

# MAHARASHTRA POLLUTION CONTROL BOARD

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Near Sion Circle, Sion (E),  
Mumbai - 400 022

**Consent order No:-** *Formate 1.0/ BO/CAC-Cell/ EIC No NM-4703-13/15thCAC/8982*  
**Date-** *25/10/2013*

To,  
M/s Zydus Takeda Healthcare Pvt. Ltd.,  
Plot No. C-4, TTC Indl. Area, MIDC, Thane-Belapur Road,  
Village- Pawane, Navi Mumbai-4000705

**Subject: Renewal of consent to Operate with amendment for change in product-mix RED category.**

**Ref: 1.** Earlier Consent granted vide no. consent no :- Format 1.0/BO/PAMS/OEIC-NO.NM-4438-13/CC/CAC-6843 dated 16/08/2013  
**2.** Minutes of CAC meeting held on 14.10.2013

Your application CE1307000541

Dated: 24.07.2013

**For: Renewal of consent to Operate with amendment for change in product-mix 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 under Rule 5 of the Hazardous Wastes (M, H & T M) Rules 2008 is considered and the consent is hereby granted subject to the following terms and conditions and as detailed in the schedule I, II, III & IV annexed to this order:**

1. The consent is granted for a period from date of issue of consent to 30.04.2016.
2. The actual capital investment of the industry is Rs.140.55 Crs. (As per C.A.Certificate submitted by industry)
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity in MTA
1	5-Difluoromethoxy-2 Mercapto1 H-Banzimidazole (KSM-6)	60.00
2	2-Chloromethyl-3-4-Dimethoxy Pyrimidine Chloride (KSM-14)	60.00
3	Pantoprazole Sodium	65.00
4	Drapidil	20.00
5	Urapidil Hydrochloride	1.27
6	Policresulen	110.00
7	Bamifylline	4.00
8	Podophyllotoxin	0.03
9	Lornoxicam	3.00
10	Suxamethonium Chloride	4.00
11	Sulfametrole	2.50
12	Midodrin Hydrochloride	0.60
13	Warfarin Sodium	0.60
14	Aprindine	1.00
15	Ethamivan	2.50
16	Hexabendine	0.45

17	Hexaprenaline	0.45
18	Distigmin Bromide	0.60

4. Conditions under Water (P&CP), 1974 Act for discharge of effluent:

Sr. no.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	200	As per Schedule -I	CETP
2.	Domestic effluent	25	As per Schedule -I	CETP

5. Conditions under Air (P&CP) Act, 1981 for air emissions:

Sr. no.	Description of stack / source	Number of Stack	Standards to be achieved
1.	Boiler-02 nos./ furnace oil /Piped Natural Gas.	01 Combined stack	As per Schedule -II
2.	Process vents	10 nos.	As per Schedule -II
3.	DG set (1000KVA & 1500 KVA)	02 nos.	As per Schedule -II
4.	Dust collector	01 no.	As per Schedule -II
5.	Fume Extractor	05 no.	As per Schedule -II
6.	Fire Hydrant pump	01 no.	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Drum (Non contaminated)	200 kg/day	NA	Sale to Authorized recycler
2	Plastic Carboys (Non contaminated)	100 kg/day	NA	Sale to Authorized recycler
3	Fiber Board drum ( Non contaminated)	100 kg/day	NA	Sale to Authorized recycler
4	PVC and paper	100 kg/day	NA	Sale to Authorized recycler
5	Other (metallic and glass scrap deactivated carbon and fiber pads)	175 kg/day	NA	Sale to Authorized recycler
6	Domestic canteen waste	100 kg/day	NA	Authorized local disposal system.

7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	Spent/ Used Oil	5.1	2	MT/A	Sale	Sale/Recycle/Reprocess
2	Contaminated aromatic, aliphatic or naphthanic solvents	20.1	180	MT/A	CHWTSDF/ sale/ Recycle	CHWTSDF/ sale/Recycle
3	Spent solvents	20.2	4574.5	MT/A	CHWTSDF/ sale/Recycle/ Reprocess/ Recover	CHWTSDF/ sale/Recycle/ Reprocess/ Recover
4	Distillation residue	20.3	3816	MT/A	TEE plant/ CHWTSDF	CHWTSDF/ sale/Recycle/ Reprocess /Recover /reuse
5	Process waste & Residue	28.1	45	MT/A	Sale/ CHWTSDF	CHWTSDF/ sale/Recycle/ Reprocess /Recover /reuse
6	Spent carbon/Spent catalyst	28.2	45	MT/A	CHWTSDF	CHWTSDF/ Sale/ Reprocess
7	Date-Expired, discarded & off specification	28.3	16	MT/A	CHWTSDF	CHWTSDF
8	Spent mother liquor	28.4	4000	MT/A	CHWTSDF/ sale/ Triple Effect Evaporator	CHWTSDF/ sale/Triple Effect Evaporator
9	Spent Organic solvent (Chlorinated & non chlorinated solvents)	28.5	1500	MT/A	CHWTSDF/ sale/Recycle/R eprocess/Reco ver/ reuse	CHWTSDF/ sale/Recycle/ Reprocess/ Recover /reuse
10	Chemical containing residue from decontamination and disposal	33.1	100	MT/A	CHWTSDF/ Treatment in ETP	CHWTSDF/ Treatment in ETP
11	Sludge from treatment of waste water arising out of cleaning containers	33.2	4	MT/A	Treatment in ETP/ CHWTSDF	CHWTSDF/ sale/Recycle/ Reprocess/Recover reuse

12	Discarded containers	33.3	244	MT/A	Decontaminat e/ puncture/disp osal through MPCB approved party.	Sale
13	Scrubber blow down effluent	34.1	2128	MT/A	Treatment in ETP/TEE & Sale	CHWTSDF/ sale/Recycle/ Reprocess/ Recover
14	Chemical sludge from ETP / TEE plant	34.3	1535	MT/A	In house	CHWTSDF
15	Chemical sludge from Oil & Grease skimming residue	34.4	1	MT/A	CHWTSDF	CHWTSDF
16	Contaminated filter bags	35.1	3	MT/A	CHWTSDF	CHWTSDF
17	Spent catalyst	35.2	6	MT/A	Recycler/ Reprocess	Sale/Recycle/ Reprocess
18	Spent carbon/Spent catalyst	35.3	20	MT/A	CHWTSDF	CHWTSDF
19	Sludge and filter contaminated with oil	3.3	12	MT/A	Sale / CHWTSDF	Sale / CHWTSDF
20	Spent ion exchange resin containing Toxic metal	34.2	2	MT/A	CHWTSDF	CHWTSDF
21	Sludge from wet scrubber	36.1	15	MT/A	CHWTSDF/ Triple Effect Evaporator /Sale	CHWTSDF/ Triple Effect Evaporator / Sale
22	Flue gas cleaning	36.2	6	MT/A	CHWTSDF	CHWTSDF/ sale
23	Distillation residue from contaminated organic solvent	36.4	3	MT/A	In house treatment in TEE / CHWTSDF	CHWTSDF/ In- house treatment in TEE
24	E-waste	E-waste	2	MT/A	Sale/Recycler/ CHWTSDF	Sale/Recycler/C HWTSDF

8. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
10. This consent is issued in accordance with MoEF, Govt of India circular dated December 14, 2006 stating that in cases of change of product-mix, changes in the quantities or the numbers of product may be allowed without E.C by the concerned SPCB provided such changes in the quantities of product are in the same category and are with the previously granted overall total limits.
11. This consent is issued by overriding consent no: - Format 1.0/BO/PAMS/O/EIC NO.NM-4438-13/CC/CAC-6843 dated 16/08/2013.

For and on behalf of the  
Maharashtra Pollution Control Board

(Rajeev Kumar Mital, IAS)  
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	75,100	011153	17/Jul/2013	SBI Bank
2	25,000	011210	22/Jul/2013	SBI Bank
<b>Fees details of previous consent</b>				
1	37,5100	164328	21.10.2013	SBI Bank
2	56,6284	164398	31.10.2013	SBI Bank

Copy to:

1. Regional Officer-Navi Mumbai and Sub-Regional Officer, Navi Mumbai 1 MPCB: They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. CC/CAC desk- for record & website updation purposes.

## Schedule-I

### Terms & conditions for compliance of Water Pollution Control:

1) A] As per your application, you have provided the Combined Effluent Treatment Plant (ETP) with the design capacity of 225CMD.

B] The Applicant shall operate the combined effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

Sr. No.	Parameters	Standards prescribed by Board (If any)
		Limiting Concentration in mg/l, except for pH
01	pH	5.5 to 9.0
02	Oil & Grease	10
03	BOD (3 days 27oC )	100
04	Total Dissolved Solids	2100
05	TAN	50
06	Suspended Solids	100
07	COD	250
08	Chloride	600
09	Sulphate	1000

C) The treated effluent shall be disposed

i) discharge to the CETP 225.0 CMD (200.0+25.0) CMD (I.E.+D.E)

- 2) D] The sewage treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at sr. no. 1B & C of schedule I shall be applicable.
- 3) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or and extension or addition thereto.
- 4) The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.
- 5) The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 and as amended, by installing water meters, filing water cess returns in Form-I and other provisions as contained in the said act.

Sr. no.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	181.00
2.	Domestic purpose	44.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	207.00
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0.00
5.	Agriculture	5.00

- 6) The Applicant shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance / CREP guidelines.

**Schedule-II**

**Terms & conditions for compliance of Air Pollution Control:**

1. As per your application, you have provided the Air pollution control (APC) system and also erected following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO <sub>2</sub> Kg/Day
1	Process stack/vents - 10 Nos.	Scrubber	6	NA	NA	NA	NA
2	Fume Extractor-05 nos.	Scrubber	6	NA	NA	NA	NA
3	Boiler-02 nos.	Stack of Sufficient height	50 (Combined)	Furnace Oil	770 Kg/Hr	4.5%	1651.6
				Piped Natural Gas	800 SCMH	Nil	NA
4	D.G.Set (1000 KVA)	Stack of Sufficient height	7	HSD	230 Ltr/Hr	1%	110.4
5	D.G.Set (1500 KVA)	Stack of Sufficient height	7	HSD	290 Ltr/Hr	1%	139.2
6	Dust Collector	Stack of Sufficient height	6	NA	NA	NA	NA
7	Fire Hydrant Pump	Stack of Sufficient height	6	HSD	15 Ltr/Hr	1%	7.20

2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time / Environmental Clearance / CREP guidelines.
3. The applicant shall operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Particulate matter	Not to exceed	150 mg/Nm <sup>3</sup>
SO <sub>2</sub> (From Process)	Not to exceed	50 ppm
HCL	Not to exceed	35 mg/Nm <sup>3</sup>
NH <sub>3</sub>	Not to exceed	50 mg/Nm <sup>3</sup>

4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement well before its life come to an end or erection of new pollution control equipment.
5. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).



**Schedule-III**  
**Details of Bank Guarantees**

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C TO R	Rs 5 lakhs	Within 15 days	O & M pollution control systems	30.04.2016	31.08.2016

Maharashtra Pollution Control Board

## Schedule-IV

### General Conditions:

- 1) The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous waste to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- 2) If the MIDC pipeline is broken/ overflowing chamber, in such cases industry shall not discharge their treated effluent into MIDC drain, it shall be sent to CETP by tanker.
- 3) Industry should monitor effluent quality, stack emissions and ambient air quality monthly/quarterly.
- 4) 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.
- 5) Whenever due to any accident 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. In case of failure of pollution control equipments, the production process connected to it shall be stopped.
- 6) The applicant shall provide an alternate electric power source sufficient to operate all pollution control facilities installed 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 and conditions of this consent.
- 7) 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 per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- 8) The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW(MH&TM) Rules 2008, which can be recycled
- 9) /processed/reused/recovered and only waste which has to be incinerated shall go to incineration and waste which can be used for land filling and cannot be recycled/reprocessed etc should go for that purpose, in order to reduce load on incineration and landfill site/environment.
- 10) The industry should comply with the Hazardous Waste (M,H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazarsous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30<sup>th</sup> June of every year.
- 11) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 12) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent (in case of Renewal of consent).
- 13) Industry shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act,1981 and Environmental Protection Act,1986 and industry specific standard under EP Rules 1986 which are available on MPCB website([www.mpcb.gov.in](http://www.mpcb.gov.in)).
- 14) The industry shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent condition towards Environment Protection.
- 15) Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of the collection system with arrangement for measuring the flow. No effluent shall be admitted in the pipes/sewers downstream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.

- 16) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 17) The applicant shall install a separate 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.
- 18) Conditions for D.G. Set
- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
  - 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.
  - 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.
  - Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
  - 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
  - D.G. Set shall be operated only in case of power failure.
  - The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
  - The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 19) The industry should not cause any nuisance in surrounding area.
- 20) 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.
- 21) The applicant shall maintain good housekeeping.
- 22) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a statement on available open plot area, number of trees surviving as on 31<sup>st</sup> March of the year and number of trees planted by September end, with the Environment Statement.
- 23) 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 of solid waste.
- 24) The applicant shall not change or alter the 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. The industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 25) The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
- 26) The industry shall submit quarterly statement in respect of industries' obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can be downloaded from MPCB official site).
- 27) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 28) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.

29) The applicant shall comply with the conditions stipulated in Environmental Clearance granted by MoEF/GoM vide No. F. No. J-11011/372/2008-IA-II(I) dated 30/01/2009.

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Maharashtra Pollution Control Board