Facility
 - b Bioequivalence Study
 - c. Total Number of Beds : **114 Nos.** BABE/2020/0018

I. General Beds : **114 Nos**

5. Conditions under the Water (P&CP) Act, 1974:-

1. Quantity of total water consumption shall not exceed 8.00 M³/day. You shall not use the ground water without obtaining prior permission of Central Ground Water Authority.
2. You shall provide adequate treatment & disposal facility for Sewage & Effluent generated as specified in **Annexure-I**
3. You shall provide water meter at water intake point & at sewage/Effluent disposal point and shall maintain monthly records thereof.

6. Conditions under the Air (P&CP) Act,1981:-

1. You shall use the fuel for DG set as specified in the **Annexure-II**.
2. You shall provide adequate emission control system to DG set as specified in **Annexure-II**.
3. You shall strictly observe noise standards applicable for DG set stack emission and ambient noise level as per **Annexure-II**.

7. Conditions under Hazardous and Other Wastes(Management, Handling & Transboundary Movement) Rules, 2016 for treatment and disposal of hazardous waste:-

You shall have valid membership of CHWTSDF and shall dispose the Hazardous waste generated in strict compliance with said rules and maintain record thereof.

Sr No	Type of Waste	HW Category no.	Quantity	UOM	Disposal
1		HTNA	As per Actual	--NA--	NA

8. Conditions under Solid Waste Management rules 2016

1. You Shall Handover Solid waste (Other Than BMW) to Local bodies as per provisions of SWM Rules, 2016.
2. You shall Not mix general solid waste with Bio Medical Waste.

9. Conditions under BMW Management rules, 2016 (As Amended):-

1. You shall adhere to the BMW Generation quantity and storage conditions as specified in Schedule-I of BMW Management Rules, 2016, as amended.
2. You shall segregate and handover BMW to BMW T&D CTF **SMS ENVOCLEAN PVT. LTD, Mumbai** Strictly complying with the Provisions of Schedule-I and Maintain record of the same.
3. **Cytotoxic Drugs/ Waste:** You shall have separate storage, marked with the symbol of Bio Hazard & Cytotoxic Hazard for outdated, discarded, unused cytotoxic drugs/waste and submit details of Management and Handling of outdated, discarded, unused Cytotoxic drugs in the format prescribed by CPCB which is available on www.cpcb.nic.in along with Annual Report to MPCB with a copy to CPCB before 30th June of every year.
4. **Mercury Waste:** You shall manage the Mercury Waste in HCE in environmentally sound manner (including storage, spilled collection, transportation and disposal) as per guidelines published by CPCB as detailed in document entitled "Environmentally Sound Management of Mercury Waste in Health Care Facilities" (www.cpcb.nic.in).

10. You shall not undertake Modifications/ Upgradation in existing facility without obtaining prior Environment Clearance under the Provision of EIA notification, 2006 Or Consent to Establish from the MPC Board as applicable.

11. Any unauthorized change in Location, Name, personnel, equipment or working conditions as mentioned in the application by you shall constitute a breach of this CCA. In case of any change you shall apply fresh for CCA or amendment as applicable.
12. You shall not Rent, Lend, Sell, Transfer or Close Down the facility or otherwise transport / Handover the Bio-Medical waste generated for any other purpose without obtaining prior written permission of the MPC Board.
13. This Board reserves the right to review, amend, suspend, revoke, or change any of the conditions applicable under this CCA and the same shall be binding on the HCE.
14. You shall maintain records of MPC board Officers visit and shall obey all the lawful instructions issued by the Board Officers from time to time.
15. Any violation of provisions of BMW Management Rules, 2016 as amended shall attract the penal provisions of Environment (Protection) Act, 1986 and Violations under the provisions of Water (P&CP) Act 1974, Air (P&CP) act 1981 shall attract provisions of respective act including closure of the facility and prosecution.
16. This CCA shall not be construed as exemption from obtaining necessary NOC/permission from any other Government agencies as applicable.
17. You shall submit the bank guarantee of INR 2.5 lakh towards compliance of conditions as specified in Schedule III to The Regional Officer, MPCB, Mumbai within 30 days. Non submission of B.G. in specified time shall attract revocation of this CCA without further notice
18. HCE shall provide STP for treatment of sewage within a period of six months and submit BG of Rs 1 lakh towards the compliance of the same.

This consent is issued as per communication letter dated 03/11/2022 which is approved by competent authority of the board.



Received Consent/Authorization fee of -

Sr.No	Amount(Rs.)	Transaction/DR.No.	Date	Transaction Type
1	250000.00	TXN2204002005	18/04/2022	Online Payment
2	20000.00	TXN2208002998	26/08/2022	Online Payment
3	565750.00	TXN2208003001	26/08/2022	Online Payment
4	5000.00	TXN2204002007	18/04/2022	Online Payment

Copy to:

1. Regional Officer, MPCB, Mumbai and Sub-Regional Officer, MPCB, Mumbai II
- - They are directed to ensure the compliance of the consent conditions.
SRO They are directed to ensure the compliance of the consent conditions.
2. Cheif Accounts Officer, MPCB,Sion, Mumbai
3. I/C EIC- for record & website updating purpose.

Conditions under Water (P & CP), 1974 Act: (Refer Condition No. 5)

A. Water Consumption Details:-

Sr. No.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	0.00
2.	Domestic purpose	8.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	0.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Other such as agriculture, gardening, etc.	0.00

B. Conditions for Sewage & Effluent Generation, Treatment and Disposal:-

Sr. No.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1	Domestic Sewage	1.0	As per clause 'C'	Local sewer
2	Trade effluent	0	As per clause 'C'	NA

C. You shall operate the combined waste water treatment plant of adequate design and capacity to treat the domestic sewage and trade effluent so as to achieve the following standards as prescribed below under E (P) Act, 1986 and Rules made there under and recycle treated effluent after achieving standard prescribed below.

Sr. No.	Parameters	Discharge Standards applicable
		Limiting Concentration in mg/except for pH
1	pH	6.5-9.0
2	Oil & Grease	10
3	BOD (3 days 27°C)	30
4	COD	250
5	Total Suspended Solids	100
6	Bio-Assay Test	90 % survival of fish after 96 hours in 100 % effluent

D. You 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.

E. You shall provide Primary/ Secondary/ tertiary treatment system and disinfection facility.

F. The Applicant shall obtain prior consent of the Board to take steps for Expansion/Modification of any treatment and disposal system or an extension or addition thereto.

G. You shall provide Specific Water Pollution control system as per above conditions and conditions of Environmental Clearance, if applicable.

Terms & conditions for Incinerator(s) and D.G. Set(s) under Air (P & CP) Act, 1981 and Bio Medical waste management Rule, 2016: (Refer Condition No.6)

1. You shall observe following fuel pattern and erect following stack (s):

Sr. No.	Stack Attached to	Fuel Type	Quantity	Stack Height (Mtr)
1	DG 50 KVA	DIESEL	10.00 Ltr/Hr	11.00

2. The Applicant shall obtain prior permission of MPC board for providing additional control equipment with necessary specifications and operation thereof or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
3. 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, either in whole or in part as necessary).
4. Conditions for D.G. Set:-
- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically for control of noise.
 - 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.
 - You shall make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
 - Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
 - 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.
 - D.G. Set shall be operated only in case of power failure.
 - The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
 - The applicant shall comply with the notification of MoEFCC dated 17.05.2002 regarding noise limit for generator sets run with diesel.
5. You 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.

SCHEDULE-I**Authorization for Management of Bio-Medical Waste (Category and Quantity)**

The authorization is granted for Generation and Segregation of BioMedical Waste (BMW) in waste categories and quantities listed here in below:

Sr. No	Category	Type of Waste	Quantity not to exceed (Kg/Month)	Segregation Colour coding	Treatment & Disposal
1	Yellow	a) Human Anatomical waste	0.00	Yellow coloured non- chlorinated plastic bags.	Bio medical Waste shall be sent to MPCB authorized BMW-CTF SMS ENVOCLEAN PVT. LTD, Mumbai Mumbai
		b) Animal Anatomical Waste	0.00		
		c) Soiled Waste	130.00		
		d) Expired or Discarded Medicines	0.00		
		e) Chemical Waste	0.00	Separate collection system leading to effluent treatment system.	
		f) Chemical Liquid Waste	0.00		
		g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	0.00	Yellow coloured non - chlorinated plastic bags or suitable packing material.	
		h) Microbiology Biotechnology and other clinical laboratory waste	0.00	Autoclave safe plastic bags or containers.	
2	Red	Contaminated waste (Recyclable)	184.00	Red coloured non chlorinated plastic bags or containers.	Bio medical Waste shall be sent to MPCB authorized BMW-CTF SMS ENVOCLEAN PVT. LTD, Mumbai Mumbai
3	White (Translucent)	Waste sharps including Metals	20.00	Puncture proof, Leak proof, tamper proof container.	Bio medical Waste shall be sent to MPCB authorized BMW-CTF SMS ENVOCLEAN PVT. LTD, Mumbai Mumbai
4	Blue	a) Glassware	17.00	Puncture proof, Leak proof with Blue coloured marking.	Bio medical Waste shall be sent to MPCB authorized BMW-CTF SMS ENVOCLEAN PVT. LTD, Mumbai Mumbai
		b) Metallic body implants	0.00		

Responsibilities of the CTF Operator of the Facility

1. You shall handover Bio Medical waste only to MPCB Authorized Common Bio medical waste treatment and Disposal facility **SMS ENVOCLEAN PVT. LTD, Mumbai** and maintain records thereof for 5 years.
2. You shall establish bar code for handling of bio-medical waste.
3. You shall ensure segregation of Bio-Medical Waste in colour coded bags as per BMW Management Rules, 2016
4. You shall not store Bio Medical waste beyond 48 hours from the generation.
5. You shall use only non-chlorinated plastic coloured bags.
6. You shall ensure use of colour coded bins and bags for segregation of BMW as required under BMW Management Rules 2016.
7. You shall not mix General/other Solid waste with Bio Medical Waste.
8. You shall ensure segregation, treatment and disposal of General / Other Municipal solid waste as per Solid Waste Management rules, 2016.
9. 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.
10. You shall comply and strictly abide with the conditions stipulated in BMW Management Rules, 2016 as amended time to time.
11. You shall handover Plastic / Metal waste (BMW) to Common Bio medical waste treatment and Disposal facility allocated to you for treatment & disposal or plastic/metal recycler authorized by MPCB for BMW Handling and maintain records thereof & submit to MPCB in Annual report.
12. You shall provide training to all workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter and maintain record thereof.
13. You shall undertake appropriate medical examination of all BMW Waste handlers & staff at the time of induction and at least once in a year and immunize all involved in management of Bio Medical Waste for protection against diseases, including Hepatitis B and Tetanus, that are likely to be transmitted while handling bio medical waste and maintain the records for the same.
14. You shall ensure use of personal protective Equipment such as Heavy Duty Gloves (Workman's Gloves), Gum Boots or safety shoes for waste collectors, Face mask, Head Cap, Splash Proof Gowns or aprons etc., Disposal gloves by waste handlers.
15. You shall develop and operate own website. The website should be uploaded on monthly basis with all the information relating to Bio-Medical waste management including this CCA and other permission and report.
16. You shall maintain all record for Generation, for a period of five years and produce whenever asked by MPCB authorities.
17. The occupier and operator of a Health Care Establishment shall be liable for all the damages caused to the environment or the public due to improper handling of bio-medical wastes.
18. You shall ensure submission of Annual Report of BMW for the period Jan to Dec, including category and quantity of BMW Generated and Disposed in Form IV for preceding year before 30th June of every year to the Regional Office, MPCB, Mumbai and uploading the same to MPCB Portal (<https://www.ecmpcb.in/>).

Bank Guarantees

1. Bank Guarantee imposed to ensure timely compliance, to be observed by operator.

Sr.No	Activity / Condition to be Complied	Compliance Timeline (Months)	Bank Guarantee Amount
1A	Operation and Maintenance		
1	To Segregate and Handle BMW as per Schedule I	Continuous	50,000.00
2	Towards Operation and Maintenance of STP/ETP to achieve prescribed discharge standards	Continuous	50,000.00
1B	Records		
1	To Maintain records of BMW and submission of Annual Report for preceding calendar year in Form -IV before 30th June every year	Continuous	25,000.00
2	To maintain records of BMW handed over to CBMWTFD	Continuous	25,000.00
2	Performance		
1	To provide STP	Six months from date of issue of CCA.	100,000.00
Total			2,50,000.00

Note: You shall extend the previously submitted Bank Guarantee valid upto the validity of this CCA + 4 months additional.

General Conditions**The following general conditions shall apply:-**

1. You 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.
2. Whenever due to any accident or other unforeseen act or event, 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, Executive Engineer MIDC and Local Body. In case of failure of pollution control equipment's, the process connected to it shall be stopped.
3. You 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 operation to abide by terms and conditions of this consent.
4. You 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 15 of the Environment (Protection) (Second Amendment) Rules, 1992.
5. You shall comply with the Hazardous Waste (M, H & TM) Rules, 2016 and submit the Annual Returns as per Rule 20(2) of Hazardous Waste (M, H & TM) Rules, 2016 for the preceding year April to March in Form-IV by 30th June of every year to Regional Office, Mumbai.
6. You shall engage qualified staff/personnel/agency to see the day to day compliance of consent & authorization condition towards Environment Protection.
7. 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.
8. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the HCE.
9. You 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.
10. You should not cause any nuisance in surrounding area. You shall maintain good housekeeping.
11. You 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.
12. The non-hazardous solid waste arising in the HCE 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.
13. You shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification Dated. 16/11/2009 as amended.

14. You shall submit an official e-mail address and any change will be duly informed to the MPCB.
15. You shall observe provisions of E-waste (Management) Rules 2016 & as amended time to time and Batteries (Management and Handling) Amendment Rules, 2010.
16. An inspection book shall be opened and made available to the Board's officers during their visit to the HCE.
17. In case you use/ handle/ generate the cytotoxic waste you shall strictly adhere to the standards/ SOPs applicable and waste shall be labelled specifically as "Cytotoxic Waste" with symbol on waste containers/ bags and shall handover to BMW CTFs.
18. You shall obtain required permissions from competent authority for radio active material user/ handling/ disposal of waste before commencement of such activity.
19. The Energy source for lighting purpose shall preferably be LED based.
20. You 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
21. You shall provide personal protection equipment as per norms of Factory Act 1948
22. 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.

