

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

Red/L.S.I

Date: 16/8/2012

Consent No. : BO/PAMS/O/EIC NO.NM-3898-12/CC- (A)-566

Consent to Operate 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 / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

CONSENT is hereby granted to

M/s Reliance Life Sciences Pvt. Ltd.
Plot No. R-282, TTC Indl. Area,
MIDC Rabale, Thane Belapur Road,
Navi Mumbai, Thane, -400701

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Operate is granted for a period up to:- 30.04.2016
2. The Consent is valid for the manufacture of -
 - i. R & D activity pertaining to clinical testing and research, medical, Bio-technology industrial Bio-technology, Plant Biotechnology and for the following product Manufacturing.
 - ii. For cGMP Units-

Sr. No.	Product Name	Maximum Quantity	UOM
1	Therapeutic Protein	25	Kg/M
2	Monoclonal Antibodies	50	Kg /M
3	Cell and Gene Therapies	1000	Procedures
4	Bio-Chemicals and Nutraceuticals	3300	Kg/M
5	Plasma Proteins		
	a) Intermediates	35000	Kg/M
	b) Albumin	21000	Kg/M
	c) Immunaoglobulin	3500	Kg/M
	d) Factor VIII	24000	Kg/M
6	Biotechnology by products		
	Spent Celite	9000	Kg/M

iii. For API Units

Sr. No.	Product Name	Maximum Quantity	UOM
1	Clopidogrel	25	Kg/M
2	Temozoloamide	80	Kg /M
3	Zoledronic Acid	8	Kg/M
4	Rizatriptan Benzoate	10	Kg/M
5	Arepiparazole	15	Kg/M
6	Irbesartan	25	Kg/M
7	Eszopiclone	25	Kg/M
8	Rocuronium Bromide	25	Kg/M
9	Aprepitant	25	Kg/M
10	Exemestane	20	Kg/M
11	Medroxy Progesterone	10	Kg/M
12	Ethyndiol diacetate	50	Kg/M
13	Estriol	15	Kg/M
14	Estradiol	20	Kg/M
15	Etynyl Estradiol	50	Kg/M
16	Medroxy Megestrol	10	Kg/M
17	Samnetrol Xinafoate	15	Kg/M
18	Finasteride	30	Kg/M
19	Dutasteride	10	Kg/M
20	Dulaxitene Hydrochloride	15	Kg/M
21	Pemetrexed disodium	25	Kg/M
Total Production Quantity		508	Kg/M

iV) For Pharmaceuticals Formulations:

Sr. No.	Product Name	Maximum Quantity	UOM
1	Formulation oral solid dosage forms including granules, bulk coated and non coated tablets, finished packed tablets	15	Million Units /A
2	Formulation oral solid dosage forms including granules, bulk capsules, finished packed capsules	15	
3	Formulation injectables	3	

Note: Maximum 6 API's to be manufactured at one time & production capacity not to exceed 50 kg/day, however total production remain unchanged, i.e.508.0 Kg/M

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 685.96 m³.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 127.1 m³.
- (iii) **Trade Effluent :**

Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards:

1	pH	Between	5.5 to 9.0
2	Oil & Grease	Not to exceed	10 mg/l
3	Suspended Solids	Not to exceed	100 mg/l.
4	BOD 3 days 27 ° C	Not to exceed	100 mg/l.
5	COD	Not to exceed	250 mg/l.
6	TDS	Not to exceed	2100 mg/l.
7	Chlorides	Not to exceed	600 mg/l
8	Phenolic Compound	Not to exceed	1.0 mg/l
9	Total Ammonical Nitrogen	Not to exceed	50.0 mg/l
10	Bio assay Test on fish should show 90 % survival in 96 Hrs.		

(iv) **Trade Effluent Disposal:** The treated industrial effluent shall be reused /recycled to the maximum extent and remaining shall send to CETP for further treatment.

(v) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.

(1)	Suspended Solids	Not to exceed	100	mg/l.
(2)	BOD 3 days 27o C.	Not to exceed	100	mg/l.

(vi) **Sewage Effluent Disposal:** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii) **Non-Hazardous Solid Wastes:**

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	Disposable Shoe Covers, Head Caps, Face Mask	3000.00	No/M	Local body
2	Glass Containers	1000.00	No/M	By Sale
3	Paper Waste	250.00	Kg/M	By Sale
4	Cable Ties, Polybags, Nylon Scrubber	3000.00	No/M	By Sale
5	Vials/Seals/Stopper during Machine Trial	20000.00	No/M	By Sale
6	Aluminium Foil/PVC Scrap	500.00	Kg/M	By Sale
7	Air Filters(Different Sizes)	500.00	No/M	By Sale
8	Tyvek Bags(Different Sizes)	1000.00	No/M	Local body
9	Cardboard Boxes	500.00	No/M	By Sale

(viii) **Other Conditions:** Industry should monitor effluent quality regularly.

4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and amendment Rules, 2003 there under

The daily water consumption for the following categories is as under:

(i) Domestic purpose	...	154.00 CMD
----------------------	-----	------------

- (ii) Water gets Polluted & Pollutants are Biodegradable ... 829.65 CMD
- (iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic ... 0.00 CMD
- (iv) Industrial Cooling, spraying in mine pits or boiler feed ... 581.00CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. CONDITIONS UNDER AIR ACT :

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards:

a. Control Equipment:

- i. Scrubber of adequate capacity should be provided to limit emissions and also to any other sources of emissions.
- ii. Adequate fume extraction system followed by dust collector of sufficient capacity should be provided at all dust-generating locations and operated properly.
- iii. There shall not be any fugitive (secondary) emissions

b. Standards for Emissions of Air Pollutants:

- | | | |
|-----------------------|---------------|--------------------------|
| (i) SPM/TPM | Not to exceed | 150.0 mg/Nm ³ |
| (ii) HCL | Not to exceed | 35.0 mg/Nm ³ |
| (iii) NH ₃ | Not to exceed | 50.0 mg/Nm ³ |
| (iv) SO ₂ | Not to exceed | 3852.0 Kg/day |

- (ii) The applicant shall observe the following fuel pattern:-

Sr. No.	Type Of Fuel	Quantity	UOM
1	Furnace Oil	42800	Kg/Day
2	HSD	33840	Kg/day

- (iii) The applicant shall erect the chimney(s) of the following specifications:-

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Boiler	33.00
2	Boiler (2 No)	48.00 Each
3	Incineratcr	30.00
4	D.G Set (2575 KVA) (2 Nos)	10.00 above the roof
5	D. G.Set (2500 KVA)	21.00

- (iv) 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.
- (v) 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.

(vi) **Other Conditions:**

- 1) The industry should not cause any nuisance in surrounding area.
- 2) The industry should monitor stack emissions and ambient air quality Regularly.

6. 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. The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- d. 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.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. 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.
- g. D.G. Set shall be operated only in case of power failure.
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.

7. CONDITIONS UNDER HAZARDOUS WASTE (MANAGEMENT, HANDLING & TRANSBOUNDARY MOVEMENT) RULES, 2008:

- (i) The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	28.1 Residues and wastes*	3750.00	KG/M	Incineration MWML Taloja
2	28.4 Date-expired, discarded and off- specification drugs	101.00	Kg/M	Incineration MWML Taloja
3	5.1 Used / Spent oil	200.00	Kg/M	Sale to authorized recycler
4	20.1 Contaminated aromatic, aliphatic or naphthenic solvents may or may not be fit for reuse	2.00	T/M	CHWTSDF
5	20.2 Spent aqueous ethanol	196.00	T/M	Treat in ETP/ s to authoriz

				recycler
6	20.2 Sent solvents (Ethyl acetate, Butanol, Isopropanol, Methanol)	08.00	T/M	Sale to authorized recycler
7	28.2 Spent Catalyst /Spent Carbon	50.00	Kg/M	
8	28.5 Spent Organic Solvents	150.00	Kg/m	CHWTSDF
9	34.1 Flue Gas cleaning residue	700.00	Kg/M	CHWTSDF
10	34.2 Spent ion exchange resin containing toxic metals	100.00	Kg/M	CHWTSDF
11	34.3 Chemical sludge from waste water treatment plant	1000.00	Kg/M	CHWTSDF
12	33.3 HDPE / LDPE/PVC container	6.00	MT/A	Sale to authorized Recycler/re-processor
13	E-Waste electronic and electrical equipment	1.00	MT/A	Sale to authorized Recycler/re-processor

(ii) Treatment: - NIL

8. Whenever due to any accident or gas leakage 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 Collector, Directorate of Industry, Safety and Health, Police Station, Fire Brigade, Directorate of Health Services, Department of Explosives, Board and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emission and ensure that the emissions do not cause any harm or nuisance in the surrounding. The industry should not restart the process without permission of the Board and other statutory organization as require under the law.

9. Industry shall comply with following additional conditions:

- i. The applicant shall maintain good housekeeping and take adequate measures for control of pollution from all sources so as not to cause nuisance to surrounding area / inhabitants.
- ii. The applicant shall bring minimum 33% of the available open land under green coverage/ tree plantation.
- iii. Solid waste - 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 to dumping ground.
- iv. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by he applicant 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 & conditions of this consent regarding pollution levels.
- v. The applicant shall not change or alter 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.
- vi. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous wastes to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- vii. The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.

- viii. 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.
- ix. As inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- x. The applicant shall install a separate electric 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.
- xi. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes / sewers down- stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection System.
- xii. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
11. This consent shall not be construed as any exemption from obtaining necessary No Objection Certificate from other Government agencies as may deemed fit necessary.
12. If CETP cannot operate efficiently for achieving standards and problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.
13. This consent is issued as per the decision taken in the meeting of the Consent Appraisal Committee of the Board held on 3/07/2012.
14. The Capital investment of the industry is Rs. 230.05 Cr
(Existing C.I. Rs. 208.90 Cr + Expansion Rs. 21.15 Cr)


(Milind Mhaiskar, IAS)
Member Secretary

To,
M/s Reliance Life Sciences Pvt. Ltd.
Plot No. R-282, TTC Indl. Area,
MIDC Rabale, Thane Belapur Road,
Navi Mumbai, Thane, -400701

Copy to :

RO, Navi Mumbai /SRO, Navi Mumbai- II

- They are directed to ensure the compliance of consent conditions.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	50000/-	005281	20 Dec 2011	ICICI Bank
2	100/-	005283	20 Dec 2011	ICICI Bank
3	150000/-	007446	16 July 2012	ICICI Bank