

# 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: 29/01/2015

Consent No: BO/AS(T)/R/EIC NO AD-15570-14/CC-1025

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 & Transboundry Movement) Rules 2008

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

CONSENT is hereby granted to

M/s Ajanta Pharma Limited,  
11 KM stone Gut No.378 Plot No.8,  
Aurangabad Pune Highway Village-waluj,  
Tal-Gangapur Dist- Aurangabad.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(MH&TM) 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: 31.08.2017
2. The Consent is valid for the manufacture of -

Sr. No	Name of Product	Category	Maximum Quantity final. (MT/Month)
1	Lumefantrine	Antimalerial	2
2	Artemether		0.5
3	Nepafenacil	Anti-inflammatory	0.1
4	Loteprednol Etabonate		0.1
5	Bromfenac Sodium		0.05
6	Mesalamine		0.2
7	Nimesulide BP		1
8	Indometacin BP		0.5
9	Prednisolone Acetate		0.2
10	Tafluprost		0.01
11	Iguratimod		0.1
12	Desonide 21 - Phosphate		0.1
13	Malcofenamate		0.1
14	Fenspriride Chlorhydrate		0.1
15	Levobetaxolol HCl		0.2
16	Fluorometholone acetate Usp		0.05
17	Amtolmetin Guacyl	Analgesic	0.2

18	Naproxcinod		0.2
19	Nramaxane Mesylate		0.2
20	Tofacitinib		0.1
21	Nadifloxacin		0.25
22	Zucapsasin		0.1
23	Elaprazole	Treatment of dyspepsia, peptic ulcer disease (PUD), gastroesophageal reflux disease	0.5
24	Aripiprazole		0.2
25	Lafutidine		0.2
26	Lansoprazole		0.5
27	Euliconazole		0.1
28	Remabipide		0.2
29	Deferasirox		0.1
30	Olopatadine		Anti-allergic, Antihistaminic
31	Bilastine	0.1	
32	Betotastine Besilate	0.1	
33	Flupertine maleate	0.1	
34	Facilonalil	0.002	
35	Palonsetron HCL	0.05	
36	Roflumilast	0.1	
37	Latanoprost	Antiglaucoma	0.01
38	Brinzolamide		0.1
39	Bimatoprost		0.01
40	Picotamide	Antithrombotic, fibrinolytic, Anticoagulant	1
41	Clopidogrel Bi Sulphate		0.5
42	Ulipristal		0.05
43	Ursodiol		0.01
44	Dabigatran		0.1
45	Rosuvastatin calcium	Antilipemic	0.2
46	Ivabradine		0.2
47	Colesevelam		0.2
48	Olnesartan	Antihypertensive, Antianginal, Antiarrhythmic	0.2
49	Metoprolol succinate		0.5
50	Ropinirole HCL		0.2
51	Entacapone		0.2
52	Solfenacin Succinate		0.2
53	Aclidinium bromide		0.1
54	Perindopril Alginate		0.2
54	Azelidipine		0.2
55	Cilnidipine		0.2
56	Azilsartan Medoxomil		0.2
57	Delmopinol		0.1
58	Efonidipine HCL ethanolate	0.2	
59	Genifloxacin Mesylate	Anti-bacterial	0.3
60	Tavaborole		0.1
61	Mimocycline HCL		0.05
62	Besifloxacin HCL		0.1

63	Sodium hyaluronate		0.1
64	N-Acetyl ti-camocin		0.5
65	Hydrochlorous acid		0.2
66	Efinaconazole		0.1
67	L- Methyl folate	Treatment of Acute Coronary Syndrome	0.2
68	Teneligliptin	Anti-diabetic	0.2
69	Sitagliptin		0.1
70	viladagliptin		0.1
71	Alogliptin		0.1
72	Linagliptin		0.1
73	Sildenafil citrate Mask complex	In treatment of premature ejaculation	2
74	Vardenafil HCL		0.2
75	Dapoxetine HCL		0.2
76	Montelukos		0.1
77	Sildenafil		0.2
78	Phentermine HCL	Treatment of attention deficit hyperactivity disorder, chronic fatigue syndrome, and major depressive disorder	0.1
79	Difluprednate		0.1
80	Alcaftadine		0.2
81	Aconamide HCL		0.2
82	Retapamulin	Dermatitis, Allergies	0.2
83	Febuxostat	Antianginal	1.5
84	Monetasone Furoate	Glucocorticoid	0.2

(Total Quantity should not exceed 21.042 MT/M)

### 3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 21.5M<sup>3</sup>.  
(ii) The daily quantity of sewage effluent from the factory shall not exceed 1.5M<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:

S. No.	Parameters	Between	Limits
1	pH	Between	5.5 to 9.0
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	Chlorides	Not to exceed	600 mg/l
8	Sulphates	Not to exceed	1000 mg/l
9	TAN	Not to exceed	50 mg/l
10	Bromine	Not to exceed	03 mg/l

(iv) **Trade Effluent Disposal:** The treated effluent shall be recycled / reused to the maximum extent & remaining shall be sent to 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	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
		Nil		

(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	...	5.00	CMD
(ii) Water gets Polluted & Pollutants are Biodegradable	...	25.00	CMD
(iii) Water gets Polluted, Pollutants are not Biodegradable & Toxic	...	0.00	CMD
(iv) Industrial Cooling, spraying in mine pits or boiler feed	...	10.00	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. Air pollution control system of sufficient capacity shall be provided to all dust generating locations and operated properly.
- II. There shall not be any secondary (fugitive) emissions.

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

(i) SPM/TPM	Not to exceed	150.0 mg/Nm <sup>3</sup>
(ii) SO <sub>2</sub>	Not to exceed	201 Kg/day
(iii) NH <sub>3</sub>	Not to exceed	5 PPM
(iv) SO <sub>2</sub> (process)	Not to exceed	50.0 mg/Nm <sup>3</sup>
(v) Hydrobromic acid mist	Not to exceed	35.0 mg/Nm <sup>3</sup>

### Standards for Stack Emissions:

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

Sr. No.	Type Of Fuel	Quantity	UOM
1	LDO	480.0	Lit/ Hr
2	FO	700.00	Lit/ Hr

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

Sr. No.	Chimney Attached To	Height in Mtrs.	APCS
1	Boiler	30.00	Stack
2	DG-Set( 400 KVA)	4.5	Stack
3	Process Vent	20	Scrubber

- (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.

### 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 75 dB(A) during day time and 70 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	5.1 Used /spent oil.	25.00	Lit/M	Sale to authorized recycler
2	20.2 Spent solvents	7.50	MT/M	Sale to authorized recycler
3	20.3 Distillation residue	0.50	MT/M	CHWTSDF
4	28.1 Spent carbon Sludge of AlCl <sub>3</sub>	0.50	MT/M	CHWTSDF
5	33.3 Discarded containers / barrels / liners	125	No/M	Sale to authorize recycler
6	34.3 Chemical sludge from waste water treatment	0.15	MT/M	CHWTSDF

- (ii) Treatment: - NIL

- a. The unit has to display and maintain the data online outside the factory main gate in Marathi & English both on a 6'x4' display board in the manner and the report of the compliance along with photograph shall be submitted to this office & concerned Regional Office/ Sub Regional Office.

- 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 per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
  - ix. An 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.
10. This consent shall not be construed as any exemption from obtaining necessary No Objection Certificate from other Government agencies as may deemed fit necessary.
11. Board has reserved right to review amend, suspend, revoke, etc. this consent same shall binding on industry.
12. This consent is issued as per power delegation to HOD's vide office order No 31/2013 dated 01.03.2013
13. Industry shall extend existing Bank Guarantee of Rs. 5 lakh valid up to 31.12.2017 towards O & M and compliance of consent conditions.
14. This consent is issued in accordance with MoEF ,GOI circular dtd December 14,2006 stating that in case of change of product mix ,change in quantities Or the number of product may be allow without EC by concern SPCB provided such changes in the quantities of products are in the same category & are with previously granted overall total limits.



15. This consent is granted on the basis of the certificate of " No increase in pollution load" issued by Dept. of Environment Science of Dr. Babasaheb Ambedkar Marathwada University Aurangabad.

16. The Capital investment of the industry is Rs. 13.40 Cr.  
(Previous CI-Rs. 13.00 Cr. + increase in CI Rs.40 lakh)

*Mirashe*  
28/11/15

(P.K.Mirashe)

Assistant Secretary (Technical)

To,  
M/s Ajanta Pharma Limited,  
11 KM stone Gut No.378 Plot No 8,  
Aurangabad Pune Highway  
Village-waluj, Tal-Gangapur  
Dist-Aurangabad.

Copy to :

1) Regional Officer, Aurangabad /SRO, Aurangabad 1

They are directed to ensure the compliance of consent condition

2) CAO/CESS,

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	2,50,000/-	002108	07/07/2014	IDBI

(Balance fees Rs. 97000/- will be consider during next renewal of consent)