



ANDHRA PRADESH POLLUTION CONTROL BOARD
ZONAL OFFICE: VISAKHAPATNAM

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REGD.POST WITH ACK.DUE
CONSENT ORDER FOR ESTABLISHMENT

Order.No. 7589-VSP/APPCB/ZO-VSP/CFE/2015-

Date: 16.12.2015

Sub: **APPCB, ZONAL OFFICE, VISAKHAPATNAM - CONSENT FOR ESTABLISHMENT (Expansion) for increased water consumption and wastewater generation - M/s.Hospira Healthcare India Pvt. Ltd, Plot No.111 & 123 and 116, 117, 118 & 119, JN Pharmacy, Parawada (M), Visakhapatnam - Consent for Establishment of the Board under Sec.25 of Water (Prevention and Control of Pollution) Act, 1974 and under Sec.21 of Air (Prevention and Control of Pollution) Act, 1981 - Issued - Reg.**

- Ref:
1. CFO order No.7589-VSP/APPCB/ZO-VSP/CFO/2015-1171 dt.12.10.2015
 2. Industry's CFE application received on 17.11.2015 and additional information on 23.11.2015 at APPCB, Regional Office, Visakhapatnam.
 3. APPCB, Regional Office, Visakhapatnam verification report dt.01.12.2015, received by Zonal Office, Visakhapatnam on 02.12.2015.
 4. CFE Committee meeting held on 15.12.2015 at APPCB, Zonal Office, Visakhapatnam.

- I The industry obtained CFO of the Board vide reference 1st cited, for existing capacities as mentioned below:

Sl. No.	Name of the Products and By-products	Capacity (Millions/month)
	Products	
1.	Terminal sterilized vials	26.66
2.	Terminal sterilized ampoules	4.75
3.	Asceptic filled vials	8.33
4.	Dry powder lyophilized vials	1.92
	Total	41.66

- II In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (Expansion) for increased water consumption and wastewater generation due to change in the ramp up plan, vial configuration from 2 ml to 100 ml, with an additional project cost of Rs.929 Cr (Rupees nine hundred and twenty nine only) without increase of production capacities.
- III As per the application, the above activity is to be located at Plot No.111 & 123 and 116, 117, 118 & 119, JN Pharmacy, Parawada (M), Visakhapatnam.
- III. The above site was inspected by the EE & AEE-I, A.P Pollution Control Board, Regional office, Visakhapatnam on **01.12.2015** and found that the site is surrounded by **East : 40 ft Road & Industrial Plots; West : Industrial Plots & 40 ft Road; South: 40 ft Road & M/s. Eisai Pharmaceuticals Ltd.;; North: 40 ft Road & M/s Alvira.**

SCHEDULE - A

1. Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned below.
 - a) Industrial cooling.
 - b) Domestic purposes.
 - c) Processing whereby water gets polluted and pollutants are easily bio-degradable.
2. The industry shall provide a minimum stack height (H) to the DG sets as per the following formula.
$$H = h + 0.2 \text{ SQRT (KVA)}$$

KVA = Total generation capacity, h = Height of building where DG Set is installed.
3. The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time measured from a distance of 5mtrs from the DG Set.
4. The industry shall install and commission appropriate control and ventilation system for controlling the air pollution.
5. The industry shall take appropriate measures to ensure that the ground level concentrations shall comply with revised National Ambient Quality Norms notified by MoE&F, GoI on 16.11.2009.
6. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. The applicant shall maintain good house keeping both within the factory and in the premises. All pipe valves, sewers, and drains shall be leak proof.
7. The solid waste arising in the premises shall be properly collected and disposed off.
8. There shall not be any perceptible odour outside the industry's premises.
9. All the rules and regulations notified by Ministry of Environment and Forests, Govt. of India in respect of noise pollution control measures shall be followed to avoid nuisance to public.
10. The proponent shall take measures to comply with the provisions laid down under Noise pollution (Regulation and Control) Amendment Rules, 2010 dated 11.01.2010 issued by MoE&F, GoI to control the noise to the prescribed levels.
11. The applicant shall obtain Consents for operation regularly from APPCB, as required Under Sec. 25/26 of the Water (P&C of P) Act, 1974 and Under Sec. 21/22 of the Air (P&C of P) Act, 1981, for operation of the industry, before starting trial production. The Consent for Operation will be accorded only after ensuring compliance of all the conditions stipulated in this order.
12. The applicant shall comply with and carryout conditions issued by the Board in this consent order scrupulously. The applicant is liable for legal action as per the provisions of the relevant Acts in case of non-compliance of any conditions of the consent order.
13. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21 (4) of Air (Prevention and Control of Pollution) Act, 1981 to review any or all the conditions imposed herein and to make such alternation as deemed fit and stipulate any additional conditions for the purpose of the Act by the Board.
14. The applicant shall exhibit the consent of the Board in the factory premises at a conspicuous place for the information of the inspecting officers of different departments.
15. Andhra Pradesh Pollution Control Board reserves the right to review, impose additional condition or conditions, revoke, change or alter the terms and conditions of this Order. Also the Board reserves the right to withdraw the CFE without any prejudice/ notice on receiving any complaints by the Board regarding Environmental Pollution problems caused by the industry.
16. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as civil liability.
17. Rain Water Harvesting (RWH) structure (s) shall be established on the plant site so that the ground water is recharged by the storm water.
18. The industry shall comply with Rules & Regulations notified by Ministry of Law and Justice, Govt. of India, regarding the Public Liability Insurance Act, 1991.
19. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water rules, 1976 and Air Rules 1982, to such authority (herein after referred to as the Appellate Authority) constituted under Section 28 of the Water (prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

	down under Schedule-I, under Rule-3 of Environmental (Protection) Rules, 1986	overflow water pumped to pre treatment facility of the industry for further treatment.
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4. The industry shall regularly transport the washings – 110 KLD, QC & Micro lab washings – 32 KLD, boiler blow down – 36 KLD, utility rejects – 515 KLD, cooling blow downs – 119 KLD and domestic wastewater – 115 KLD to CETP of M/s.Ramky Pharmacy (I) Pvt. Ltd., Parawada, Visakhapatnam for proper treatment and disposal.
5. The industry shall provide flow meters to record the water consumption and wastewater generation from the unit and shall maintain log registers to record wastewater sent to CETP of M/s.Ramky Pharmacy (I) Pvt. Ltd., .
6. The industry shall not discharge any wastewater outside the factory premises under any circumstances.
7. The industry shall construct detoxification facility to detoxify the used drums. After detoxification the treated wastewater shall be sent to CETP along with LTDS effluents.
8. The industry shall construct lined collection tanks above ground level and report compliance to the Board within 3 months.
9. Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned below.
 - a) Industrial cooling, spraying in mine pits or boiler feed.
 - b) Domestic purposes.
 - c) Processing, whereby water gets polluted and pollutants are easily bio- degradable.
 - d) Processing, whereby water gets polluted and the pollutants are not easily bio- degradable.

10. The industry shall comply with the following for controlling air pollution. (After expansion)

Sl. No	Details of Stack	Stack 1	Stack 2
a)	Attached to:	Oil fired Boiler	DG Sets
b)	Capacity of Oil fired Boiler / D.G. Set	3 X 15 TPH (One standby)	6 X 2750 KVA (standby)
c)	Fuel used	HSD	HSD
d)	Stack height from G.L.	52 M	30 M
e)	Details of Air Pollution Control Equipment:	-	Acoustic system
f)	Standards to be complied	SPM – 115 mg/Nm ³	

11. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
12. The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.
13. The proponent shall comply with the following after expansion:

Sl. No	Hazardous /Solid Waste generated from	Existing as per CFO order dated 12.10.2015	Quantity proposed	Stream	Method of Disposal proposed
A.	Hazardous Wastes:				
1.	Off, Specification products / expired Raw material	2 MT/month	5 MT/month	28.3 of Schedule - I	To TSDF, Parawada, Visakhapatnam
2.	Date expired, discarded, off specification products	0.1 MT/month	3 MT/month	28.4 of Schedule - I	To TSDF, Parawada, Visakhapatnam
3.	Date expired, discarded and off specification laboratory chemicals / samples (solid & liquid)	500 Lts / month	2 MT/month	28.4 of Schedule - I	To TSDF, Parawada, Visakhapatnam
4.	Sludge from ETP tanks	1 MT /month	1 MT/month	34.3 of Schedule - I	To TSDF, Parawada, Visakhapatnam

13. The industry shall take appropriate measures to ensure that the ground level concentrations shall comply with revised National Ambient Quality Norms notified by MoE&F, GoI on 16.11.2009.
14. The industry shall take measures to comply with the provisions laid down under Noise pollution (Regulation and Control) Amendment Rules, 2010 dated 11.01.2010 issued by MoE&F, GoI to control the noise to the prescribed levels.
15. The industry shall not manufacture any extra products or extra capacities without obtaining CFE/CFO of the Board.
16. The industry shall not cause any air pollution / odour nuisance in the surrounding environment.
17. The industry shall collect the Hazardous waste generated i.e., spent organic solvents, residues and waste, off specification products, date expired, discarded drugs, oil soaked cotton waste and discarded lab chemicals properly and shall lift the hazardous waste to TSDF, Parawada / authorized cement industries regularly for incineration and submit details regularly to RO, Visakhapatnam.
18. The industry shall collect the Hazardous waste generated i.e., ETP Sludge and Waste resigns properly and shall lift the hazardous waste to TSDF, Parawada.
19. The industry shall not dispose any solid waste outside the industry's premises
20. The industry shall dispose off specification products and rejected & expired drug materials to TSDF, Parawada.
21. The industry shall strictly maintain registers pertaining to generation and disposal of off-specification products and rejected & expired drug materials as the unit is dealing with oncology drug formulations.
22. The industry shall develop 33% of the total area as thick green belt all along the boundary of the unit and also in the vacant places with all tall growing trees with wide leaf area.
23. The industry shall comply with all the Rules and Regulations specified in Water (P&C of P) Act, 1974, Air (P&C of P) Act, 1981 and Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and their amendments issued thereof.
24. The industry shall not take up trial production for proposed activity without obtaining Consent for Operation of the Board.
25. The industry shall comply with all the directions issued by the Board from time to time.
26. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control Acts.
27. The Board reserves its right to modify above conditions or stipulate any further conditions and to take action including revoke of this order in the interest of environment protection.
28. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.


JOINT CHIEF ENVIRONMENTAL ENGINEER

To
M/s. Hospira Healthcare India Pvt. Ltd.,
Plot No.111 & 123 and 116, 117, 118 & 119,
JN Pharmacy, Parawada (M),
Visakhapatnam