

MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

Consent order No :- Formate 1.0/ BO/CAC-Cell/ EIC No PN-27554-15/15th CAC-6343
Date- 13/05/2016

To,
M/s Lupin Limited (Research Park)
46A/47A, Village -Nande
Tal-Mulshi Dist-Pune

Subject: 1st operate for R & D and renewal of existing consent and amalgamation of both the consents under RED category.

Ref : 1. Existing consent granted vide no Formate 1.0/BO/CAC-CELL/EIC No PN 21409-14/24th CAC- 2357 dated 02.03.2015.

2. Consent to establish granted vide no BO/ZO(PAMS)/RO-Pune/EIC PN- 8703-11/E/CC-37 dated 13.03.2011

3. Your application approved in CAC meeting held on 09.03.2016.

Your application: CO1512000325

Dated: 07.11.2015

For: 1st operate for R & D and renewal of existing consent and amalgamation of both the consents.

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 5 of the Hazardous Wastes (M, H & T M) Rules 2008 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 is granted for a period from 01.05.2016 to 30.04.2018.
2. The actual capital investment of the industry is Rs.734.3 Crs. (As per C.A.Certificate submitted by industry).
3. The Consent is valid for the manufacture of -

Sr. No.	Product / By-Product Name	Maximum Quantity
1.	Research & Development activity of pharmaceutical products	NA

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	340 *	As per Schedule -I	100% recycle
2.	Domestic effluent	195	As per Schedule -I	

*including 1 CMD received from sister concern M/s Lupin Ltd, Panchsheel Tech Park, Hinjewadi and 5 CMD effluent received from LBC Pashan facility).

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	DG sets (1500KVA, 625 KVA, 1010 KVA X 2, 2250 KVA X 2,	6	As per Schedule -II
2.	Incinerator(50 Kg/Hr.)	1	As per Schedule -II
3.	Boiler(3 TPH)	1	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Canteen waste	As and when generated	NA	for piggeries
2	Packing material, paper, card board	As and when generated	NA	Sale
3	MS metal scrap and Empty glass bottles	As and when generated	NA	sale

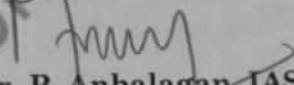
7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	Used oil/ Spent Oil	5.1	804	Lit/Month	NA	Sale to authorized Reprocessors / CHWTSDF for incineration
2	Spent organic solvents	28.5	As & when generated	NA	CHWTSDF	CHWTSDF for incineration
3	Discarded contains/liners/ barrels	33.3	43.44.	KL/Month	NA	Sale to authorized re-processor/ CHWTSDF for incineration
4	Chemical Sludge from Waste Water Treatment Plant	34.3	As and when generated	NA	In-house	Sale to authorized recycler after decontamination/ disposal to CHWTSDF for landfilling/ incineration
5	Process Residue & waste	28.1	57.60	MT/ Month	NA	CHWTSDF for land filling or

						incineration
6	Salts from ATDF	34.3	90	MT/ Month	NA	CHWTSDF for land filling

8. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
10. M/s Lupin Ltd (Research Park), Tal Mulshi shall sign bi-lateral agreement with M/s Lupin Ltd, Panchsheel Tech Park, Hinjewadi and M/s Lupin Bioresearch Center, Pashan, Pune for joint responsibility of the treatment of their effluent. If M/s Lupin Ltd (Research Park), Tal Mulshi fails to treat their effluent, M/s Lupin Ltd, Panchsheel Tech Park, Hinjewadi and M/s Lupin Bioresearch Center, Pashan, Pune should make their own arrangement for the treatment of effluent. In case of the non-compliance of proper O&M, discharging pollutants, both of them will be jointly & severally liable for the same & any legal obligation, action etc.
11. Industry shall comply the conditions of Environmental Clearance granted by GoM on 03.09.2012.

For and on behalf of the
Maharashtra Pollution Control Board


(Dr. P. Anbalagan, IAS)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	48,74,780/-	441141	05/11/2015	Citi Bank

Copy to:

1. Regional Officer -Pune and Sub-Regional Officer-Pune-2., MPCB, They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. CC/CAC desk- for record & website updation purposes.

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

- 1) A] As per your application, you have provided the 2 nos of Effluent Treatment Plant (ETP) with the design capacity of 250 CMD & 300 CMD. The treated effluent from the both the ETPs is led to two stage RO followed by MEE and ATFD.
- 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	Standards prescribed by Board (If any)
		Limiting Concentration in mg/l, except for pH
01	pH	5.5 - 9.0
02	Oil & Grease	10
03	BOD (3 days 27°C)	100
04	Total Dissolved Solids	2100
05	Mercury	0.01
06	Arsenic	0.20
07	Chromium (Hexavalent)	0.10
08	Lead	0.10
09	Cyanide	0.2
10	Phenolics (C ₆ H ₅ OH)	1.0
11	Sulphide (as S)	2.0
12	Suspended Solids	100
13	COD	250
14	Chloride	600
15	Sulphate	1000

- C) The treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way for gardening/outside factory premises. Total treated water recycled = 492.2 CMD where 33.6 CMD is recycled in process and 458.6 CMD in cooling towers.
- 2) A.] As per your consent application, you have provided the septic tank. The overflow of the septic tank is connected to ETP.
- B] In case the treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at sr. no.1 B & C of schedule I shall be applicable.
- 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

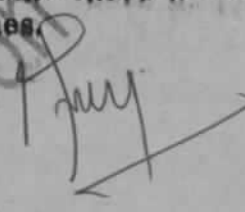
obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or/and extension or addition thereto.

- 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) 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, spraying in mine pits or boiler feed	0
2.	Domestic purpose	215
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	173.4
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0
5	Plantation/ Gardening	100

- 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.

Maharashtra Pollution Control Board



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 also erected following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO ₂ Kg/Day
1	DG set(1500KVA)	Stack	32	HSD	250 Lit/hr	0.25	26.4
2	DG set(625KVA)	Stack	10	HSD	150 lit/hr	0.25	15.8
3	DG set(1010 KVA) X2 Nos	Stack	32 (Each)	HSD	180 lit/hr (each)	0.25	19.0 each set
4	BMW Incinerator	Stack & Venturi with scrubber	30	HSD	30 lit/hr	0.25	3.36
5	Boiler (3TPH)	Stack	34	FO	200 Kg/Hr.	4.5	432
6	DG set (2250KVA)x 2nos.	Stack	30 (each)	HSD	547 Kg/hr (each)	0.25	65.76 (each)

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 operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

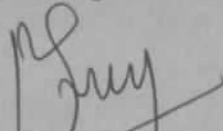
TPM	Not to exceed	150 mg/Nm ³ .
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4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
5. 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).

6. STANDARDS FOR INCINERATORS:

All incinerators shall meet the following operating and emission standards

A. Operating Standards



1. Combustion efficiency (CE) shall be at least 99.00%.

2. The Combustion efficiency is computed as follows:

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

3. The temperature of the primary chamber shall be 800 ± 50 deg. C^o.

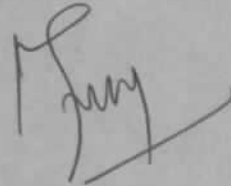
4. The secondary chamber gas residence time shall be at least I (one) second at 1050 ± 50 C^o, with minimum 3% Oxygen in the stack gas.

B. Emission Standards

Parameters	Concentration mg/Nm ³ at (12% CO ₂ correction)
(1) Particulate matter	150
(2) Nitrogen Oxides	450
(3) HCl	50
(4) Minimum stack height shall be 30 metres above ground	
(5) Volatile organic compounds in ash shall not be more than 0.01%	

Note :

- Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limits, if necessary.
- Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- Chlorinated plastics shall not be incinerated.
- Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling Rules,) 1989.
- Only low sulphur fuel like L.D.0dLS.H.S.1Diesel shall be used as fuel in the incinerator.

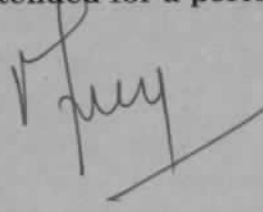


Maharashtra Pollution Control Board

Schedule-III
Details of Bank Guarantees

Sr No.	Consent (C to E/O/R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to R	Rs 5 lakh*	Submitted	O & M of PCS	30.04.2018	30.08.2018
2	C to R	50000 *	Submitted	To Segregate and Handle BMW as per Rule	30.04.2018	30.08.2018
3	C to R	25000 *	Submitted	To conduct and meet sterilization validation test and temperature test for autoclave.	30.04.2018	30.08.2018
4	C to R	25000 *	Submitted	To Maintain records of BMW and submission of annual Report in Form - II before 31st January	30.04.2018	30.08.2018
5	C to R	25000 *	Submitted	To Maintain records of BMW material received / delivered to authorized party CBMWTSDF (Transporter only)	30.04.2018	30.08.2018
6	C to R	50000 *	Submitted	To Provide separate BMW storage facility	30.04.2018	30.08.2018

*The BGs at Sr no 1 to 6 shall be extended for a period upto 30.08.2018.



Maharashtra Pollution Control Board

Schedule-IV

I) Terms & Conditions for compliance of Biomedical Waste Management

1. The "authorized Person" Administrator, M/s. Lupin Limited (Research Park) 46A/47A, Village -Nande Tal-Mulshi Dist-Pune shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.

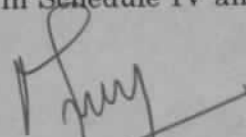
2. The combined consent is granted for generation, storage, treatment, transportation and disposal of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below:

Sr. No.	Category	Description	Quantity not to exceed (Kg/M)	Segregation Color coding	Treatment & Disposal
1	Cat -2	Animal waste	1450.00	Yellow	Incineration (on-site and/ or off-site)
2	Cat-3	Microbiology & Biotechnology Waste	1520.0	Yellow	Incineration (on-site and/ or off- site)/ Autoclave
3	Cat-4	Waste Sharps	5.0	Blue / white translucent	Disinfection by chemical treatment) and shredding
4	Cat-5	Discarded Medicines and Cytotoxic drugs	7.0	Yellow	Incineration (on-site and/ or off- site)
5	Cat-6	Soiled Waste (TPM)	25.0	Yellow	Incineration (on-site and/ or off-site) / Autoclave
6	Cat-7	Solid Waste	12.0	Red.	Disinfection by chemical treatment shredding
7	Cat-8	Liquid waste	5.0	Plastic container	Disinfection by chemical treatment followed by treatment in ETP
8	Cat-9	Incineration ash	As per actuals	Black	CHWTSDF

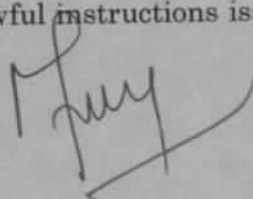
3. (i) BMW shall not be mixed with other wastes or reused or sold in any form.

(ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-II prior to storage, treatment and disposal. The containers shall be labeled according to Schedule III of BMW Rules 1998.

(iii) If a container containing BMW is to be transported from the premises where BMW is generated to any waste treatment facility outside the premises, the container shall, apart from the Label prescribed in Schedule III, also carry information prescribed in Schedule IV and shall be transported by authorized Transporter only.



- (iv) Notwithstanding anything contained in the Motor Vehicles Act, 1988 or Rules there under, BMW shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.
- (v) No untreated BMW shall be kept stored beyond a period of 48 hours.
- (vi) Necessary protective gear for the waste handlers shall be provided by the firm Authority.
- (vii) You shall ensure proper collection of mercury spillage arising mainly due to breakage of thermometers pressure gauges (Sphygmomanometers) other equipments used in health care facilities (HCFs) as well as its storage in accordance with the Hazardous waste (Management & Handling) Rules (presently these Rules has to be read as 'Hazardous Waste (Management & Handling and Trans boundary Movement) Rules, 2008) and returning it to the instrument manufacturers apart from necessary taking steps to ensure that the spilled mercury does not become a part of bio-medical or other solid wastes generated from the HCFs.
- (viii) Authorized person shall obtain prior permission from MPCB for generation & disposal, if Bio-Medical waste quantity of category specified exceed the limits authorized at condition No. 2. Above
4. (i) You shall submit an Annual Report to the prescribed authority in Form-II by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.
- (ii) You shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of BMW in accordance with these Rules and any guidelines issued.
- (iii) All records shall be subject to inspection and verification by the prescribed authority at any time.
5. When any accident occurs at any institution or facility or any other site where BMW is handled or during transportation of such waste, the authorized person shall report the accident in Form III to the prescribed authority forthwith.
6. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.



Schedule-V

General Conditions:

- 1) 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.
 - 2) Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
 - 3) 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.
 - 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) 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.
 - 6) The firm 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) The industry 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) The industry should 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 applicant.
 - 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) 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).
 - 12) The industry shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent 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 factory.
- M. Jey*

- 15) 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.
- 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) The industry should not cause any nuisance in surrounding area.
- 18) 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.
- 19) The applicant shall maintain good housekeeping.
- 20) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a statement on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end, with the Environment Statement.
- 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) 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.
- 23) 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.
- 24) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 25) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.