

MAHARASHTRA POLLUTION CONTROL BOARD

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Consent order No. - *Format I.0/ BO/CAC-Cell/EIC No AD-14150-13/1st CAC- 4715*
Date: 09/01/2015

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: Consent to Establish for Expansion under RED category.
Ref : 1. Existing Consent granted vide no. BO/CAC-Cell/EIC No.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 15.04.2015.

Your application: CE1502000433
Dated: 09/01/2015

For: Consent to Establish for Expansion.
under Section 25 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 up to commissioning of unit or 5 years whichever is earlier.
2. The proposed capital investment of the industry is Rs.610 Crs. (As per Undertaking submitted by industry).The total CI of the industry is Rs 1112.63 crs. [Rs 502.63 (existing) +Rs 610 crs (proposed)]
3. The Consent is valid for the manufacture of -

Sr. No.	Product Name	Maximum Quantity in MTA
1	Alendronate Sodium Trihydrate	0.850
2	Almotriptan Malate	0.017
3	Alosetron HCl	0.003
4	Aripiprazole	0.66 (-)
5	Armodafinil	1.020
6	Atorvastatin Calcium	0.595
7	Aztreonam	1.000
8	Biopenam	1.522
9	Cetirizine HCL	0.064
10	Cilastatin Sodium Sterile	1.700
11	Clopidogrel Hydrogen Sulphate	3.550
12	CRAMs products	27.200
13	Dabigetron etexilate	0.170
14	Dalfampridine	0.170
15	Darifenacin hydrobromide	0.026

17	Dexlansoprazole	2.580
18	Dicyclanole	0.120
19	Divalproex Sodium	66.500
20	Doxonem	3.500
21	Doxonem	3.500
22	Duloxetine HCl	2.017
23	Electriptan HBr	0.043
24	Eprosartan	2.600
25	Esomeprazole Magnesium	0.070
26	Eszopiclone	0.021
27	Ertapenem	3.500
28	Ezetimibe	0.007
29	Felodipine	0.357
30	Faropenem Sodium	0.800
31	Fesoterodine fumarate	0.014
32	Formatfinance (DPOC-4088)	0.677
33	Frovatriptan Succinate	0.000
34	Gabapentin encarbil	0.340
35	Gemiflexacin Mesylate	0.170
36	Granisetron HCl	0.085
37	Ibandronate Sodium	0.388
38	Hoperidone	0.027
39	Imipenem monohydrate sterile	1.700
40	Lansoprazole	1.207
41	Levetiracetam	20.571
42	Levofloxacin Hemipentahydrate	4.800
43	Linagliptin	0.170
44	Losarton Potassium	0.850
45	Lurasidone	0.170
46	Memantine HCl	1.768
47	Meropenem Sterile	20.000
48	Modafinil	2.595 (-)
49	Montelukast sodium	0.020
50	Naratripton HCl	0.170
51	Nebivolol	0.170
52	Nisoldipine	0.408
53	Olanzapine	0.442
54	Olmesartan Medoximil	0.085
55	Paliperidone	0.068
56	Palonosetron HCl	0.002
57	Pamidronic Acid	0.170
58	Panipenem	0.900
59	Pantoprazole	1.000 (-)
60	Phenytoin Sodium	0.340
61	Piperacillin Acid	49.000
62	Pitavistatin calcium	0.009
63	Pramipexole	0.017
64	Prasugrel HCl	0.014
65	Quetapine Hemifumarate	3.750
66	Raloxifine HCl	0.026
67	Rasagiline Mesylate	0.015
68	Rabeprazole Sodium	1.020
69	Risedronate Sodium	0.357

70	Rivastigmine Tartarate	0.400
71	Roflumilast	0.170
72	Ranmirale	0.110
73	Rosuvastatin	0.170
74	Sildenafil	0.170
75	Sildenafil	0.017
76	Sitagliptin	0.170
77	Sumatriptan Succinate	3.500
78	Tadalafil	1.700
79	Tazobactam	6.000
80	Tebipenem	0.500
81	Telmisartan	0.340
82	Terbinafine HCl	12.879
83	Toxerodine Tartarate	0.238
84	Trans- Resveratrol	0.170
85	Venlafaxine HCl	7.500
86	Vilazodone	0.170
87	Zaleplon	0.102
88	Zolmitriptan Tartarate	0.170
89	Zoipidem Tartarate	0.170
	Total	264
By-product		
1	Crude perkacit	20.00
2	Crude M-salt	22.00
3	Crude spirobase	140.00
4	Crude adduct salt	155.00
5	Crude bromo salt	100.00
6	Crude imidazole	5.00
7	Crude Soium sulphate	32.00
8	Crude Sodium chloride	50.00
9	Crude phosphate salt	55.00
10	Iodide solution (100% basis)	145.00
11	Recovered solvents	800.00
	Total	1524

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	336.00	As per Schedule -I	Zero discharge
2.	Domestic effluent	55.00	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 No.1(12 MT/hr.)	1	As per Schedule -II
2	Boiler No.2(12 MT/hr)	1	As per Schedule -II
3	DG (1250 KVA)	1	As per Schedule -II
4	DG (1250 KVA)	1	As per Schedule -II

5	DG (1240 KVA)	1	As per Schedule -II
6	DG (1000 KVA)	1	As per Schedule -II
7	DG (1500 KVA)	1	As per Schedule -II
8	Transformer	1	As per Schedule -II
9	General ventilation scrubber (3000 CFM)	1	As per Schedule -II
10	Dispensing Scrubber(1500 CFM)	1	As per Schedule -II
11	General ventilation scrubber (3000 CFM)	1	As per Schedule -II
12	Dispensing Scrubber(3000 m3/hr)	1	As per Schedule -II
13	Dispensing Scrubber(4000 CFM)	1	As per Schedule -II
14	Dispensing Scrubber(3000 m3/hr)	1	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UoM	Treatment	Disposal
1	Canteen Waste	2000 Kg/M	----	Composting
2	Office Waste	3000 Kg/M	----	Sale
3	Packing Waste	33000 Kg/M	-----	Sale

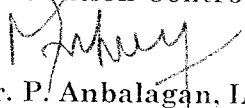
7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UoM	Treatment	Disposal
1	Used / Spent oil	5.1	1.00	MT/Y	---	Sent to authorized party
2	Waste / Residues containing oil	5.2	1.00	MT/Y	---	Sent to authorized party
3	Spent Solvents	20.2	1026.00	MT/Y	---	Sent to authorized party
4	Distillation Residues	20.3	118.33	MT/Y	---	CHWTSDF
5	Residue & Waste	28.1	118.33	MT/Y	---	CHWTSDF
6	Spent catalyst / Spent Carbon	28.2	470.00	MT/Y	---	CHWTSDF
7	Spent mother liquor	28.4	1026.00	MT/Y	---	Sent to authorized party
8	Spent organic solvents	28.5	1026.00	MT/Y	---	Sent to authorized party
9	Discarded containers / barrels / liners	33.3	40.00	MT/Y	---	Spent catalyst to supplier for recovery, and Spent Carbon to CHWTSDF

	barrels / liners used for hazardous wastes chemicals					Carbon to CHWTSDF
11	Fluo gas cleaning	---	---	MT/Y	---	---
11	Chemical sludge from waste water treatment plant	34.2	2000.00	MT/Y	---	CHWTSDF
12	Chemical sludge, oil & grease skimming residue from industry specific effluent treatment plant	34.4	3.00	MT/Y	---	CHWTSDF
13	Distillation residue from contaminated organic solvents	36.4	118.33	MT/Y	---	CHWTSDF
14	E waste	---	2.00	MT/Y	---	CHWTSDF

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 authority.
10. The treated trade effluent shall be 100% recycled in the process to achieve zero discharge.
11. Industry shall comply with the conditions of EC and consent to establish and submit BG of Rs 10 lakh for the compliance of the same.
12. The applicant shall install online effluent quality monitoring systems at the outlet of effluent treatment plant for measurement of consented parameters by 30.06.2015 & to connect and upload the online effluent monitoring data at MPCB and CPCB server in time bound manner . Industry shall submit BG of 100 % of the cost of the online monitoring systems for ensuring timely installation of online monitoring systems by 30.06.2015. BG shall be discharged if industry installs the same. If the industry fails to install the same by 30.06.2015, the consent to operate will be withdrawn and the BG will be forfeited. This is in accordance with the CPCB directions dated 02.03.2015.

For and on behalf of the
Maharashtra Pollution Control Board


(Dr. P. Anbalagan, IAS)
Member Secretary

Received Consent fee of -

S. No.	Amount (Rs.)	DD No.	Date	Drawn On
1	12,20,100/-	470503/470504	18.12.2014	Citi Bank

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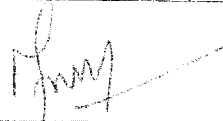
1. Regional Officer -Aurangabad and Sub-Regional Officer-Aurangabad MPCB, Aurangabad
They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. CC/CAC desk- for record & website updation purposes.

Schedule-I

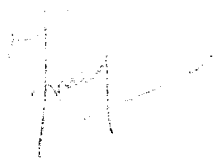
Part A - Conditions for compliance of Water Pollution Control

1. A] As per your application, you have proposed to install the Effluent Treatment Plant (ETP) with the design capacity of 300 CMD) comprising of primary, secondary and tertiary treatment followed by RO and MBBR.
B] The treated effluent shall be 100% recycled in the process to achieve zero discharge. In no case effluent shall find its way for gardening/outside factory premises.
2. A.] As per your consent application, you have proposed to install the sewage treatment system with the design capacity of 55 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.
- 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	105.00
2.	Domestic purpose	60.00
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	---
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	230.00
5	Gardening	10.00



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 and Environmental Clearance (EC) guidelines.



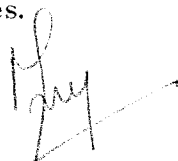
Schedule-II

Terms & conditions for compliance of Air Pollution Control:

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 This system and also proposed to erect following stack (s) and to observe the following fuel pattern:-

Sl. No.	Equipment	Type	Capacity	Fuel	Quantity	SO ₂	SO _x
1	Boiler No.1(12 MT/hr.)	Stack	50.0	Furnace Oil - 42 MTD	21.0 MT/day	4.5	1890
2	Boiler No.2(12 MT/hr)	Stack	50.0		21.0 MT/day	4.5	1890
3	DG (1250 KVA)	Stack	17.0	Diesel- 25 MTD	4.63 MT/day	0.5	46.3
4	DG (1250 KVA)	Stack	17.0		4.63 MT/day	0.5	46.3
5	DG (1250 KVA)	Stack	11.5		4.63 MT/day	0.5	46.3
6	DG (1500 KVA)	Stack	12.0		5.56 MT/day	0.5	55.6
7	DG (1500 KVA)	Stack	12.0		5.56 MT/day	0.5	55.6
8	Dispensing Scrubber(1500 CFM)	Scrubber	10.7	---	---	---	---
9	General ventilation scrubber (3000 CFM)	Scrubber	10.0	---	---	---	---
10	Dispensing Scrubber(1500 CFM)	Scrubber	10.7	---	---	---	---
11	General ventilation scrubber (3000 CFM)	Scrubber	10.0	---	---	---	---
12	Dispensing Scrubber(3000 m3/hr)	Scrubber	13.0	---	---	---	---
13	Dispensing Scrubber(4000 CFM)	Scrubber	6.5	---	---	---	---
14	Dispensing Scrubber(3000 m3/hr)	Scrubber	13.0	---	---	---	---

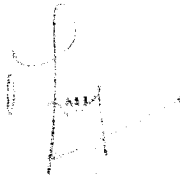
2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time / Environmental Clearance / CREP guidelines.



3. The applicant shall operate and maintain above mentioned air pollution control systems, so as to achieve the level of pollutants as the following standards.

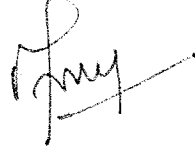
Particulate matter	Not to exceed	150 mg/Nm ³
NOx	Not to exceed	50 ppm

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

Sl. No.	Consent No./ E/O/R)	Amount Rs	Subject in Detail	Type of BM	Complian ce Period	Validity Period
1	C to E	Rs 10 lakhs	Within 15 days from the date of issue of consent	Towards compliance of EC and consent conditions	30.05.2020	30.09.2020
2	C to E	100 % of the cost of the online monitori ng systems (emissio ns and effluent which ever applicab le)	Within 15 days from the date of issue of consent	The applicant shall install online continuous stack emission monitoring system and online effluent quality monitoring systems at the outlet of effluent treatment plant for measurement of consented parameters by 30.06.2015 & to connect and upload the online emissions and effluent monitoring data at MPCB and CPCB server time bound manner	30.06.2015	30.10.2015



Schedule-IV

General Conditions:

- 1) The applicant shall provide facility for collection of environmental samples and samples of effluents, effluent effluents, air emissions and hazardous wastes. The board staff at the discretion of the board shall have access to the facility for collection of samples in this behalf.
- 2) Industry should monitor effluent quality, stack emissions and ambient air quality monthly.
- 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
- 8) /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 obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Unit/ Activity.**
- 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 adopt an acoustic enclosure for control of noise. The acoustic enclosure shall be constructed in such a way as to ensure the minimum noise level, including 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 quarterly statement in respect of industries' obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can be downloaded from MPCB official site).
- 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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