

MAHARASHTRA POLLUTION CONTROL BOARD

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Mumbai - 400 022

Consent order No :- Formate 1.0/ BO/CAC-Cell/ EIC No NK-15829-13/1st CAC/4082
Date-30/04/2014

To,
Sandoz Pvt. Ltd.
L-1, Addl. MIDC Mahad
Raigad,-402301

Subject: Amendment for change in product-mix in existing consent RED category.
Ref : 1. Earlier Consent granted vide no. BO/PAMS/Amend/EIC NoRD-2289-12/CAC-603 dated 21/09/2012.

2. Minutes of CAC meeting held on 15.04.2014

Your application:CE1305000609
Dated:24.05.2013

For: Consent Amendment for change in product-mix in existing consent 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 30.06.2015.
2. The actual capital investment of the industry is Rs.124.899 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	Rifampicin	213
2	Central Nervous System(CNS) a) Quetiapine Hemifumate b) Escitalopram c) Setraline Hydrochloride d)Aripriprazole, e) Pramipxole, f) Paroxetine Hydrochloride, g) Montelukast	100
3	Cardiovascular: a) Rosuvastin salt b) Valinester Tosylate (Diovan H7) c)Candesartan, d)Atrovastion e) API Intermediates f) Tigecyline.	142
4	Antiulceratnt: a) Pentaprazole, b) Lansoprazole	40
5	Antidiabetic (Rosiglitazone) : a)Antibacterial b)Moxifloxacin c) Mycophenolate Mofetile	15
6	Antithrombic: a) Clopidogrel HCL, b) Venlafaxine	15
7	Lactobionic Acid	25
8	Methyl Ergometrine maleate/Posoconazole	0.065
9	Antiemetic agent: a) Fosaprepitant b) Aprepitant	1.3
10	Prostatic Hyperblasia Therapy: a) Silodosin	0.5
11	Feboxostat	0.7
	By-products	

1	Composted Biomanure from Mycelium cake	1800
2	Solvents (spent) for the sale authorized recycler	1200
3	Piperazine diacetate (crude)	120

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	877	As per Schedule -I	CETP
2.	Domestic effluent	50	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(2 NOS)	1	As per Schedule -II
2.	(Carbon Absorption system(CAS))	2	As per Schedule -II
4	Process vents	8	As per Schedule -II
3.	DG set (2 x 1250 KVA, 1500 KVA)	3	As per Schedule -II
4.	Incinerator	1	As per Schedule -II

6. Condition for Non hazardous solid wastes.

Sr. No.	Type of waste	Quantity	UOM	Disposal
1.	Bagasse briquette ash	2.0	MT/D	Landfill within premises

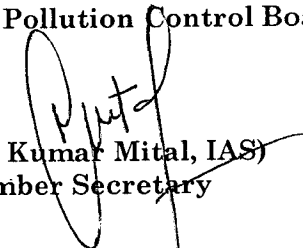
7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal	
1	Spent catalyst / spent carbon	28.2	1334.00	Kg/D	—	Incineration on site or sent to CHWTSDF Taloja	
2	Filters and filter material which have organic liquid in them	35.1	167.00	Kg/D	—	CHWTSDF Taloja for Incineration	
		Spent Catalyst					35.2
		Spent Carbon					35.3
3	Contaminated aromatic, and aliphatic Solvent not for originally intended use	20.1	1000.00	Kg/D	—	Sale to MPCB Approved reprocessor	
4	Chemical sludge from waste water treatment	34.3	2800.00	Kg/D	—	CHWTSDF , Taloja	

5	Spent mother liquor	28.4	3334.00	Kg/D	—	CHWTSDF, Taloja for Incineration
6	Wastes/residue containing oil	5.2	39.0	Kg/D	—	Sale to MPCB approved party/ Incineration site
	Used or Spent oil	5.1				
7	Incineration Ash of Flue gas cleaning residue	36.2	1167.00	Kg/D	—	CHWTSDF, Taloja
8	Distillation residues	20.3	1717.00	Kg/D	—	CHWTSDF, Taloja for Incineration
9	Off specification products	28.3	20.0	Kg/D	—	CHWTSDF, Taloja for Incineration/On site Incineration
10	Distillation residues from contaminated organic solvent	36.4	300.00	Kg/D	—	CHWTSDF, Taloja for Incineration / On site Incineration
11	Sludge from wet scrubbers Sludge from Multiple Effect evaporator (MEE)	36.1	1.75	Tons /D	—	CHWTSDF, Taloja for Incineration

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 granted on the basis of the certificate of “no increase in pollution load” dated 25.07.2013 by ICT, Mumbai.
12. This consent is issued by overriding consent no: - BO/PAMS/Amend/EIC NoRD-2289-12/CAC-603 dated 21.9.2012.

For and on behalf of the
Maharashtra Pollution Control Board


(Rajeev Kumar Mital, IAS)
Member Secretary

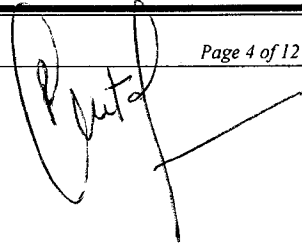
Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	6000	39168	29.12.2012	SBI Bank

Copy to:

1. Regional Officer -Raigad and Sub-Regional Officer-Mahad 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.

Maharashtra Pollution Control Board



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) for trade effluent and domestic effluent with the design capacity of 1000.0 CMD.

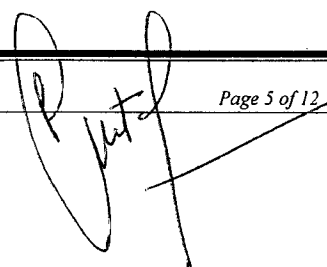
B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

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	BOD 3day's at 27°C	100mg/lit
03	Oil & Grease	10 mg/l
04	Suspended Solids	100 mg/l.
05	COD	250 mg/lit
06	Ammonical nitrogen (as N)	50 mg/l.
07	Mercury	0.01mg/lit
08	Arsenic	0.2 mg/l
09	Hexavalent Chromium	0.1 mg/l
10	Lead (as Pb)	0.1 mg/l.
11	Cyanide (as CN)	0.2 mg/l.
12	Phenolics (C ₆ H ₅ OH)	1.0 mg/l.
13	Sulphides (As S)	2.0 mg/l
14	Phosphate (As P)	5.0 mg/l
	Bioassay Test: 90% survival of fish after first 96 hrs. in 100 % effluent. (Test should be carried out as per IS: 6582-1971	

C) The treated effluent shall be discharge to the CETP

D) In case the treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at sr. no.1 B & C of schedule I shall be applicable.

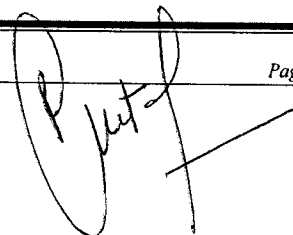
2) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall 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.



- 3) 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.
- 4) 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	365
2.	Domestic purpose	50
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	795
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic.	0.0
5	Plantation /Gardening	35

- 5) 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	Boiler (I & II)	Stack with Bag Filters	54	Furnace Oil	9 KL/D	4.5	810
				Bagasse briquette	28.0 MT/D	0.2	112
2	Incinerator	Stack	30	HSD	120 Lit/Hr	1	57.6
3	D.G.Set (2 X1250 KVA & 1 x 1500 KVA)	Stack	17 each	HSD	1 MT/D	1	20
4	Carbon Absorption System	Stack	20	—	—	—	—
5	Process vents (8 nos)	Acid Alkali Scrubber	17 each	—	—	—	—

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 .
HCL	Not to exceed	35 ppm
NO _x /SO ₂	Not to exceed	50 ppm

4. Emissions from Incinerator:

Parameter	Emission (mg/Nm ³)	Limit
Particulate matter	50	
HCL	50	
SO ₂	200	
CO	100	
TOC	20	
Total dioxins and furans	0.1ngTEQ/Nm ³	
Sb+As+Pb+Cr+Co+Cu+Mn+ Ni+V+Cd+Th+Hg and their compounds	1.5	

- a) All monitored values shall be corrected to 11 % oxygen on dry basis.
- b) The CO₂ concentration In tail gas shall not be less than 7%

c) In case, halogenated organic waste is less than 1% by weight in input waste, all the facilities in twin chamber incinerator shall be designed so as to achieve a minimum temperature of $850+25^{\circ}\text{C}$ in primary chamber and 950°C in secondary combustion chamber and with a gas residence time in secondary combustion chamber not less than 2 (two) seconds, or all the facilities in single chamber incinerator for gaseous hazardous waste shall be designed so as to achieve a minimum temperature of 950°C in the combustion chamber with a gas residence time not less than 2 (two) seconds.

or

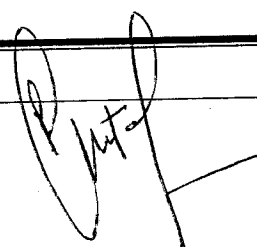
In case halogenated organic waste is more than 1% by weight in input waste, waste shall be incinerated only in twin chamber incinerators and all the facilities shall be designed to achieve a minimum temperature of $850+25^{\circ}\text{C}$ in primary chamber and 1100°C in secondary combustion chamber with a gas residence time in secondary combustion chamber not less than 2 (two seconds).

- d) Scrubber meant for scrubbing emissions shall not be used as quencher.
- e) Incineration plants shall be operated (combustion chambers) with such temperature, retention time and turbulence, as to achieve Total Organic Carbon (TOC) content in the incineration ash and residue less than 3%, and their loss on ignition is less than 5% of the dry weight. In case of non-conformity, ash and/or residue shall be re-incinerated.
- f) The incinerator shall have a chimney of at least thirty metre height.
5. 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.
6. 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	Submissi on Period	Purpose of BG	Complian ce Period	Validity Date
1	C to R	Rs 5 lakhs	Within 15 days from the date of issue of consent	O & M of Pollution Control System.	30.06.2015	31.10.2015

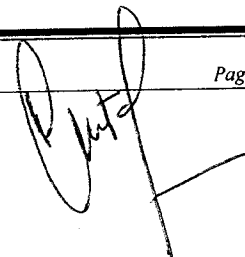
Maharashtra Pollution Control Board



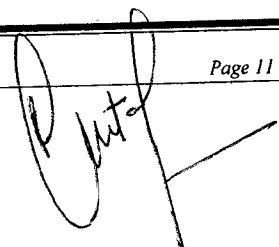
Schedule-IV

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 /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 Hazardous 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 should comply with the Hazardous Waste (M, H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Wastes (M,H &TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 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
 - 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
- 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 yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end.
- 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 official e-mail address and any change will be duly informed to the MPCB.
- 27) 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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Maharashtra Pollution Control Board

