

**No. J-11011/207/2003 – IA II (I)**  
Government of India  
Ministry of Environment & Forests  
**I. A. Division**

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Paryavaran Bhawan,  
CGO Complex, Lodi Road,  
New Delhi – 110 003

Dated the June 21, 2005

**To**

The Authorized Signatory,  
M/s Aurobindo Pharma Limited, Unit-V  
Plot no.2, Maitrivihar, Ameerpet  
Hyderabad- 500038  
Andhra Pradesh

**Sub: Bulk drug Unit by M/s. AUROBINDO PHARMA LTD, UNIT-V at Pashamailaram, District Medak, Andhra Pradesh.**

Sir,

This has reference to your letter no. nil dated 5<sup>th</sup> May, 2005 on the above subject enclosing application, EIA /EMP report , questionnaire seeking environmental clearance for the above project under the Environmental Impact Assessment Notification,1994 and communication EC/PH/ PCB/RO-I.SRD/05-349 dated 30<sup>th</sup> April 2005 from /Regional Office-I of APPCB.

2.0. The Ministry of Environment and Forests has examined your application along with EIA / EMP report. It is noted that the proposal is for environmental clearance of bulk drug unit for manufacture of 7-ADCA (168 TPA), 7-ACA(24 TPA), Cephalexin (192 TPA), Cefadroxil (24TPA), Cefradine (24 TPA), Cefotaxime Acid (30TPA), Ceflothin (24TPA), Ceftriaxone disodium (30TPA), Ampicillin trihydrate/Ampicillin anhydrous (540TPA) and Roxithromycin (24TPA). The unit is located in an area of 6.879 ha. in District, Medak in Andhra Pradesh. Water requirement for the unit is 295.1 m3/d which is met from the ground water source and APIIC supply. About 2.03 TPD of solid waste would be generated, of which 0.65 TPD will be the process sludge and 1.38TPD will be the forced evaporation salts. The organic waste will be incinerated. Ash obtained from the incinerator and evaporation salt will be sent to TSDF of Hyderabad Waste Management Project at Dundigal. NOC from Andhra Pradesh Pollution Control Board for the products being manufactured was obtained on 16.08.2003. Public hearing panel has considered the project in the meeting held on 13.4.2005. Cost of the Project is Rs. 51.72 crore.

3.0. The Ministry of Environment and Forests hereby accords environmental clearance to the above project under EIA Notification dated 27<sup>th</sup> January, 1994 as amended subsequently, subject to strict compliance of the following conditions:

**A SPECIFIC CONDITIONS**

- i. The gaseous emissions (SO<sub>x</sub>, NO<sub>x</sub>) particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- ii. Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the SPCB.
- iii. For control of air emissions, the reactors shall be provided with scrubbers and stack height as per Central Pollution Control Board guidelines.
- iv. Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emission as far as possible. Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum. All venting equipment shall have vapour recovery system.
- v. Industry shall switch over to aqueous based coating film in place of use of Methylene Chloride in coating operation and to non-halogenated solvents in place of halogenated solvents in a phased manner.
- vi. Hazardous and toxic waste generated during process like distillation residue, spent carbon, spent mixture solvents, process organic residue should be incinerated in a properly designed incinerator with energy recovery facility. The incinerator shall meet the CPCB standards and guidelines.
- vii. Hazardous Air Pollutants (HAP) emitted from process shall be identified, assessment shall be made both for stack/vent emissions and work zone environment/ambient environment.
- viii. Air emission of VOC's from reactor vents, material loading and unloading, acid gases (halogen acids, SO<sub>2</sub>, etc.), fugitive emissions from pumps, valve, tanks shall be monitored and emission shall be controlled.
- ix. The company shall undertake following Waste Minimization measures :-
  - Metering and control of quantities of active ingredients to minimize waste.
  - Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
  - Use of automated filling to minimize spillage.
  - Use of "Close Feed" system into batch reactors.
  - Venting equipment through vapour recovery system.
  - Use of high pressure hoses for equipment clearing to reduce wastewater generation.

- x. Fugitive emissions in the work zone environment, product, raw material storage area shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB.
- xi. Effluent generation shall not increase 178 m3/d. The effluent shall be segregated into high and low COD streams. The low TDS effluent after primary and secondary treatment and meeting the norms shall be sent to CETP at Patancheru through tankers for further treatment. Due care shall be taken to prevent leakage of effluent, while loading, unloading and transportation. Waste water manifest system shall be provided along with every tanker for proper handling of effluent. The company shall install reverse osmosis plant to treat the high TDS effluent. The high TDS rejects shall be evaporated in Multiple Effect Evaporator. The condensate shall be given biological treatment. The salt obtained after drying shall be disposed into secured landfill (TSDF) after packaging in HDPE bags. The domestic waste water shall be sent to the septic tank followed by the soak pit.
- xii. Solid waste generated from the process shall be incinerated. The incinerator ash and salts from the multiple effect evaporator shall be sent to TSDF of Hyderabad Waste Management Project at Dundigal. Boiler ash shall be sold to the brick manufacturers.
- xiii. The company shall develop rainwater harvesting structures to harvest the run off water for recharge of ground water.
- xiv. The company shall obtain permission from state government authorities to draw ground water.
- xv. Green belt shall be provided in 25% of the plant area to mitigate the effects of fugitive emission all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.
- xvi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xvii. The Company shall undertake eco-development measures including community welfare measures in the project area for the overall improvement of the environment. The eco-development plan should be submitted to the APPCB within three months of receipt of this letter for approval.

**B. GENERAL CONDITIONS**

- i. The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh State Pollution Control Board.
- ii. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.

- iii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- iv. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000. Authorization from the SPCB shall be obtained for collection, treatment, storage, disposal of hazardous wastes.
- v. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the State Pollution Control Board must be obtained for collections/treatment/storage/disposal of hazardous wastes.
- vi. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. DBA (day time) and 70 dBA (night time).
- vii. The project proponent shall also comply with all the environmental protection measures and safeguards recommended in the Environmental Impact Assessment Notification, 1994 report.
- viii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- ix. The project authorities shall earmark separate funds to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
- x. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office at Bangalore/ SPCB/Central Pollution Control Board. A six monthly compliance status report shall be submitted to monitoring agencies.
- xi. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at <http://envfor.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of



the locality concerned and a copy of the same shall be forwarded to the Ministry's Regional Office at Bangalore.

xii. The project authorities shall inform the Regional office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

4.0. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

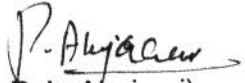
5.0. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

6.0. The above conditions will be enforced, inter alia under the provisions of the Water(Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

(Dr. P. L. Ahujarai)  
Director

Copy to :-

1. The Secretary, State Deptt. of Environment, Government of Andhra Pradesh, Mantralaya, Hyderabad.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. The Chairman, Andhra Pradesh State Pollution Control Board, 2<sup>nd</sup> Floor, HUDA Complex, Maitrivaram, S.R.Nagar, Hyderabad- 500 038.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17<sup>th</sup> Main Road, Koramangala, Bangalore-560034.
5. JS(CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.- 110003.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi- 110003.
7. Guard file.
8. Record file.
9. Monitoring file.

  
(Dr. P. L. Ahujarai)  
Director