

MAHARASHTRA POLLUTION CONTROL BOARD

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Near Sion Circle, Sion (E),
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Consent order No :- Formate 1.0/ BO/CAC-Cell/ EIC No RD-2593-13/18th CAC - 587
Date- 20/01/2014

To,
M/s. Cipla Ltd. Plot No A-2,
MIDC Patalganga,
Tal Khalapur, Dist Raigad

Subject: Consent to First Operate RED category.

Ref : 1. Earlier Consent granted vide no. BO/PAMS/E/EIC NO.RD-2482-11/CC CAC-34 dated 30/11/2011.

2. Minutes of CAC meeting held on 08.01.2014

Your application CO1306000326

Dated: 18/04/2013

For: Consent to First 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 Waste (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 the date of issue of consent to 30/04/2015
2. The actual capital investment of the industry is Rs. 208.00 Crs. (As per Undertaking submitted by the industry).
3. The Consent is valid for the manufacture of

Sr. No.	Product /By-Product Name	Maximum Quantity in MT/A
1.	Antihistaminic/ Anti-Inflammatory Drugs:	17.0
	Loraketone/Loratidine and its derivative Desloratadine and its derivatives of Fexofenadine hydrochloride and its derivatives Or Promethazine hydrochloride and its derivatives OR Celecoxib and its derivatives OR Etoricoxib and its derivatives OR Meloxicam and its derivatives or Rofecoxib and its derivatives OR Piroxicam V OR Letirunomide and its derivatives OR Tramadole Hydrochloride and its derivatives OR Valdecoxib and its derivatives OR Parecoxib Sodium and its derivatives OR Divalproex Sodium and its derivatives OR Raloxifene Hydrochloride and its derivatives OR Mometosone Furate and its derivatives OR Lumefantrine & its derivates.	
2.	Antidepressant Drugs	27.0
	Fluxetine Hydrochloride and its derivatives OR Racemic Alcohol/ Paroxitine Hydrochloride and its derivatives OR Venlafaxine Hydrochloride and its derivatives OR Bupropion Hydrochloride and its derivatives OR Citalopram Hydrobromide and its derivatives OR Duloxetine Hydrochloride and its derivatives OR Reboxetine Methane Sulfonate and its derivatives OR Sertraline Hydrochloride and its derivatives OR Torseamide and its derivative OR Escitalopram oxalate & its derivatives	

3.	Hormones	3.50
	Mesterolone and its derivatives OR HPC V OR Testosterone Enanthate and its derivatives OR Norethisterone and its derivatives OR Levonorgestryl and its derivatives OR Mifepristone and its derivatives	
4.	Antibacterial / Antifungal / Antiviral Drugs	52.0
	Sulfamoxole and its derivatives OR Trimethoprim and its derivatives OR Ciprofloxacin and its derivatives OR Difloxacin and its derivatives OR Enrofloxacin and its derivatives OR Gatifloxacin and its derivatives OR Linezolid and its derivatives or Levofloxacin Hemihydrate and its derivatives OR Norfloxacin and its derivatives OR Ofloxacin and its derivatives OR Sparfloxacin and its derivatives OR Fluconazole and its derivatives OR Terbinafine Hydrochloride and its derivatives OR Aciclovir and its derivatives OR Didanosine and its derivatives OR Efavirin and its derivatives OR Lamivudine and its derivatives OR Nelfinavir Mesylate and its derivatives OR Praziquantel and its derivatives	
5.	Cardiac Drugs / Erectile Dysfunction	25.0
	Xantinol Nicotinate and its derivatives OR Atorvastatin Calcium and its derivatives OR Fluvastatin Sodium and its derivatives OR Oxymetazoline Hydrochloride and its derivatives OR Pitavastatin and its derivatives OR Pitavastatin Sodium and its derivatives OR Simvastatin and its derivatives OR sildenafil Citrate and its derivatives OR Apomorphine and its derivatives	
6.	Laxative / Anti alcerative Drugs	127.0
	Bisacodyl and its derivatives OR Normacol and its derivatives OR Famotidine and its derivatives OR Lansoprazole and its derivatives OR Omeprazole , Omeprazole Magnesium/ Sodium and its derivatives OR Pantaprazole and its derivatives OR Rabeprazole and its derivatives	
7.	Antihypertensive Drugs	24.0
	Clonidine Hydrochloride and its derivatives OR Di- Pyridamole and its derivatives OR Verpamil Hydrochloride and its derivatives OR Amlodipine Besylate Hydrochloride and its derivatives Atenolol and its derivatives OR Benzapril Hydrochloride and its derivatives OR Candesartan Cilexetil and its derivatives OR Carvedilol and its derivatives Diltiazem Hydrochloride and its derivatives OR Enalapril Maleate and its derivatives OR Metolazone and its derivatives OR Ramipril and its derivatives OR S- Amlodipine Besylate and its derivatives OR Terazosin Hydrochloride Dihydrate and its derivatives Or Telmisartan & its Derivatives	
8.	Anti- Asthamatic Drugs	72.0
	Theophylline and its derivatives OR Etofyline and its derivatives OR Diprophylline and its derivatives OR Montelukast Sodium and its derivatives OR Salbutamol & its derivatives	
9.	Antiepileptic Drugs	16.0
	Carbamazepine and its derivatives	
10	Anti Diabetic Drugs	24.0
	Sulphonamide / Glibenclamide / Glyburide and its derivatives OR Glimperide and its derivatives OR Pioglitazone Hydrochloride and its	

	derivatives OR Repaglenide and its derivatives	
11	Antispasmodic Drugs	6.0
	Mebeverine Hydrochloride and its derivatives	
12	Anti Cancer / Antineoplastic Drugs	1.0
	Fosfestrol and its derivatives OR Cyclophosphamide and its derivatives OR Exemestane and its derivatives	
13	R&D Centre	-
	Total	394.50

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	130	As per Schedule -I	100% Recycle
2.	Domestic effluent	20	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 (3TPH, 2X 2TPH)	2	As per Schedule -II
2.	Process scrubbers for reactors	5	As per Schedule -II
3.	DG set (1500 KVA, 250 KVA)	2	As per Schedule -II

6. 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	Residue and wastes	28.1	16	MT/M	N.A	CHWTSDF
2	Spent catalyst/spent carbon off specification products	28.2	2	MT/M	N.A	CHWTSDF
3	Spent Mother Liquor	28.4	59	MT/M	N.A	Sale to register recycler/CHWT SDF
4	Spent Organic Solvents	28.5	70	MT/M	N.A	Sale to register recycler/CHWT SDF
5	Chemical Sludge from ETP	34.3	10	MT/M	N.A	CHWTSDF
6	Used/Spent Oil	5.1	4	MT/M	N.A	Sale to register recycler
7	Date expired, discarded and off-specification drugs/medicine	28.3	59	MT/M	N.A	CHWTSDF

7. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
8. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
9. Industry shall comply the para no 6 of RRZ policy dated 13.07.2009 regarding modernization/expansion/change in product mix without increase in pollution load.
10. Industry has completed R & D plant without obtaining C to E and violated the environmental laws. Hence it was decided to obtain a resolution from the Company's Board that they have completed R & D activity and violated the provisions of Environmental Laws and in future, they will not do such violations. If the industry authority fails to submit the above said resolution within one month period, consent will be treated as cancelled.

For and on behalf of the
Maharashtra Pollution Control Board

(Rajeev Kumar Mittal, IAS)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	832000 /-	43155		Axis Bank
2	100/-	43160		Axis Bank
3	3,20,000	Balance fees from previous consent.		

The balance fees of Rs 5,36,000/- shall be considered at the time of next renewal

Copy to:

1. Regional Officer - Raigad and Sub-Regional Officer- Raigad-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 150 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 27oC)	100
04	Total Dissolved Solids	2100
05	Phenolics (C6H5OH)	1.0
06	Sulphide (as S)	2.0
07	Phosphate(as P)	5.0
08	Suspended Solids	100
09	COD	250
10	Chloride	600
11	Sulphate	1000
12	Total Ammonical Nitrogen	50

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 and tertiary treatment followed by Reverse Osmosis and UF shall be recycled for utility. The rejects of RO & UF are treated in MEE and VTFD. 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.

D] The domestic effluent will be mixed along with trade effluent at secondary stage for further treatment as the industry is having Biological treatment system for the treatment of trade effluent.

E] 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	175
2.	Domestic purpose	50
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	150
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	Nil
5.	Other such Agriculture/Gardening	46

- 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:

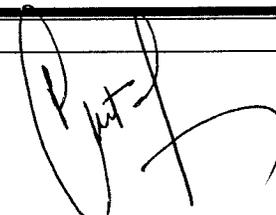
1. As per your application, you have provided the Air pollution control (APC) system and also erected following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO ₂ Kg/Da ₂
1	Boiler (3TPH)	Stack	32 mtrs	Furnace Oil	130 Litres/Hr	4.5	280
2	Boiler 2X 2TPH	Stack	32 mtrs combined	Furnace Oil	100 Litres/Hr each	4.5	432
3	Process scrubbers for reactors	Stack	3.2 mtrs,3.7 mtrs,3.7 mtrs,3.2 mtrs,3.7 mtrs	N.A	N.A	N.A	N.A
4	DG set 250 KVA	Stack	7 mtrs	HSD	35 litres/Hr	1	16.8
5	DG set 1500 KVA	Stack	30 mtrs	HSD	210 litres/Hr	1	100.8

2. Industry shall operate only one boiler (Either 3 TPH or 2 x 2 TPH) at a time.
3. 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.
4. 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 mg/Nm ³
NH ₃	Not to exceed	50 ppm
HBr	Not to exceed	35 mg/Nm ³

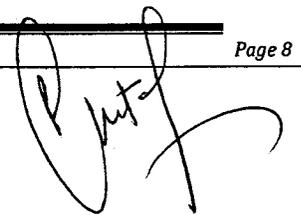
5. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
6. The Board reserves its 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	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C T O O	Rs 10 lakhs	Within 15 days from the date of issue of consent.	O & M of pollution control system	30.04.2015	31.08.2015
2	C T O O	Rs 2 lakhs	Immediate	Towards submission of Board Resolution	Within one month from date of issue of consent	20.05.2014

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 Hazardous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th 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**
- 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).
- 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.

