

MAHARASHTRA POLLUTION CONTROL BOARD

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Kalpataru Point, 2nd - 4th Floor

Opp. Cine Planet Cinema,

Near Sion Circle, Sion (E)

Mumbai-400 022.

Red/L.S.1

Date: 16/08/2013

Consent No: BO/AST/RO Pune/EIC No PN-15818-12/R/CC/6827

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 SciGen BioPharma Pvt.Ltd.

Plot no. 18, International Biotech Park, Phase - II,
MIDC Hinjewadi, Tal - Mulshi, Pune-411057.

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:31/12/2013.
2. The Consent is valid for the manufacture of--

Sr. No.	Product Name	Maximum Quantity
1	R- Insulin	75 Kg/M
2	Interferon	170 Kg/M
3	Human Growth Harmon	420 Kg/M
4	Hepatitis B, Vaccine	840000 No/M
5	Human Granulocyte colony stimulating factor (rHU G-CSF)	84 Grams/M
6	Carboxy peptidase B (CPB)	84 Grams/M

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 119.00m³.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 15.00m³.

(iii) Trade Effluent :

Treatment: The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment by Ultra Filter, Reverse Osmosis Regeneration System for process effluent 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	Suspended Solids	Not to exceed	100.00 mg/l.
3	BOD 3 Days 27 degree C	Not to exceed	30.00 mg/l.
4	COD	Not to exceed	250.00 mg/l
5	Oil & Grease	Not to exceed	10.00 mg/l
6	T.D.S	Not to exceed	2100.0 mg/l
7	Chlorides	Not to exceed	600.0 mg/l
8	Sulphates	Not to exceed	1000.0 mg/l

- (iv) **Trade Effluent Disposal:** The treated trade effluent shall be recycled at maximum extent & remaining shall be disposed on own land for gardening. There should not be any discharge outside factory premises.
- (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	Packing material	0.30	Ton/Y	By sale
2	Office waste material	0.40	Ton/Y	By sale
3	Air Filter- liquid	836.00	Nos./Y	By sale
4	Contaminated & disposal hand gloves, aprons, cloths	0.30	Ton/Y	By sale
5	Resins from DM Plant	1680.00	Ltr/A	By sale
6	Canteen Waste	0.60	Ton/Y	Used as manure
7	Broken glass	0.30	Ton/Y	By sale
8	Used oil from eatables	0.04	Ton/Y	By sale

- (viii) **Other Conditions:** Industry should monitor effluent quality regularly from MoEF approved laboratory

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 ... 15.00 CMD
 (ii) Water gets Polluted & Pollutants are Biodegradable ... 127.00 CMD

- (iii) Water gets Polluted. Pollutants are not Biodegradable & Toxic ... 0.00 CMD
- (iv) Industrial Cooling, spraying in mine pits or boiler feed ... 111.00CMD

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 :

6.

- (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:** Industry shall provide necessary APC devices to control the emissions.

b. **Standards for Stack Emissions:**

- a. SPM/TPM Not to exceed 150 mg/Nm³
- b. SO₂ Not to exceed 144 kg/Day

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	HSD	220.00	Kg/hr
2	LDO	3996.00	Kg/day

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	DG Set (1250 KVA)	7.0 (above the roof)
2	Boiler of 2.8 TPH	33.00

- (iii) 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.

- (iv) 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.

7. 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.

8. 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	235.0	Kg/M	CHWTSDf
2	28.2 Spent catalyst / spent carbon	65.0	Kg/M	CHWTSDf
3	28.3 Date-expired, discarded and off-specification drugs	50.0	Kg/M	CHWTSDf
4	28.4 Spent mother liquor	8.00	m3/D	CHWTSDf
5	34.3 Chemical sludge from waste water treatment	6.0	MT/M	CHWTSDf
6	34.4 Chemical sludge, oil and grease skimming residues	9.0	Kg/M	CHWTSDf

- (ii) Treatment: - NIL
- (iii) Whenever due to any accident or release of gases 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 Factorie

and Local Body and the production process should be stopped by taking all necessary safety measures. The industry shall also monitor the emissions 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 organizations 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 pre 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.
- ix. 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.
- x. 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.
- xi. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

10. Industry shall submit Bank Guarantee of Rs 5.00 lakhs within 15 days towards O & M of pollution control system which shall be valid for a period up to 30.04.2014.
11. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
12. The industry shall also comply with the Industry specific standards notified under Environment Protection Act.
13. This consent is issued pursuant to the decision of the 7th Consent Committee of 2013 held on 10.07.2013.
14. The Capital investment of the industry is Rs. 70.72 crores.

For and on behalf of the
Maharashtra Pollution Control Board

(V.M.Motghare)
Member Secretary

To,
M/s SciGen Biopharma Pvt.Ltd.
Plot No.18.International Biotech Park, Phase - II,
MIDC Hinjewadi,Tal - Mulshi,
Pune-411057.

Copy to:

- 1) Regional Officer, MPCB, Pune} They are directed to ensure the compliance of consent conditions.
- 2) Sub-Regional, Officer, Pune-I, Mumbai - I} They are directed to ensure the compliance the consent conditions.
- 3) Chief Accounts Officer, MPCB, ,Mumbai.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	115000	007378	14 Dec 2011	HDFC Bank