

MAHARASHTRA POLLUTION CONTROL BOARD

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Kalpataru Point, 3rd & 4th floor, Sion- Matunga
Scheme Road No. 8, Opp. Cine Planet Cinema, Near
Sion Circle, Sion (E),
Mumbai - 400 022

Consent order No: - Formate 1.0/ BO/CAC-Cell/ EIC No

Date-13/07/2015

/3rd CAC/ 7754

To,
M/s Hospira Healthcare India Private Limited
L-9 & L-8(part), MIDC, Gut No.36, 37 & 38,
CIDCO, Village-Vitawa, Waluj,
Dist.-Aurangabad-431136

Subject: 1st Consent to Operate for additional standby FO fired boiler and amendment in existing consent for change in product mix and their amalgamation under RED category.

Ref : 1. Existing Consent granted vide no. Formate 1.0/ BO/CAC-Cell/EICNo.AD-14150-13/2nd CAC-4517 dtd.12/05/2014 which is valid upto 30.04.2016.
2. Your application approved in CAC meeting held on 24.06.2015.

Your application: CO1504000091

Dated: 20.03.2015

For: 1st Consent to Operate for additional standby FO fired boiler and amendment in existing consent for change in product mix and their amalgamation 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 the date of issue of consent up to 30.04.2016.
2. The actual capital investment of the industry is Rs.543.8 Crs. (As per CA certificate submitted by industry).
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity in MTA
1	Alendronate Sodium Trihydrate	0.500
2	Almotriptan Malate	0.010
3	Alosetron HCl	0.002
4	Aripiprazole	1.200
5	Armodafinil	0.200
6	Atorvastatin Calcium	0.100
7	Aztreonam	0.100
8	Biopenam	0.500
9	Cetirizine HCL	1.200
10	Cilastatin Sodium Sterile	5.300
11	Clopidogrel Hydrogen Sulphate	0.500
12	CRAMs products	16.000
13	Dabigetron etexilate	0.100
14	Dalfampridine	0.100

15	Darifenacin hydrobromide	0.015
16	Desloratadine	0.050
17	Dexlansoprazole	0.500
18	Dipyridamole	0.100
19	Divelproex Sodium	1.000
20	Doripenem	0.500
21	Dronedarone	0.100
22	Duloxetine Hydrochloride	0.400
23	Eletriptan HBr	0.025
24	Eprosartan	0.100
25	Esomeprazole Magnesium	0.041
26	Eszopiclone	0.100
27	Ertapenem	2.500
28	Ezetimibe	0.004
29	Felodipine	0.210
30	Faropenem Sodium	0.200
31	Fesoterodine fumarate	0.008
32	Formatfinance (DPOC-4088)	0.045
33	Frovatriptan Succinate	0.005
34	Gabapentin encarbil	0.200
35	Gemiflexacin Mesylate	0.100
36	Granisetron HCl	0.050
37	Ibandronate Sodium	0.800
38	Iloperidone	0.016
39	Imipenem monohydrate sterile	5.300
40	Lansoprazole	0.710
41	Levetiracetam	0.200
42	Levofloxacin Hemipentahydrate	1.603
43	Linagliptin	0.100
44	Losarton Potassium	0.500
45	Lurasidone	0.100
46	Memantine HCl	1.040
47	Meropenem Sterile	35.000
48	Modafinil	5.500
49	Montelukast sodium	0.012
50	Naratripton HCl	0.100
51	Nebivolol	0.100
52	Nisoldipine	0.240
53	Olanzapine	0.600
54	Olmesartan Medoximil	0.050
55	Paliperidone	0.040
56	Palonosetron HCl	0.001
57	Pamidronic Acid	0.100
58	Panipenem	0.100
59	Pantoprazole	4.000
60	Phenytoin Sodium	0.200
61	Piperacillin Acid	40.000
62	Pitavistatin calcium	0.005
63	Pramipexole	0.020
64	Prasugrel HCl	0.008
65	Quetapine Hemifumarate	0.500
66	Raloxifine HCl	0.015
67	Rasagiline Mesylate	0.050

68	Rabeprazole Sodium	0.050
69	Risedronate Sodium	0.210
70	Rivastigmine Tartarate	0.150
71	Roflumilast	0.100
72	Ropinirole	0.070
73	Rosuvastatin	0.100
74	Rufinamide	0.100
75	Silodosin	0.010
76	Sitagliptin	0.100
77	Sumatriptan Succinate	4.500
78	Tadalafil	1.500
79	Tazobactam	5.000
80	Tebipenem	0.500
81	Telmisartan	0.200
82	Terbinafine HCl	9.500
83	Tolterodine Tartarate	0.140
84	Trans- Resveratrol	0.100
85	Venlafaxine HCl	0.500
86	Vilazodone	0.100
87	Zaleplon	0.150
88	Zolmitriptan Tartarate	0.100
89	Zolpidem Tartarate	0.100
90	Lidocaine hydrochloride monohydrate	2.000
91	Succinylcholine chloride Dihydrate	5.000
92	Bupivacaine Hydrochloride monohydrate	4.000
93	Etomidate	0.500
94	Sodium Nitroprusside	0.150
95	Tromethamine	2.000
	Total	166.005

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	480	As per Schedule -I	Recycled in utilities and remaining on land for gardening.
2.	Domestic effluent	40	As per Schedule -I	On land for gardening

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 X 5 MT/H)	2	As per Schedule -II
2.	Boiler(12 MT/Hr.)	1	As per Schedule -II
3	Process vents	26	As per Schedule -II
4.	DG sets (1250 KVA X 4, 500 KVA, 750 KVA, 1500 KVA)	7	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Canteen Waste	600 kg/m	—	Composting
2	Office Waste	2000 kg/m	—	Sale
3	Packing waste	1000 kg/m	—	Sale

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

Sr. No.	Type Of Waste	Categor y	Quantity	UOM	Treat ment	Disposal
1	Used/spent oil	5.1	4	MT/A	—	Sent to Authorized party
2	Wastes/residues containing oil	5.2	4	MT/A	—	Sent to Authorized party
3	Spent solvents	20.2	10	MT/A	—	Recovered in SRP/Sent to Authorized party
4	Distillation residues	20.3	15	MT/A	—	CHWTSDF
5	Residues and wastes	28.1	25	MT/A	—	CHWTSDF
6	spent catalyst / spent carbon	28.2	200	MT/A	—	Spent catalyst to supplier for recovery, and Spent Carbon to CHW TSDF
7	Spent mother liquor	28.4	150	MT/A	—	CHW TSDF/ Sent to Authorized party
8	Spent organic solvent	28.5	362	MT/A	—	Recovered in SRP /Sent to Authorized party
9	Discarded containers / barrels / liners used for hazardous wastes/chemicals	33.3	20	MT/A	—	Recovered in SRP /Sent to Authorized party
10	Flue gas cleaning residue	34.1	3	MT/A	—	CHWTSDF
11	Chemical sludge from waste water treatment plants	34.3	1455	MT/A	—	CHWTSDF
12	Chemical sludge, oil & grease skimming residue from industry-specific effluent treatment plants	34.4	2	MT/A	—	CHWTSDF
13	Distillation residue	36.4	125	MT/A	—	CHWTSDF

from contaminated organic solvents						
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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 EC 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" dtd 16.03.2015 issued by ICT, Mumbai.
12. This consent is granted by overriding consent no Formate 1.0/ BO/CAC-Cell/EICNo.AD-14150-13/2nd CAC-4517 dtd.12/05/2014.
13. As per CPCB directions dated 02.03.2015, installation of online continuous effluent monitoring systems is applicable for bulk drug industry. Also online continuous stack emission monitoring systems is not applicable being an API unit. However, as per the CPCB guidelines dated 07.11.2014, being a zero discharge unit, industry shall install the Camera and flow meter at the start of recycle of treated effluent.

For and on behalf of the
Maharashtra Pollution Control Board


(Dr. P. Anbalagan, IAS)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	75000	783343	12.03.2015	Citi Bank
2	100	783344	12.03.2015	Citi Bank
3	75000	852764	24.03.2015	Citi Bank
Previous consent fees				
1	2010520	790989	1/11/2013	SBI
2	100000	790986	1/11/2013	SBI
3	100	790987	1/11/2013	SBI
4	335087	797268	05/05/2014	SBI

Copy to:

1. Regional Officer -Aurangabad and Sub-Regional Officer-Aurangabad-I MPCB Aurangabad. 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 480 CMD comprising of primary, secondary, tertiary & UF & RO treatment for low COD stream (390 CMD). The reject from RO is treated with High COD stream (90 CMD). High COD stream is treated in ATFD.
- B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent and treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way for gardening or outside factory premises.
- 2) A.] As per your consent application, you have provided the sewage treatment system with the design capacity of 55.00 CMD.
- B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards/ prescribed under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.
- | | | | | |
|-----|-------------------|---------------|-----|-------|
| (1) | Suspended Solids. | Not to exceed | 50 | mg/l. |
| (2) | BOD 3 days 27°C. | Not to exceed | 30 | mg/l. |
| (3) | COD | Not to exceed | 100 | mg/l |
- C] The treated sewage shall be disposed on land for gardening.
- 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	270
2.	Domestic purpose	40
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	350
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	50
5.	Agriculture	30

- 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	Boiler (5 MT/Hr.)	Stack	38	F.O.	7.5 KL/D	4.5	675
2	Boiler (5 MT/Hr.)	Stack	38	F.O.	7.5 KL/D	4.5	675
3	Boiler (12 MT/Hr.)	Stack	50	F.O.	18.5 KL/D	4.5	1665
4	D.G. Set 1250 KVA	Stack	17	Diesel	6 KL/D	1	120
5	D.G. Set 1250 KVA	Stack	17	Diesel	6 KL/D	1	120
6	D.G. Set 500 KVA	Stack	12	Diesel	1.9 KL/D	1	38
7	D.G. Set 750 KVA	Stack	10	Diesel	2.5 KL/D	1	50
8	D.G. Set 1250 KVA	Stack	11.5	Diesel	6 KL/D	1	120
9	D.G. Set 1500 KVA	Stack	12	Diesel	7.2 KL/D	1	144
10	D.G. Set 1250 KVA	Stack	12	Diesel	6 KL/D	1	120
11	Process Stack	Bromine Scrubber	10	---	---	---	---
12	Process Stack	HCL Scrubber	10	---	---	---	---
13	Process Stack	RM Scrubber	06	---	---	---	---
14	Process Stack	6APA Scrubber	06	---	---	---	---
15	Process Stack	AHU Bleeding Vent Scrubber	06	---	---	---	---
16	Process Stack	Gen Vent Scrubber	10	---	---	---	---
17	Process Stack	Bromine Scrubber	10	---	---	---	---
18	Process Stack	6APA Scrubber	10	---	---	---	---
19	Process Stack	Gen Vent Scrubber	10	---	---	---	---
20	Process Stack	HCL	8.5	---	---	---	---

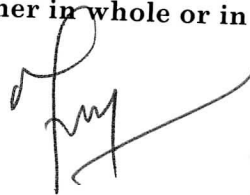
21	Process Stack	Scrubber Dispencing Scrubber	06	---	---	---	---
22	Process Stack	Dispencing Scrubber	10	---	---	---	---
23	Process Stack	HCL Scrubber	10	---	---	---	---
24	Process Stack	Gen Vent Scrubber	9.8	---	---	---	---
25	Process Stack	Dispencing Scrubber	13	---	---	---	---
26	Process Stack	Dispencing Scrubber	6.5	---	---	---	---
27	Other	PD Lab	7.0	---	---	---	---
28	Other	RM Dispencing	10.7	---	---	---	---
29	Other	HVAC	6.7	---	---	---	---
30	Process Stack	Gen Vent Scrubber	10	---	---	---	---
31	Process Stack	Dispencing Scrubber	10	---	---	---	---
32	Process Stack	HCL Scrubber	10.0	---	---	---	---
33	Process Stack	Gen Vent Scrubber	9.6	---	---	---	---
34	Other	RM Store Dispencing Room	9.0	---	---	---	---
35	Other	RM Store Dispencing Room	9.0	---	---	---	---
36	Other	NPNC 2	7.0	---	---	---	---

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 Process	Not to exceed	2070 Kg/D
HCL	Not to exceed	35 mg/Nm ³
Bromine	Not to exceed	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
1	C to R	Rs 5,00,000	Submitted	O & M of Pollution Control System	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) 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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