

# MAHARASHTRA POLLUTION CONTROL BOARD

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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: 21 /04/2012

Consent No: BO/PAMS/E/EIC NO.NM-3433 -11/CC- 343

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 Zydus Nycomed Healthcare Pvt Ltd.  
Plot No. C-4, MIDC Pawane,  
Thane Belapur Road, Vashi  
Navi Mumbai

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: 31.03.2013
2. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity	UOM
01	Pantoprazole Sodium	75.00	Ton/A
02	Warfarin Sodium	0.60	Ton/A
03	Sulfametrole	2.00	Ton/A
04	Aprindine	1.00	Ton/A
05	Ethamivan	2.50	Ton/A
06	Lornoxicam	2.50	Ton/A
07	Suxamethonium chloride	3.00	Ton/A
08	Hexabendine	0.45	Ton/A
09	Hexaprenaline	0.45	Ton/A
10	Distigmin Bromide	0.60	Ton/A
11	Podophylotoxin	0.008	Ton/M
12	Urapidil	15.00	Ton/A
13	Urapidil Hydrochloride	0.80	Ton/A
14	5- Difluoromethoxy -2- Mercapto1 H-Banzimidazole (KSM-6)	75.00	Ton/A
15	2- Chloromethyl-3-4- Dimethoxy Pyrimidine Chloride (KSM-14)	75.00	Ton/A
16	Policresulen	60.00	Ton/A
17	Bamifylline	21.50	Ton/A
18	Midorin Hydrochloride	0.60	Ton/A

### 3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed **200.0 M<sup>3</sup>**.  
(ii) The daily quantity of sewage effluent from the factory shall not exceed **25.0 M<sup>3</sup>**.  
(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	BOD 3 days 27 deg C	Not to exceed	100 mg/l
3	Oil & Grease	Not to exceed	10 mg/l
4	Suspended Solids	Not to exceed	100 mg/l.
5	COD	Not to exceed	250 mg/l.
6	Total Dissolved Solids	Not to exceed	2100 mg/l.
7	Chlorides	Not to exceed	600 mg/l.
8	Sulphates	Not to exceed	1000 mg/l.
9	TAN	Not to exceed	50 mg/l.

- (iv) **Trade Effluent Disposal:** The treated effluent shall be recycled to the maximum extent and remaining treated effluent shall be sent to CETP. There shall not be any discharge outside the 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 applicant shall mix sewage effluent into trade effluent before treatment and same mixed effluent shall be further treated in ETP.

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

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
01	Drums (Noncontaminated)	200.00	Kg/Day	Sale
02	Plastic Carboys (Noncontaminated)	100.00	Kg/Day	Sale
03	Fiber Board drum (Noncontaminated)	100.00	Kg/Day	Sale
04	PVC and paper	100.00	Kg/Day	Sale
05	Other (metallic and glass scrap deactivated carbon and fiber pads)	175.00	Kg/Day	Sale
06	Domestic canteen waste	100.00	Kg/Day	Authorized local disposal system

- (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 ... 44.0 CMD  
(ii) Industrial processing ... 207.00 CMD  
(iii) Industrial Cooling, spraying in mine pits or boiler feed ... 181.00 CMD

(iv) Agriculture / Gardening

...

05.00 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:**

- I. Scrubber system of sufficient capacity provided to all process reactors and any other sources of gaseous emissions such as, SO<sub>2</sub>, HCL etc.  
II. There shall not be any secondary (fugitive) emissions.

**b. Standards for Emissions of Air Pollutants:**

- |       |                                |               |                        |
|-------|--------------------------------|---------------|------------------------|
| (i)   | SPM/TPM                        | Not to exceed | 150 mg/Nm <sup>3</sup> |
| (ii)  | SO <sub>2</sub>                | Not to exceed | 1651.6 Kg/day          |
| (iii) | SO <sub>2</sub> (from process) | Not to exceed | 50 ppm                 |
| (iv)  | HCL                            | Not to exceed | 35 mg/Nm <sup>3</sup>  |
| (v)   | NH <sub>3</sub>                | Not to exceed | 50 mg/Nm <sup>3</sup>  |

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	Furnace Oil*	770.0	Kg/Hr
2	HSD	520.0	Ltr/Hr
3	PNG	800.00	SCMH

\* In absence or non-availability of PNG Furnace oil will be used.

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

Sr. No.	Chimney Attached To	Height in Mtrs.
1	Process vent ( 8 Nos)	6.00
2	Fume Extractor (5 Nos)	6.00
3	D.G. Set (1500 KVA)	7.00 *
4	D.G. Set (1000 KVA)	7.00 *
5	Dust collector	6.00
6	Fire Hydrant Pump	6.00
7	Boiler (2 Nos)	50.00 (Combined)
8	Process Vent (2 Nos)	6.00

\* above the height of building where it is installed.

- (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 & TRANSBOUNDRY MOVEMENT) RULES, 2008:**

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

Sr. No.	Type Of Waste	Quantity	UOM	Disposal
01	5.1 Used / Spent Oil	2.00	MT/A	Sale to authorized reprocessor
02	20.1 Contaminated aromatic, aliphatic or naphthenic solvents	180.0	MT/A	Sale to authorized reprocessor
03	20.2 Spent Solvents	4700.0	MT/A	CHWTSDF or sale to MPCB authorized party for recycle
04	20.3 Distillation Residues	3816.0	MT/A	CHWTSDF or Triple Effect Evaporator (TEE)
05	28.1 Process residue and wastes	38.0	MT/A	CHWTSDF or Sale to

				authorized reprocessor
06	28.2 Spent Catalyst / spent carbon	10.00	MT/A	CHWTSDF
07	28.3 Date- Expired, discarded and off specification drugs	4.00	MT/A	CHWTSDF
08	28.4 Spent Mother liquor	4000.0	MT/A	Shall be treated in their TEE or sale to authorized reprocessor
09	28.5 Spent Organic Solvent (Chlorinated and non chlorinated solvents)	1500.0	MT/A	In house recovery / MPCB authorize party
10	33.1 Chemical containing residue from decontamination and disposal	35.0	KL/A	CHWTSDF or treatment in ETP
11	33.2 sludge from treatment of waste water arising out of cleaning containers	4.00	MT/A	CHWTSDF
12	33.3 Discarded containers	244.00	MT/A	Decontaminate / puncture / disposal through approved unit MPCB
13	34.1 Scrubber blow down effluent	2128.0	KL/A	CHWTSDF or TEE or ETP
14	34.3 Chemical sludge from ETP and TEE	1535.0	MT/A	CHWTSDF
15	34.4 Chemical sludge from oil and grease skimming residue	1.0	MT/A	CHWTSDF
16	35.1 Contaminated filter bags	1.0	MT/A	CHWTSDF
17	35.2 Spent Catalyst	6.00	MT/A	Sale to authorized reprocessor
18	35.3 Spent Carbon	20.0	MT/A	CHWTSDF or Sale to authorized reprocessor
19	3.3 Sludge and filter contaminated with oil	12.00	MT/A	CHWTSDF or Sale to authorized reprocessor
20	34.2 Spent Ion Exchange resin containing Toxic Metals	0.50	MT/A	CHWTSDF
21	36.1 Sludge from wet scrubbers	15.0	MT/A	CHWTSDF or Triple Effect Evaporator (TEE)/ sale to MPCB authorized party for recycle
22	36.2 Flue Gas Cleanings	3.0	MT/A	CHWTSDF
23	36.4 Distillation residue from contaminated organic solvent	3.0	MT/A	CHWTSDF
24	E-Waste	2.0	MT/A	CHWTSDF or Sale to authorized reprocessor

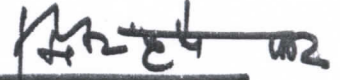
(ii) Treatment: - NIL

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 30<sup>th</sup> day of September every year, the Environmental Statement Report for the financial year ending 31<sup>st</sup> 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.
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 does not operate efficiently and problem of pollution occurs, industry should voluntarily stop the production or total effluent should be reused.
  13. This consent overrides to the earlier consent and subsequent amendments vide Nos.
    - 1) BO/RO-Navi Mumbai/PCI-I/EIC-NM-1706-10/O/CC-233 date 19.10.2010.
    - 2) BO/RO-Navi Mumbai/WPAE/EIC-NM-1703-10/O/CC-280 date 24.12.2010.

14. The applicant shall comply with the conditions stipulated in Environmental Clearance.
15. This consent is issued as per the decision taken in the meeting of the Consent Committee of the Board held on 03/04/2012 with the approval of Hon'ble Chairman of the Board.
16. The Capital investment of the industry is Rs 88.18 Crore

  
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(Milind Mhaiskar)  
Member Secretary

To,  
M/s Zydus Nycomed Healthcare Pvt Ltd.  
Plot No. C-4, MIDC Pawane,  
Thane Belapur Road, Vashi  
Navi Mumbai

Copy to :  
RO, Navi Mumbai /SRO Navi Mumbai I  
-- They are directed to ensure the compliance of consent conditions.  
CAO/Cess Branch/Master file.

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
01	250000/-	017514	21 Mar 2005	UTI Bank
02	225100/-	087401	11 Feb 2010	SBI Bank
03	97825/-	398330	20 Aug 2010	SBI Bank
04	150100/-	074267	19 Feb 2010	Axis Bank