

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 PN-20939-14/8thCAC/ 6778

Date: 18/07/2014

M/s. Cipla Limited.
Plot No D-07, MIDC Kurkumbh,
Tq. Daund, Dist. Pune

Subject: Renewal of Consent to Operate under RED category.

Ref : 1. Earlier Consent granted vide no. *Formate 1.0/ BO/CAC-Cell/ EIC No PN-18096-13/14thCAC/ dated 25/10/2013.*

2. Minutes of CAC meeting held on 30.06.2014

Your application: CO1403000346

Dated: 26.02.2014

For: Renewal of 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 01.05.2014 to 30.04.2018.
2. The actual capital investment of the industry is Rs. 265.48 Crs. (As per C.A. Certificate).
3. The Consent is valid for the manufacture of

Sr. No.	Product / By-Product Name	Maximum Quantity in MT/A	
1	Bulk Drug (API)		
A	Anti-inflammatory	1	Celecoxib
		2	Fluticascode Propionate
		3	Meloxicam
		4	Beclomethasone Dipropionate
		5	Mometasone Furoate
		6	Budesonide
		7	Loteprednol Etabonate
B	Anti-Retrovirals/Anti-Bacterial	1	Famciclovir
		2	Lamivudine
		3	Ciprofloxacin Hydrochloride
		4	Norfloxacin
		5	Fluconazole
C	Anti-Diabetic	1	Pioglitazone Hydrochloride
		2	Nateglinide
D	Anti-Psychotic	1	Citalopram Hydrochloride
		2	Paroxetine Hydrochloride
		3	Sertaline Hydrochloride
		4	Olanzapine
		5	Quetiapine Fumerate
		6	Ziprasidone Hydrochloride
		7	Aripiprazole

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	Used /spent oil	5.1	400	Lit/M	--	Sale to authorized reprocessor
2	Discarded containers barrels / liners	33.3	400.00	Nos./M	--	Sale to authorized party
3	Chemical sludge from waste water treatment	34.3	1500	Kg/m	--	CHWTSDF
4	Sludge from wet scrubbers	36.1	5000	Kg/M	--	CHWTSDF
5	Sludge from MEE system	36.1	30	MT/M	--	CHWTSDF
6	Spent solvents	20.2	150	KL/M	--	Sale to authorized reprocessor
7	Spent catalyst / spent carbon	28.2	500	Kg/m	--	CHWTSDF
8	Date-expired, discarded and off-specification drugs	28.3	5000	Kg/M	--	CHWTSDF
9	Spent organic solvents	28.5	5000	Lit/M	--	Sale to authorized reprocessor
10	Spent mother liquor	28.4	750	m3/dilution with water/ M	In-house	MEE

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.

For and on behalf of the
Maharashtra Pollution Control Board

(Rajeev Kumar Mital, IAS)
Member Secretary

E	Cardiac	1	Carvedilol
		2	Losartan Potassium
		3	Clopidogril Bisulphate
		4	Ramipril
F	Bronchodialator	1	Salbutamol Sulphate
		2	Formoterol Fumarate
G	Anti-Emetic	1	Ondencetron Hydrochloride
H	Bone Resorption Inhibitor	1	Pamidronic Acid/Disodium
		2	Alendronate Sodium Trihydrate
I	Anti-Parkinsonian	1	Pramipexole Dihydrochloride
J	Sedative	1	Zolpiderm Tartrate
		2	Rizatriptan Benzoate
K	Anti-Obesity	1	Sibutramine Hydrochloride
Total Capacity			160 MT/Year

2] Formulations: The total equivalent weight of the formulation products manufacturing shall not to exceed 325 MT/year

Sr. No.	Product / By-Product Name	Maximum Quantity in MT/A
1	Tablets as approved by FDA	Total quantity: 2000 Million Nos./Year
2	Capsules as approved by FDA	Total quantity: 170 Million Nos./Year,
3	Soft Gelatin products as approved by FDA	Total quantity: 21.2 Million Nos./Year
4	Suppositories and Oral Paste as approved by FDA	Total quantity: 12 Million Nos./Year,
5	Sachets as approved by FDA	Total quantity: 85 lac Nos./Year

Industry shall manufacture 12 products at a time on a campaign basis.

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	330	As per Schedule -I	100% Recycle
2.	Domestic effluent	70	As per Schedule -I	100% Recycle

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 & Thermopack	02	As per Schedule -II
2.	Process Stacks	23	As per Schedule -II
3.	DG set	05	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Plastic Scrap, Glass scrap, Wooden Scrap, Metal Scrap	250 MT/Year	Nil	Sale to authorized party

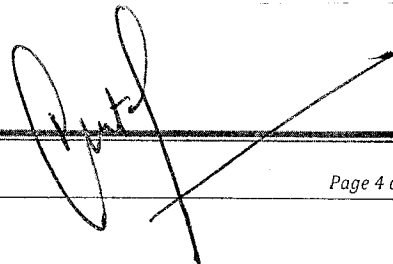
Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	The balance fees of Rs 23,00,826/- as per the consent no Formate L.0/BO/CAC-cell/EICNoPN-18096-13/14thCAC/9057 dated 25.10.2013 is considered at the time of this renewal.			

The balance fees of Rs 176986 from the above will be considered at the time of next renewal by the Board.

Copy to:

1. Regional Officer - Pune and Sub-Regional Officer- Pune-I, MPCB, Pune. 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 400 CMD.

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 27°C)	30
04	Total Dissolved Solids	2100
05	Chromium (Hexavalent)	0.10
06	Phenolics (C ₆ H ₅ OH)	1.0
07	Sulphide (as S)	2.0
08	Phosphate (as P)	5.0
09	Suspended Solids	100
10	COD	250
11	Chloride	600
12	Sulphate	1000

C) The treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way outside factory premises. The low COD effluent after biological treatment followed by Reverse Osmosis shall be recycled for utility and High COD effluent shall be treated in Multiple Effect Evaporator (MEE) and VTFD to get solid concentrate. The Solids generated will be sent to CHWTSDF.

2) A.] As per your consent application, you have provided the septic tanks. The overflow of septic tank will be mixed along with trade effluent for further treatment

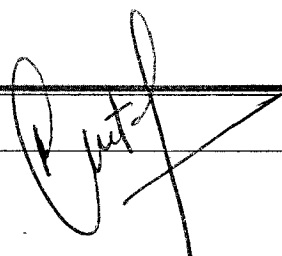
B] In case the treatment system is combined for trade effluent and sewage then the standards and disposal path prescribed at sr. no.1 B & C of schedule I shall be applicable.

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	200
2.	Domestic purpose	82
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	315
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	Nil
5.	Other such Agriculture/ Gardening	200

- 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 Stacks (23)	Wet Scrubber	2.5, 2.5, 10, 5, 25, 11, 14.5, 12, 11, 3, 11, 2, 3.5, 2.2, 2.2, 11.5, 11.5, 2.2, 2.5, 10.5, 10.5, 10.5, 15, 2.5, 4.5.	--	--	--	--
2	Thermopack	Stack	30	Diesel	5.0 KL/Month	4.5	0.75
3	Boiler (2 nos)	Stack	Common chimney of 30	Furnace Oil	4.5 KL/Day	4.5	16.58
4	D.G.Set (3x1250 KVA)	Stack	7.5 each	Diesel	24.0 KI/Month	1	0.02
5	D.G.Set (1500 KVA)	Stack	14.71	Diesel			
6	D.G.Set (750 KVA)	Stack	5.5	Diesel			

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 ppm
NO _x	Not to exceed	50 ppm
Halogen	Not to exceed	0.3 ppm

4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration 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
	C T O R	Rs 5 lakhs	Submitted	O & M of pollution control system	30.04.2018	31.08.2018

* The existing BG of Rs 5 lakhs towards O & M of pollution control system shall be extended upto the period of 31.08.2018.

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) Industry ~~should~~ monitor effluent quality, stack emissions and ~~ambient air~~ quality ~~monthly/quarterly~~.
- 3) 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.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) 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.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 10) **The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent .**
- 11) 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).
- 12) 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.
- 13) 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.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 15) 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.

16) 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

17) The industry should not cause any nuisance in surrounding area.

18) 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.

19) The applicant shall maintain good housekeeping.

20) 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.

21) 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.

22) 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.

23) 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.

24) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.

25) 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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