

MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 4010437/4020781
/4037124/4035273
Fax : 24044532/4024068 /4023516
Email : enquiry@mpcb.gov.in
Visit At : <http://mpcb.gov.in>



Kalpataru Point, 3rd & 4th floor, Sion- Matunga
Scheme Road No. 8, Opp. Cine Planet Cinema, Near
Sion Circle, Sion (E),
Mumbai - 400 022

Consent order No :- Format 1.0 / BO / ACT / EIC No-TN- 4509 - 13 / R / CAC - 6403

Date- 31/07/2013

To,
M/s Lupin Ltd, T-142 ,
Sr. No.30/10 to 13, 64/7,
MIDC Tarapur, Tal. Palghar,
Dist. Thane.

Subject: Renewal of Consent to Operate, Consent to 1st Operate for change in product mix and Amalgamation of Consents under Red category.

- Ref : 1. Earlier Consent to operate granted vide no. BO/ZO-PAMS/EIC No. TN-3281-11/Auto-Renewal/CC-CAC-491 DTD. 12.07. 2012
2. Earlier Consent to Establish granted vide no. BO/JD-PAMS/TN-3874-12/E/CAC-795 dtd. 23.01.2013
3. Minutes of CAC meeting held on 12.07.2013

Your application
Dated:20/05/2013.

For: Renewal of Consent to Operate, Consent to 1st Operate for change in product mix and Amalgamation of 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 01.08.2013 to 30.04.2014.
2. The actual capital investment of the industry is Rs. 628.94 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 in MTA
Please refer Annexure -I		

Total production quantity of 41 Nos. of Bulk Drug products shall not exceed 1,449.75 TPA and that of 2 Nos. of byproducts shall not exceed 273.75 TPA.

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	1050	As per Schedule -I	400 CMD of the treated effluent shall be recycled in process/utilities and effort shall be made to utilize treated effluent upto a maximum of 150 CMD for gardening except during Monsoon. Remaining shall be discharged into TEPS CETP.
2.	Domestic effluent	95	As per Schedule -I	

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.	Boiler (5 Nos.)	3 Nos.	As per Schedule -II
2.	Process vents	24 Nos.	As per Schedule -II
3.	DG sets	09 Nos.	As per Schedule -II
4	Power generators	02 Nos.	As per Schedule -II

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

Sr.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	Distillation Residue	20.3 / 36.4	2.4	MT/day	--	CHW-TSDF or to Authorised party
2	Spent Carbon	28.2 / 35.3	0.510	MT/day	--	CHW-TSDF or to Authorised party
3	Used Oil	5.1	0.025	MT/day	--	Sale to registered recycler or to CHW-TSDF
4	Waste/residue containing Oil	5.2	0.02	MT/day	--	Sale to registered recycler or to CHW-TSDF
5	Process Waste	28.1	3.7	MT/day	--	CHW-TSDF
6	Spent Catalyst	28.2	0.367	MT/day	--	Manufacturer for recycling or to CHW-TSDF or to registered recycler
7	Date Expired , discarded and off specification Products	28.3 / 28.4	As and when generated		--	Onsite recycling and reuse, to manufacturer for recycling or to CHW-TSDF
8	Spent Solvent / Spent ML	20.2 / 28.5	370.42	MT/day	--	Onsite Recovery and reuse onsite or sale off site, Off site recovery or sale to authorized Recyclers, to CHW-TSDF
9	Discarded containers/ Barrels/ Bags/ Liners	33.3	As and when generated		--	Sale or return to supplier after decontamination
10	Chemical containing residue from decontamination and disposal	33.1	As and when generated		--	CHW-TSDF
11	Dried solids for dryer (dry basis)	28.1/34.3	4.0	MT/day	--	CHW-TSDF

7. Conditions under Non Hazardous and disposal of non hazardous waste:

Sr.No.	Type of Waste	Quantity	Treatment	Disposal Method and its destination
1	Mycelia Waste	18.1 MT/ Day	Composting	Sale to Authorized party
2	Bio- Sludge (ETP)	5.82 MT/Day	Composting	Sale to Authorized party
3	Ash from Agro- Waste Boiler	9.50 MT/ day	--	Used as manure OR Sale to brick manufacturers

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. This Consent is issued pursuant to the decision of the Consent Appraisal Committee meeting held on 12/07/2013.

For and on behalf of the
Maharashtra Pollution Control Board

(V.M. Motghare)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
01	12,57,988/-	536080	13.05.2013	SBI

The balance fees of Rs. 3,14,470/- with the Board will be considered at the time of next renewal of Consent to Operate.

Copy to:

1. Regional Officer - Thane and Sub-Regional Officer- Tarapur -I.
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 Effluent Treatment Plant (ETP) with the design capacity of 1200 CMD.
 B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards/ prescribed under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

Sr No.	Parameters	Standards as per EP Act,1986	Standards prescribed by Board (If any)
I. Compulsory Parameters		Limiting Concentration in mg/l, except for pH	Limiting Concentration in mg/l, except for pH
01	pH	5.5-9.0	5.5 to 9.0
02	Suspended Solids	100	100
03	BOD (3 days 27oC)	100	100
04	COD	250	250
05	Oil & Grease	10	10
06	TAN	50	50
07	Sulphides	2	2
08	Phenolic Compound	1	1
09	Phosphates	5	5

C] The treated effluent shall be disposed as follow:

- (i) 400 CMD shall be recycled in process/utilities,
- (ii) effort shall be made to utilize upto a maximum of 150 CMD of the treated effluent instead of fresh water for gardening during demand period so as to reduce the net dischargeable effluent into TEPS CETP from 745 CMD up to 595 CMD except during no demand.

2. A] The domestic effluent (95 CMD) after septic tank, shall be mixed with trade effluent for further treatment in the ETP.
 B] As per your consent application, you have provided the septic tank for sewage treatment with the design capacity of 120 CMD.
3. The industry shall provide water meter at ETP with lock and key arrangement.
4. The industry shall maintain register for recording recycle of the treated effluent.
5. 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 and extension or addition thereto.
6. 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.
7. 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	1100
2.	Domestic purpose	120
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	900
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0
5.	Gardening	150

8. 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.

Schedule-II

Terms & conditions for compliance of Air Pollution Control:

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

Sr. No.	Stack Attached To	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO ₂ Kg/Day
1	Boiler(12 TPH) 1 No.	57 (Combined Stack)	Furnace oil	937 MT/Month	4.5	2810
	Boiler(10 TPH) 1 No.					
2	Boiler(10 TPH) 1 No.	45	Furnace oil			
3	Boilers(8TPH) 2 Nos.	30 (Combined Stack)	Agro Waste	1903 MT/ Month	--	--
4	Scrubbers- 24 nos.	5	--	--	--	--
5	Power Generator Set 2 Nos. (2.5 MW each)	48 each	Furnace Oil	414 MT/Month	4.5	1242
6	D.G.Sets -- 2 Nos. (2.5 MW each)	30	HSD	157 MT/Month	1	124
7	D.G.Sets -- 4 Nos. (1.2 MW each)	6.9				
8	D.G.Sets -- 3 Nos. (1.6 MW each)	8.0				

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:

Particulate matter	Not to exceed	150 mg/Nm ³ .
SO ₂	Not to exceed	4,176 kg/day
HCL	Not to exceed	35 ppm
Cl ₂	Not to exceed	3 ppm
SO ₂ (Process)	Not to exceed	50 ppm
SPM/TPM (For Agro Waste Fuel Boiler)	Not to exceed	500 mg/Nm ³ .

The industry shall continuously operate & maintain air pollution control equipments to control the emission of VOCs. Following VOCs shall be monitored on monthly basis:

Sr. No.	Solvents/ Compounds used in process
1	Toluene, Cyclohexane, MIBK, MEK, Acetone
2	Ethyl Acetate, Methanol,
3	Chloroform, MDC, Acetonytryl

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.

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. 5.0 lakhs	Within 30 days	Towards operation and maintenance of pollution control systems	31.04.2014	30.11.2014

The applicant shall extend the existing B.G. of Rs. 5.0 Lakh after its expiry on 31/07/13 towards O&M of pollution control systems.

Schedule-IV

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) If the MIDC pipeline is broken/ overflowing chamber, in such cases industry shall not discharge their treated effluent into MIDC drain, it shall be sent to CETP by tanker.
- 3) Industry should monitor effluent quality, stack emissions and ambient air quality monthly.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) The industry shall recycle/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.
- 9) 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.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/ Activity (in case of Consent to establish).

- 12) 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).
- 13) 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).
- 14) 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 Wastes (M, H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 15) 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.
- 16) 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.
- 17) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 18) 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.
- 19) 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 MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 20) The industry should not cause any nuisance in surrounding area.
- 21) 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.
- 22) The applicant shall maintain good housekeeping.
- 23) 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.

- 24) 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.
- 25) 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.
- 26) 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.
- 27) 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).
- 28) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 29) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.
- 30) The industry shall comply with the conditions of the Environmental Clearance granted by SEIAA, GoM vide letter No. EC(Lupin)-2009/153/CR.167/TC.1 dtd. 16/11/10 & amendments vide letter dtd. 4/01/11.
- 31) Industry shall develop green belt on land bearing survey nos. 30/3, 30/6, 30/7, 30/8/1,162/2, 30/4, 30/9, 30/14 & 164/1 and use it for the welfare activities of the staff only. Industry shall not carry out any industrial activity on these survey nos. without prior permission of the Board.

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Annexure-I

Sr. No.	Product / By-Product Name	Maximum Quantity in MT/A
1	Rifa S, Rifa O & Rifampcin	300.00
2	Lovastatin	44.00
3	Rifabutin	3.00
4	Simvastatin	50.00
5	Zolpidem tartarate	1.00
6	Sertralin	55.00
7	Rifaximin	33.00
8	Pentaprazole	1.00
9	Pyrazinamide	250.00
10	Levitracitam	360.00
11	Carvediol & Carvediol phospate	1.00
12	Ethambutol	4.50
13	Risperidone	0.25
14	Amlodipine Besilate	8.00
15	Azythromycin	1.50
16	R& D batches	5.00
17	Losartan pottasium	50.00
18	Lamivudine	4.00
19	Imipramine HCl	1.50
20	Imipramine Palmoate	0.70
21	Desloratidine	1.00
22	Fenofibrate / Choline Fenofabrate	30.00
23	Omeprazole/Clindamycin	1.50
24	Levofloxacin	10.00
25	Memantine	0.50
26	Ziprasidone	8.00
27	Valsartan	80.00
28	Quetiapine Fumarate	45.00
29	Sumatriptan Succinate	0.50
30	Irbesartan	20.00
31	Escitalopram Oxalate	4.00
32	Abacavir	4.7
33	Efavirenz	17
34	Tenofavir	8
35	Emitricitabin	10
36	Ranolazine	35
37	Gatifloxacin	0.01
38	Rabiprazole	0.75
	Total	1449.41

By-product List

1	Trans sertralin	182.50
2	Piperazine diacetate	91.25

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