

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/ UANno 0000000405/Autorenewal/ CAC-0744
Date-25/07/2016

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 under RED category.
Ref : 1. Earlier Consent granted vide no. Formate 1.0/BO/CAC-Cell/EIC No. NM-4954-13/22nd CAC/1808 dated 26.02.2014.

Your application: 160229FT2019
Dated: 24.02.2016

For: Renewal of 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 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 01.05.2016 to 30.04.2021.
2. The actual capital investment of the industry is Rs.158.2 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 MT/A
1	5-Difluoromethoxy-2 Mercapto 1 H-Banzimidazole (KSM-6)	55.00
2	2-Chloromethyl-3-4-Dimethoxy Pyrimidine Chloride (KSM-14)	55.00
3	Pantoprazole Sodium Sesquihydrate	65.00
4	Urapidil	20.00
5	Urapidil Hydrochloride	1.27
6	Policresulen 50% W/W Solution	110.00
7	Bamifylline Hydrochloride	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 Hydrochloride	1.00
15	Ethamivan	2.50

16	Hexabendine	0.45
17	Hexaprenaline	0.45
18	Distigmin Bromide	0.60
19	Alogliptin Benzoate	10.00

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	Combined treatment in ETP

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/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 to authorized ed recycler/reprocessor
2	Contaminated aromatic , aliphatic or napthanic solvents	20.1	180	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor/
3	Spent solvents	20.2	4574.5	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor
4	Distillation residue	20.3	3816	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor/Reuse
5	Process waste & Residue	28.1	45	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor/Reuse
6	Spent carbon/Spent catalyst	28.2	45	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor
7	Date-Expired, discarded & off specification	28.3	16	MT/A	-----	CHWTSDF
8	Spent mother liquor	28.4	4000	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor /Triple Effect Evaporator
9	Spent Organic solvent (Chlorinated & non chlorinated solvents)	28.5	1500	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor

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10	Chemical containing residue from decontamination and disposal	33.1	100	MT/A	-----	CHWTSDF/ Treatment in ETP
11	Sludge from treatment of waste water arising out of cleaning containers	33.2	4	MT/A	-----	CHWTSDF/ Sale to authorized recycler/reprocessor
12	Discarded containers	33.3	244	MT/A	-----	Sale to authorized party.
13	Scrubber blow down effluent	34.1	2128	MT/A	-----	CHWTSDF/ Sale to authorized ed recycler/reprocessor/ Recovery
14	Chemical sludge from ETP / TEE plant	34.3	1535	MT/A	-----	CHWTSDF
15	Chemical sludge from Oil & Grease skimming residue	34.4	1	MT/A	-----	CHWTSDF
16	Contaminated filter bags	35.1	3	MT/A	-----	CHWTSDF
17	Spent catalyst	35.2	6	MT/A	-----	Sale to authorized recycler/reprocessor
18	Spent carbon/Spent catalyst	35.3	20	MT/A	-----	CHWTSDF
19	Sludge and filter contaminated with oil	3.3	12	MT/A	-----	Sale to authorized party / CHWTSDF
20	Spent ion exchange resin containing Toxic metal	34.2	2	MT/A	-----	CHWTSDF
21	Sludge from wet scrubber	36.1	15	MT/A	-----	CHWTSDF/ Triple Effect Evaporator / Sale to authorized party
22	Flue gas cleaning	36.2	6	MT/A	-----	CHWTSDF/ Sale to authorized party

23	Distillation residue from contaminated organic solvent	36.4	3	MT/A	-----	CHWTSDF/ In- house treatment in TEE
24	E-waste	E-waste	2	MT/A	-----	Sale to authorized Recycler/CHWTS DF

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 under the auto renewal policy of the Board vide letter No MPCB/AS(T)/TB/B-5088 dated 03.12.2015 as per self certificate submitted by Mr Ravichandran Managing Director.
11. The M.P.C.Board reserves the right to revoke the consent any time for any violations.
12. The industry shall inform the Board in each financial year about the change in Capital Investment of the industry. In case. If the Capital Investment is increased by an amount upto 10 %, then industry shall make payment of corresponding fees for consent to establish and also difference in consent to operate fees for the corresponding block year. In case there is increase in Capital investment by over 10% , then the industry shall submit a fresh application in prescribed form.

For and on behalf of the
Maharashtra Pollution Control Board

Mirashe
21/7/16
(P.K.Mirashe)
Member Secretary

Received Consent fee of-

Sr. No.	Amount(Rs.)	DD. No./NEFT No	Date	Drawn On
1	949260	170977	22.01.2016	SBI
2	732840	AXTB1619 74465089	15.07.2016	Axis Bank

Copy to:

1. Regional Officer-Navi Mumbai and Sub-Regional Officer-Navi Mumbai, 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 Effluent Treatment Plant (ETP) with the design capacity of 225CMD.

B] The Applicant shall operate the 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 27°C)	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 discharge to the CETP. 225.0 CMD (200.0 CMD I.E +25.0 CMD D.E)

2) A] As per your consent application, the domestic effluent is treated in ETP.

B] 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	
5.	Gardening/Agriculture	5.0

- 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 ₂ 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. (1 stand-by)	Stack of Sufficient height	40 (Combined)	Furnace Oil	385 Kg/Hr	4.5%	1651.6
				Piped Natural Gas	400 SCM/H	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 ³
SO ₂ (From Process)	Not to exceed	50 ppm
HCL	Not to exceed	35 mg/Nm ³
NH ₃	Not to exceed	50 mg/Nm ³

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	Submitted *	For O & M of pollution control system	30.04.2021	31.08.2021

*The BG of Rs 5 lakh obtained towards O & M of PCS shall be extended for a period upto 31.08.2021.

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.
- 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/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.
- 9) 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 30th June of every year.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) **The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent**
- 12) 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).
- 13) 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.
- 14) 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.

- 15) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 16) 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.
- 17) 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) 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.
 - d) Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
 - e) 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
 - f) D.G. Set shall be operated only in case of power failure.
 - g) The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
 - h) The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 18) The industry should not cause any nuisance in surrounding area.
- 19) 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.
- 20) The applicant shall maintain good housekeeping.
- 21) 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 31st March of the year and number of trees planted by September end, with the Environment Statement.
- 22) 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.
- 23) 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.
- 24) 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.
- 25) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 26) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.

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