

MAHARASHTRA POLLUTION CONTROL BOARD

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Kalpataru Point, 2nd - 4th Floor,
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Near Sion Circle, Sion (E)
Mumbai - 400 022

Red/LSI

Date: 26/11/2014

Consent No: Format 1.0/BO/PSO/CC-11139

To,
M/s. Watson Pharma Pvt. Ltd.,
T 351, T451-551 and 5th floor,
International Technology center,
CBD Belapur Railway Station complex,
Navi Mumbai-400 614
e-mail :santosh.ghoderao@watsompharm.co.in

Subject: Combined Consent to Operate and BMW Authorization under RED category to Health Care Establishment (HCE).

- Ref : 1. BMW Authorization vide No. MPCB/JD(PAMS)/ BMW/ NM-3404, dated 16.01.2012
2. Your BMW authorization application received to MPCB, HQ, Sion, Mumbai on 09.10.2014 vide FTS no. 140804ft0375
3. Consent granted by Board Vide No. BO/AS(T)/ EIC No. NM-4713-13/C & O/CC-9931, dated - 02.12.2013
4. Your BMW Consent application received to MPCB, HQ, Sion, Mumbai on 17.05.2013 vide FTS no. 140228ft0135
4. Your reply received vide letter dated 01.07.2014
5. Minutes of CC meeting dated- 05.11.2014

Consent to Operate

under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981, Authorization under Rule 5 of the Hazardous Wastes (M, H & T M) Rules 2008 and Biomedical Waste (Management and Handling) Rules 1998, as amended is considered and the consent is hereby granted subject to following terms and conditions and as detailed in the schedule I, II, III, IV & V annexed to this order:

1. The CCA to operate is granted for a period from 04.06.2012 upto 04.06.2015.
2. The capital investment of the HCE is Rs. 25.61 Cr.
(C. A. Certificate submitted by the HCE)
3. The Consent is valid for the Activity of -

Sr. No.	Activity	Beds
1	Hospital	
	a) Beds	108 Nos.
	b) Total Plot Area	N.A.
	c) Total Built up Area	2604.08 sq. mtrs

M/s. Watson Pharma Pvt. Ltd.- SRO Navi Mumbai/I/H/R/L/92802000

Page 1 of 10

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

Sr. no.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	Nil	N.A.	N.A.
2.	Domestic effluent	19.0	As per Schedule -I	Municipal Sewer

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

Sr. no.	Description of stack / source	Number of Stack	Standards to be achieved
1.	D.G. Set (160 KVA)	1 no.	As per Schedule - II
2.	D.G. Set (40 KVA)	1 no.	As per Schedule - II
3.	D.G. Set (40 KVA)	1 no.	As per Schedule - II
4.	D.G. Set (40 KVA)	1 no.	As per Schedule - II

6. Non-Hazardous Solid Wastes:

Sr. No.	Type of Waste	Quantity	UOM	Treatment	Disposal
1	Sludge from Sewage Water treatment	As per Actual	MT/year	--	Municipal Landfill

7. This Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.

8. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government agencies.

9. This consent is issued subject to conditions mentioned below,

i) The "authorized Person" Vice President, M/s. Watson Pharma Pvt. Ltd., Navi Mumbai shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.

ii) Any unauthorized change in equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.

iii) If built up area exceeds more than 20,000 sq. mtrs. and if the hospital is commissioned after 14.09.2006, the project proponent shall comply EIA Notification 14.09.2006

iv) The hospital authority has to submit a self attested undertaking on letter head signed by authorized person regarding non applicability of, RRZ, CRZ, existing built up area & a copy of valid Bombay Nursing Home registration.

iii) You shall submit details of Management and Handling of outdated, discarded, unused **Cytotoxic drugs** generated in the Cancer centers, research and health care

in the format prescribed by CPCB which is available on www.cpcb.nic.in alongwith Annual Report to MPCB with a copy to CPCB before 31st January every year.

- (iv) You shall manage the **Mercury Waste** in the HCE in environmentally sound manner including storage, spilled collection, transportation and disposal as per CPCB guidelines published CPCB website www.cpcb.nic.in dated:07.09.2010 as detailed in document entitled "Environmentally Sound Management of Mercury Waste in Health Care Facilities".
- (v) You shall submit **Bank Guarantee of Rs. 3.00 Lakhs** towards compliance of condition mentioned at Annexure – IV to Regional Office, Navi Mumbai within 30 days.
- (vi) You shall submit compliance of Bank Guarantee conditions every six months to Regional Officer, Aurangabad for verification purpose.
- (vii) You shall submit application for renewal of Combined Consent and Biomedical Waste authorization before 120 days along with appropriate fees.

For and on behalf of the
Maharashtra Pollution Control Board


(Rajeev Kumar Mital)
Member Secretary

Received Consent / Authorization fee of –

Sr. No.	Amount (₹)	DD. No.	Date	Drawn On
1	2,25,100/-	446177	25.02.2014	HDFC Bank
2	15,000/-	364992	30.07.2014	HDFC Bank
The remaining fee of Rs. 11,247/- shall be considered while renewal of CCA				

Copy to:

1. Regional Officer – MPCB ,Navi Mumbai and Sub –Regional Officer – Navi Mumbai-I, MPCB – They are directed to ensure the compliance of the CCA conditions.
2. Chief Accounts Officer, MPCB, Mumbai- for information.

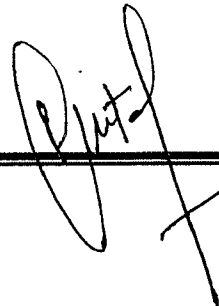
Schedule-I

D) Terms & Conditions for compliance of Water Pollution Control

- 1) A] You shall provide combined waste water primary treatment for the Trade effluent and domestic sewage generated from the hospital and thereafter the treated effluent shall be discharged in to Sewage Treatment Plant with the adequate design capacity followed by Chlorination and the treated water shall be disposal to Municipal Sewer / Land application after achieving standard prescribed below:
- B] The Applicant shall operate the combined waste water treatment plant to treat the trade and domestic effluent so as to achieve the following standards prescribed by the Board or under E P Act, 1986 and Rules made there under from time to time, whichever is stringent.

Sr. No.	Parameters	Discharge Standards applicable
		Limiting Concentration in mg/l, except for pH
01	pH	6.5-9.0
02	Oil & Grease	10
03	BOD (3 days 27°C)	30
05	COD	250
06	Total Suspended Solids	100
08	Bio-Assay test	90 % survival of fish after 96 hours in 100 % effluent

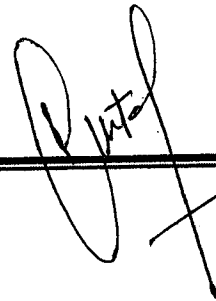
- C] The treated sewage shall be disposed on land for gardening/irrigation and excess shall be disposed to Municipal Sewage.
- 2) A] You shall provide ETP followed by sewage treatment plant (combined treatment) with the adequate design capacity.
- B] You shall operate the treatment plant so as to achieve the above discharge standards.
- 3) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waste water & the system for the disposal of effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps for expansion / modify or establish any modification to treatment and disposal system or an extension or addition thereto.
- 4) 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.
- 5) You shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time.



II) Conditions under Water (Prevention & Control of Pollution) CESS Act, 1977 as amended

The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 and as amended, by installing water meters, filing water cess returns in Form-I and other provisions as contained in the said act.

Sr. No.	Purpose for water consumed	Water Consumption quantity CMD
1.	Industrial Cooling and boiler feed etc.,	---
2.	Domestic purpose	20.0
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	--
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	---
5	Other such as agriculture, gardening, etc.	---



Schedule-II

Terms & conditions for compliance of Air Pollution Control

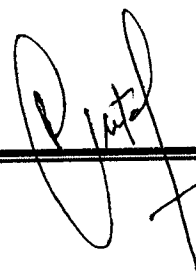
1. As per your application, you have proposed / provided the Air pollution control (APC) system and also proposed to erect/erected following stack (s) to observe the following fuel pattern-

Sr. No.	Stack Attached to	Height in meter	Type of Fuel	Quantity Kg/hr	UoM	S %	SO ₂ Kg/Day
1	D.G. Set (160 KVA)	1.10 Above the roof of building	HSD	36.0	kg/hr	--	--
2	D.G. Set (40 KVA)	0.70 Above the roof of building	HSD	7.0	kg/hr	--	--
3	D.G. Set (40 KVA)	0.70 Above the roof of building	HSD	7.0	kg/hr	--	--
4	D.G. Set (40 KVA)	0.70 Above the roof of building	HSD	7.0	kg/hr	--	--

2. The applicant shall provide stack height of 3.0 mtrs operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Particulate matter	Not to exceed	150 mg/Nm ³
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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).

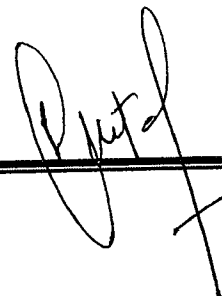


Schedule-III

Treatment and Disposal of Biomedical Waste generated from Hospital to CBMWTSDF

The authorisation is granted for generation and disposal of Bio-Medical Waste (BMW) to CBMWTSDF in waste categories and quantities listed here in below :

Sr. No.	Category	Description	Quantity not to exceed (Kg/M)	Segregation Colour coding	Treatment & Disposal
1	Cat-5	Discarded Medicines and Cytotoxic drugs	50.0	Yellow	Incineration
2	Cat-4	Waste Sharps	50	Blue / white translucent	Disinfection (chemical treatment) and mutilation / shredding
3	Cat-6	Soiled Waste	450.0	Yellow	Incineration
4	Cat-7	Solid Waste	400.0	Red.	Disinfection (chemical treatment) autoclaving / and mutilation / shredding shall be handed over to CBMWTSDF operator
No onsite treatment of BMW is permitted. The above mentioned Bio medical Waste shall be sent to Common BMW Treatment & Disposal facility authorised by MPCB i.e. M/s. Mumbai Waste Management, CBMWTSDF, Taloja, Navi Mumbai					



Schedule-IV : Bank Guarantees

Statement of conditions to be complied and Bank Guarantee imposed to ensure timely compliance to be observed by M/s. Watson Pharma Pvt. Ltd., Navi Mumbai

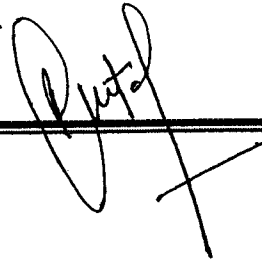
Sr. No.	Activity / Condition to be Complied	Compliance Timeline (Months)	Bank Guarantee Amount
I (A) Operation and Maintenance			
1	To Segregate and Handle BMW as per Rule	Continuous	50,000/-
2	Operation and Maintenance of combined waste water treatment plant to achieve prescribed discharged standards	Continuous	50,000/-
I (B) Records			
1	To Maintain records of BMW and submission of Annual Report in Form -II before 31 st January	Continuous	25,000/-
2	To maintain records of BMW material delivered to CBMWTSDF	Continuous	25,000/-
II Performance			
1	To provide Separate BMW storage facility As per guidelines of CPCB.	Six	50,000/-
2	To provide Effluent Treatment Plant	Six	1,00,000/-
		Total	3,00,000/-
Rupees Three Lakh only			



Schedule-V
General Conditions

The following general conditions shall apply as per the type of the industry

- 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) You should monitor effluent quality, stack emissions, noise and ambient air quality quarterly.
- 3) You 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.
- 4) 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.
- 5) 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 production to abide by terms and conditions of this consent.
- 6) 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 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- 7) You shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW (MH&TM) Rules 2008, 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.
- 8) You shall comply with the Hazardous Waste (M, H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Waste (M, H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the HCE.
- 10) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent (in case of Renewal of consent).
- 11) 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).
- 12) You shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent & authorization condition towards Environment Protection.
- 13) 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.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the HCE.



- 15) 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.
- 16) 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.
 - 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.
 - 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.
 - 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 MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel.
- 17) You should not cause any nuisance in surrounding area.
- 18) 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.
- 19) You shall maintain good housekeeping.
- 20) 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 by September end.
- 21) 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.
- 22) You 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. You will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 23) You shall submit quarterly statement in respect of obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can downloaded from MPCB official site).
- 24) You shall submit official e-mail address and any change will be duly informed to the MPCB.
- 25) You shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.
- 26) You shall observe provisions of E-waste (Management and Handling) Rules 2011 and Battery Waste (Management and Handling) Rules 2001, as amended.

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