

MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai-400 022.

RED/L.S.I

Date: ~~16/11/13~~

Consent No: BO/AS (T)/RO NM/EIC NO.NM-4614-13/E/CC-9314

06/11/2013

Consent to Establish under Section 25 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 Mylan Laboratories Ltd.
(Formerly Known as M/s Matrix Laboratories Ltd)
1-A/2 & 1-A/3, MIDC Taloja,
Tal-Panvel, Dist - Raigad

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 Establish is granted for a period up to: Commissioning of the unit or 5 years whichever is earlier.
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
1	Bosentan	2000	Kg/A
2	Dimethyl Fumarate	4500	Kg/A
3	Pregablin	5000	Kg/A
4	Proguanil HCL	2000	Kg/A
5	Zofenopril	1200	Kg/A
6	Formoterol Fumarate dihydrate	20	Kg/A
7	Salmeterol Xinafoate	30	Kg/A
8	Rivastigmine	400	Kg/A
9	Imatinib Mesylate	10	Kg/A
10	Febuxostat IB	480	Kg/A
11	Adefovir Dipivoxil	100	Kg/A
12	Frovatriptan	10	Kg/A
13	Olopatadine Hydrochloride	10	Kg/A
14	Osteoporosis (U/Development)	10	Kg/A
15	Erlotinib Hydrochloride	50	Kg/A
16	Clopidogrel hydrogen bromide	20000	Kg/A
17	Rasagiline Mesylate	5	Kg/A
18	Letrozole	500	Kg/A
19	Other Validation Products (API)	500	Kg/A
20	Vorinostat	20	Kg/A
21	Atropine	100	Kg/A
22	Tizanidine HCL	100	Kg/A
23	Roflumilast	10	Kg/A

SRO Taloja /I/R/L/91831000

24	Rotogotin	200	Kg/A
25	Pramipexole HCL	50	Kg/A
26	Capecotabine	9000	Kg/A
27	Tolvaptan	15	Kg/A
28	Diphenoxylate	1800	Kg/A
29	Fluticasone	1800	Kg/A
30	Sunitinib maleate	50	Kg/A
31	Lenalidomide	20	Kg/A

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **38.55 m³**.
(ii) The daily quantity of sewage effluent from the factory shall not exceed **7.00 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	6.5 to 8.5
2	Suspended Solids	Not to exceed	100 mg/l.
3	BOD 3 days 27 deg C	Not to exceed	100 mg/l
4	COD	Not to exceed	250 mg/l.
5	Oil & Grease	Not to exceed	10 mg/l
6	T.D.S	Not to exceed	2100 mg/l
7	Sulphate	Not to exceed	1000 mg/l
8	Chlorides	Not to exceed	600 mg/l
9	% Sodium	Not to exceed	60 % mg/l
10	Bio-assay test in fish shall show 90% survival in 96hrs		

- (iv) **Trade Effluent Disposal:** The treated effluent shall be reused for gardening up to maximum extent and remaining shall be disposed into CETP.
- (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 200 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	Metal Scrap (MS, Iron, Aluminium, GI, SS etc)	500.00	MT/A	Sale to scrap dealer or authorised reprocessing
2	Paper waste and other discarded stationery	5.00	MT/A	
3	Wood Scrap	100.00	MT/A	
4	Plastic Scrap	25.00	MT/A	
5	Glass Scrap	25.00	MT/A	
6	PVS, PVDC, Alu. Foils	25.00	MT/A	
7	Carton Boxes and packing waste	25.00	MT/A	
8	Insulation Waste	25.00	MT/A	CHWTSDF
9	Garbage (Mix)	5.00	MT/A	Used as a manure

(viii) **Other Conditions:**

1) 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	...	08.0	CMD
(ii) Water gets Polluted & Pollutants are Biodegradable	...	24.0	CMD
(iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic	...	-----	CMD
(iv) Industrial Cooling, spraying in mine pits or boiler feed	...	72.50	CMD
(v) Agriculture / Gardening	...	08.0	CMD

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:

1. Scrubber system of sufficient capacity should be provided to control the emissions and operated properly.
2. There shall not be any secondary (fugitive) emissions.

b) Standards for Emissions of Air Pollutants:

- (i) SPM Not to exceed 150 Mg/Nm³
- (ii) SO₂ Not to exceed 98.5 kg/day

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	HSD	285.00	Ltr/hr.
2	EDO	114.00	Kg/hr.

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Scrubber-1	13.00
2	Scrubber-2	16.00
3	Scrubber-3	13.00
4	Scrubber-4	13.00
5	Scrubber-5	13.00
6	Scrubber-6	13.00
7	Boiler (2 Nos.)	30.00
8	D.G. Set (500 KVA)	9.00
9	D. G. Set (15 KVA)	9.00
10	D. G. Set (1500 KVA)	9.00

(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.

c) 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.

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

The Industry shall handle hazardous wastes as specified below.

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
1	5.1 Used /spent oil	7000.00	Lit/A	Authorised recycler / Sale
2	36.3 Spent acid from batteries	90.00	No's /A	Authorised recycler
3	34.2 Toxic metal-containing residue from water purification	5.00	MT/A	CHWTSDF, Talaja
4	36.2 Ash from incineration of hazardous waste	2.00	MT/A	CHWTSDF, Talaja
5	31.1 Residues and wastes*	25.00	MT/A	CHWTSDF, Talaja
6	28.1 Residues and wastes*	228.00	MT/A	CHWTSDF, Talaja
7	28.2 Spent catalyst / spent carbon	74.00	MT/A	CHWTSDF, Talaja

8	28.3 Date-expired, discarded and off-specification drugs	2.00	MT/A	CHWTSDF, Taloja
9	28.5 Spent organic solvents	10000.00	KL/A	Authorised recycler / Sale
10	33.3 Discarded containers / barrels / liners	12000.00	No's /A	Sale after detoxification
11	33.3 Discarded containers / barrels / liners	10000.00	Kg/A	Sale after detoxification
12	34.3 Chemical sludge from waste water treatment	40.00	MT/A	CHWTSDF, Taloja
13	E-waste	25.0	MT/A	Authorised recycler Dismantler/ Collection center / Back to supplier

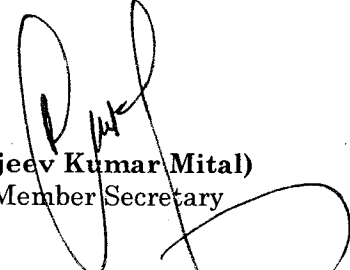
(ii) Treatment: - NIL

7. 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.

8. Industry shall comply with following general 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.
- 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.
9. The consent should not be construed as any exemption from obtaining necessary NOC from other Government agencies as may deemed fit necessary.
10. **The industry shall also comply with the industry specific standards notified under Environment Protection Act.**
11. If CETP does not operate efficiently and problem of pollution occurs, industry should voluntarily stop the production or total effluent should reuse.
12. The applicant shall obtain consent to operate before starting actual commercial Production
13. This consent is granted as per decision taken in Consent committee meeting with following condition:-
- The applicant should not take any effective steps for implementation of the project before obtaining Environmental Clearance as per EIA Notification 2006 and amendments thereto.**
 - As per Para 2 of EIA notification dated-14/09/2006, the effective steps include starting of any construction work or preparation of land by the project management. However as clarified by the MoEF vide office memorandum no. J-1103/41/2006-IA.II(I); Dated-19/8/2010, fencing of the site to protect it from getting encroached & construction of temporary shed(s) for the guard(s) & acquisition of land shall not be treated as an effective steps.**
 - Industry shall submit Bank Guarantee of Rs 5 lakh towards compliance of consent conditions for a period of one year in favour of "Regional Officer, MPCB, Navi Mumbai" within 15 days.**
14. This consent is issued as per the decision taken in the meeting of the Consent Committee of the Board held on 15/10/2013.
15. The Capital investment for expansion is Rs. 30 Cr.


(Rajeiv Kumar Mital)
Member Secretary

To,
M/s Mylan Laboratories Ltd.
(Formerly Known as M/s Matrix Laboratories Ltd)
1-A/2 & 1-A/3, MIDC Taloja,
Tal-Panvel, Dist - Raigad

Copy to:

1) Regional Officer, MPCB, Navi Mumbai 2) Sub Regional Officer, Talaja -They are directed to obtain BG of Rs 5.0 Lakh from industry towards compliance of consent conditions within 15 days, for a period of one year and ensure the compliance of consent conditions.

3) Chief Account Officer, MPCB, Mumbai, 4) Cess Branch, MPCB, 5) Master File.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	17500/-	024176	18 April 2013	HDFC Bank

Maharashtra Pollution Control Board