

# MAHARASHTRA POLLUTION CONTROL BOARD

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**Consent order No :- Format 1.0/BO/CAC-cell/RO-NM/EIC-NM-4737-13/R(Amend)/CAC- 457**  
**Date- 16.1.2014**

To,  
M/s Reliance Life Sciences Pvt Ltd.  
Plot R-282, TTC Industrial Area of MIDC,  
Rabale, Thane Belapur Road, Navi Mumbai 400 701

**Subject: Amendment in Consent to Operate for inclusion of 102 no. of beds RED category.**

- Ref :**
1. Earlier Consent granted vide no. BO/PAMS/O/EIC NO.NM-3898-12/CC-CAC-566 dtd 16/8/2012 valid upto 30.4.2016.
  2. BMW Authorisation granted vide no. MPCB/PAMS/BMW/NM-12/NM-13/2012 dtd 19.10.2012 valid upto 31.7.2013.
  3. Minutes of 18<sup>th</sup> CAC meeting of 2013-14 held on 6.1.2014.

Your application

Dated: 4.7.2013

For: Amendment in Consent to Operate for inclusion of 102 no. of beds 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 amendment in consent is granted for a period from date of issue to 30/04/2016.
2. The actual capital investment of the industry is Rs.290.55 Crs. (As per C.A.Certificate submitted by industry)
3. The Consent is valid for the R & D Activity pertaining to clinical testing and research having 102 beds, medical, Bio-technology, industrial Bio-technology, Plant Bio-technology and for the following product Manufacturing -

Sr. No.	Product / By-Product Name	Maximum Quantity in MT/A
1.	List Attached	

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	694.96	As per Schedule -I	Recycle / CETP
2.	Domestic effluent	127.1	As per Schedule -I	Recycle / CETP

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.	3 nos. of Boiler	3	As per Schedule -II
2.	3 nos. of DG set (2 x 2575 KVA) & 2500 KVA	3	As per Schedule -II
4.	Incinerator	1	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Empty glass bottles	6 MT/A	No	Sale
2	Wooden boxes	12 MT/A	No	Sale
3	Sweeping (Mixed materials)	64 MT/A	No	Sale
4	Cardboard boxes	24 MT/A	No	Sale
5	Plant tissue culture waste	100 MT/A	No	NMMC
6	HDPE/ LDPE/ PVC Container Non contaminated	3 MT/A	No	Sale
7	Disposal of Shoe Covers, Head Caps, Face Mask	3000 No/M	No	Local Body
8	Glass Container	1000 No/M	No	Sale
9	Paper Waste	250 Kg/M	No	Sale
10	Cable Ties, Polybags, Nylon Scrubber	3000 No/M	No	Sale
11	Vials/Seals/Stopper during Machine Trial	20000 No/M	No	Sale
12	Aluminium Foil/PVC Scrap	500 Kg/M	No	Sale
13	Air Filters ( Different Sizes )	500 No/M	No	Sale
14	Tyvek Bags ( Different Sizes)	1000 No/M	No	Local Body
15	Cardboard Boxes	500 No/M	No	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, Spent oil	5.1	200	Kg/M		Sale to authorized recycler
2	Contaminated aromatic, aliphatic or naphthenic solvents may or may not be fit for reuse	28.1	2	MT/M		CHWTSDF
3	Spent aqueous ethanol	20.2	196	MT/M		Treat in ETP/sale authorized recycler
4	Spent solvents (Ethyl acetate, butanol,	20.2	8	MT/M		

	Isopropanol, Methanol					
5	Residues and wastes	28.1	3750	Kg/M		CHWTSDF
6	Spent catalyst/ spent carbon	28.2	50	Kg/M		
7	Date expired, discarded and specification drugs/ medicines	28.4	101	Kg/M		CHWTSDF
8	Spent organic solvents	28.5	150	Kg/M		CHWTSDF
9	Flue gas cleaning residue	34.1	700	Kg/M		CHWTSDF
10	spent ion exchange resin containing toxic metals	34.2	100	Kg/M		CHWTSDF
11	Chemical sludge from waste treatment plant	34.3	1000	Kg/M		CHWTSDF
12	HDPE/ LDPE/ PVC container	33.3	6	MT/A		Sale to authorized recycler/ re- processor
13	E -Waste electronic & electrical equipment		1	MT/A		Sale to authorized recycler/ re- processor

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 with overriding effect over previous consent no. BO/PAMS/O/EIC NO. NM - 3898-12/CC-CAC - 566 dtd 16.8.2013.

For and on behalf of the  
Maharashtra Pollution Control Board

(Rajeev Kumar Mital, IAS)  
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	100/-	010750	5/07/2013	ICICI Bank
2	480000	011483	12/9/2013	ICICI Bank

Copy to:

1. Regional Officer -Navi Mumbai and Sub-Regional Officer-Navi Mumbai-II, 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 Effluent Treatment Plant (ETP) for treatment of sewage & trade with the design capacity of 860.0 CMD.

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 as per EP Act,1986
		Limiting Concentration in mg/l, except for pH
01	pH	6.0-8.5
02	Oil & Grease	10
03	BOD (3 days 27oC )	100
04	Total Dissolved Solids	2100
05	Ammonia (NH <sub>3</sub> )	10
06	Suspended Solids	100
07	COD	250
08	Chloride	600

C ) The treated effluent shall be recycled/reused in the process to the maximum extent and remaining to shall be discharged to the CETP for further treatment.

2) 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.

3) 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.

4) 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	581
2.	Domestic purpose	154
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	829.65
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0

5) 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.

**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 <sub>2</sub> Kg/Day
1	Boiler 1	NA	33	Furnace Oil	14300 Kg/Day	4.5	1287
2	Boiler 2	NA	48	Furnace Oil	14300 Kg/Day	4.5	1287
	Boiler 3	NA	48	Furnace Oil	14300 Kg/Day	4.5	1287
3	D.G.Set (2575 KVA)	Acoustic Enclosure	10 Above the roof)	High Speed Diesel	11280 Kg/Day	1	225.6
	D.G.Set (2575 KVA)	Acoustic Enclosure	10 Above the roof)	High Speed Diesel	11280 Kg/Day	1	225.6
4	D.G.Set (2500 KVA)	Acoustic Enclosure	21	High Speed Diesel	11280 Kg/Day	1	225.6
4	Incinerator	Scrubber	30	High Speed Diesel	200 Kg/Day	1	4

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:

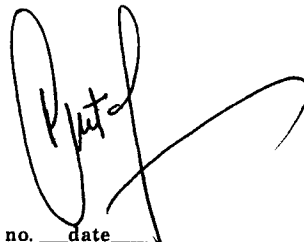
Particulate matter	Not to exceed	150 mg/Nm <sup>3</sup> .
SO <sub>2</sub> Process	Not to exceed	..... mg/Nm <sup>3</sup>
HCL	Not to exceed	35 mg/Nm <sup>3</sup>
Cl <sub>2</sub>	Not to exceed	3 ppm
NH <sub>3</sub>	Not to exceed	50 ppm

4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement 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
	Proposed					
1	CTO	Rs. 5,00,000	15 days from date of issue of consent	For O & M of ETP to achieve effluent standards.	continuous	31.8.2016

Maharashtra Pollution Control Board



## 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/quarterly.
- 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/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW(MH&TM) Rules 2008, which can be recycled
- 9) /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.
- 10) 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 Hazarsous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30<sup>th</sup> June of every year.
- 11) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 12) **The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consen.**
- 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](http://www.mpcb.gov.in)).
- 14) 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.
- 15) 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.
- 16) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 17) 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.
- 18) 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 sitting 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
- 19) The industry should not cause any nuisance in surrounding area.
  - 20) 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.
  - 21) The applicant shall maintain good housekeeping.
  - 22) 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 31<sup>st</sup> March of the year and number of trees planted by September end, with the Environment Statement.
  - 23) 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.
  - 24) 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.
  - 25) 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.
  - 26) 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 be downloaded from MPCB official site).
  - 27) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
  - 28) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.
  - 29) Affidavit undertaking in respect of no change in the status of consent conditions and compliance of the consent conditions the draft can be downloaded from the official web site of the MPCB.
  - 30) If CERP cannot operate efficiently for achieving standards and problem of pollution occurs, industry shall voluntarily stop the production or total effluent shall be reused.
  - 31) Industry shall comply with Bio-Medical Waste (Management & Handling) rules 1998 and as amended to date.

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**Annexure-I Product List**

R & D Activity pertaining to clinical testing and research having 102 beds, medical, Bio-technology, industrial Bio-technology, Plant Bio-technology and for the following product Manufacturing

S.No	Product Name	Maximum Quantity	UOM
<b>For CGMP Units</b>			
1	Therapeutic proteins	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		Kg/M
	a) Intermediates	35000	Kg/M
	b) Albumin	21000	Kg/M
	c) Immunoglobulin	3500	Kg/M
	d) Factor VIII	24000	Kg/M
6	Biotechnology by products Spent celite	9000	Kg/M
<b>For API Units</b>			
1	Clopidogrel	25	Kg/M
2	Temozolamide	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	Etyrnyl Estradiol	50	Kg/M
16	Medroxy Megestrol	10	Kg/M
17	Sannetrol 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
<b>For Pharmaceutical Formulations</b>			
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	