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.I.

Date: 21/08/2012

Consent No: BO/JDPAMS/RO-AD/EIC No. AD-7051-11/O/CC-519

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 (M, H & TM) Rules respectively].

CONSENT is hereby granted to

M/s. WOCKHARDT LTD., L-1, MIDC Chikalthana, Aurangabad, Maharashtra,

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
1	Palonosetron	20	Kg/m.
	Hydrochloride		
2	Oxybutynin Chloride	225	Kg/m.
3	Captopril	720	Kg/m.
4	CEM 101	85	Kg/m.
5	DIvalproex Sodium	33.33	Kg/m.
6	Fesoterodine fumerate	40	Kg/m.
7	ES-Omeprazole	75	Kg/m.
8	Bethanechol	150	Kg/m.
9	Desloratadine	75	Kg/m.
10	Nicardipine	85	Kg/m.
11	Cetrizine	75	Kg/m.
12	Citalopram	75	Kg/m.
13	Nadifloxcin	150	Kg/m.
14	Pioglitazone	75	Kg/m.
15	Zonisamide	150	Kg/m.
16	Zolpidem Tatterate	82.5	Kg/m.
17	Granicetron	10	Kg/m.
18	Tablets	3	Billion/Year
19	Liquid Orals	975	KL/Year
20	Injections	100	KL/Year

21	Powder	20,000	Kg/m.
<u> </u>		140	Million/Year
22	Capsules		Kg/Year.
23	Trial Batch of R & D	100	
1	Products		

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 100.21 M3.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed $36.5 \, \mathrm{M}^3$.

(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	рН	Between	6.5 to 8.5
2	Suspended Solids	Not to exceed	100 mg/I.
3	BOD 3 days 27 deg.0	Not to exceed	100 mg/I
4	COD	Not to exceed	250 mg/I.
5	Oil & Grease	Not to exceed	10 mg/l.
6	Total Dissolved Solids	Not to exceed	2100 mg/l.
7	Bio assay Test	90% survival of fish after f	irst 96 hrs in 100%
8	Sulphate	Not to exceed	1000 mg/l.
9	Chloride	Not to exceed	600 mg/l.
10	Phosphate(as P)	Not to exceed	5.0 mg/l.

- The generated tread shall be recycle/reused to the (iv) Trade Effluent Disposal: maximum extent and remaining should be disposed on land for gardening within factory premises only.
- (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.
 - Suspended Solids Not to exceed 100 mg/l. (1) 100 mg/l. Not to exceed BOD 3 days 270 C. (2)
- (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	Qty.	Disposal
1.	Polythene Bags	300 Kg/day.	
1.	HDPE Drums	60 Nos./Yr.	
3.	M. S. Drums	60 nos./ Yr.	By Sale to authorized
4.	Cotton Waste	90 Kg/Yr.	recycler.
5.	Broken Glass Bottles	90 Kg/Yr.	recycler.
6.	Corrugated boxes	150 Kg/Yr.	
7	Paper Drums	60 Nos./Yr.	

(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 ... 37.50 CMD
(ii) Industrial Processing ... 85.50 CMD
(iii) Industrial Cooling ... 99.00 CMD
(iv) Agriculture / Gardening ... - 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:

Control Equipment:

- 1. Air Pollution control equipment of sufficient capacity shall be provided to limit the emissions.
- 2. Scrubber of sufficient capacity shall be provided to mixing section.
- 3. Dust collector of sufficient capacity shall be provided to all sources of particulate matter emissions.

Standards for Stack Emissions:

(i) SPM/TPM Not to exceed 100 mg/Nm ³ (ii) SO ₂ Not to exceed 90 Kg/Day	3 101	Stack Ellissions	A A		
(ii) SO ₂ Not to exceed 90 Kg/Day	(i)	SPM/TPM	Not to exceed	100	mg/Nm ³
(ii) SO_2 Not to exceed 90 Rg/Day	` '		N. O	00	Kg/Day
	(ii)	SO_2	Not to exceed	90	NgiDay

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

Sr.No.	Type of Fuel	Quantity
1	LDQ	2.5 MT/Day.
2.	Furnace Oil	900 Lit/Day.
3.	HSD	120 Lit/Day.

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

ine appround	pair or occ the series of the	<u> </u>
Sr.No.	Chimney attached to	<u>Heights in Mtrs</u> .
1.	Boiler-I	21
2.	Boiler - II .	25
3.	D.G. Set (500 & 1010 KVA)	10 Mtrs. each
4.	Thermic Fluid Heater	24

- (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.

(v) 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 from MoEF approved laboratory..

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

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

Sr. No.	Item No. (Sch-I)	Type of Waste	Quantity	Disposal
1	5.1 & 5.2	Used/Spent Oil/ Wastes containing	1.5 Lit/Day.	CHWTSDF
2	33.3	Oil Discarded containers/barrels/liners	1080 Nos/Yr.	Sale to Authorized party after decontamination
3	34.3	Sludge from Waste water treatment	3602 Mt/Yr.	
4	28.1	Residues/wastes	2.5 Kg/D.	Inhouse ETP
5	28.4	Off-Specification products/date expired/discarded medicines.	2.5 Kg/D.	CHWTSDF

(ii) Treatment: - NIL

- 1. The authorization is hereby granted to operate a facility for collection, storage, transport & disposal of hazardous waste.
- 2. The industry should comply with the Hazardous Waste (M,H&TB) Rules, 2008.
 - a. 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 Factories 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.
 - b. 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.
 - c. It shall be ensured that the Hazardous waste is handled, managed & disposed of strictly in accordance with the Hazardous Waste (Management, Handling & Transboundry Movement) Rules, 2008 and shown & submitted to the Board as & when asked for.
- 7. 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 Factories 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.

8. 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.
- 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 Govt. agencies as may deemed fit necessary.
- 10. The industry shall also comply with the Industry specific standards notified under Environment Protection Act.
- 11. This consent is issued as per the "No increase in Pollution Load" certificate from Dr. S. S. Patil, Associated Professor, Dept. of Env. Science, Dr. BAMU, Aurangabad, dtd. 23/11/2011.

- 12. Industry has proposed product mix change within consented limits; hence the consent is issued as per MoEF circular dt. 14.12.2006.
- 13. This consent is issued pursuant to the decision taken in the 3rd Consent Committee meeting of the board held on 02/05/2012.
- 14. Capital investment of the industry is Rs. 61.33 Crores.
- 15. This is issued with the approval of Hon'ble Chairman of the Board.

(Milind Mhaiskar, IAS) Member Secretary

To, M/s. Wockhardt Ltd. L- 1, MIDC Chikalthana, Aurangabad.

Copy to:- 1) Regional Officer, MPCB, Aurangabad, 2) Sub Regional Officer, MPCB, Aurangabad – They are directed to insure 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	4,99,330/-	_ 004082∜€	27/03/2012	ICICI Bank
2	100/-	220216	03/02/2012	Saraswat Co-Op Bank