

**Dr. R.ANNAMALAI,I.F.S.,**  
DIRECTOR OF ENVIRONMENT AND  
MEMBER SECRETARY



**STATE LEVEL ENVIRONMENT  
IMPACT ASSESSMENT AUTHORITY,  
TAMILNADU,**  
4-D, Panagal Maligai, 1 Jennis Road,  
Saidapet,  
Chennai-600 015.

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**Lr.No.SEIAA/TN/EC/5(f)/006 /F-197/2009 Dated: 11 .09.2009**

To

**The General Manager,  
M/s. Aurobindo Pharma Limited,  
B2, SIPCOT Industrial Complex,  
Kudikadu Village,  
Cuddalore 607 005.**

Sir,

Sub: SEIAA, Tamilnadu - M/s. Aurobindo Pharma Limited, Plot No. B2, SIPCOT Industrial Complex, S.F.No. 128, 166,168, Kudikadu Village, Cuddalore Taluk, Cuddalore - Manufacturing of Bulk Drugs – change of products - Environmental Clearance - Regarding.

This has reference to your application No. Nil Dated: 16.12.2008 submitted to the State Level Environment Impact Assessment Authority, (SEIAA), Tamil Nadu, for Environmental Clearance. The proposal has been appraised by the State Level Expert Appraisal Committee (SEAC) in its meetings held on 19-20<sup>th</sup> March, 2009 and 29-30<sup>th</sup> June, 2009 as per the prescribed procedure in the light of provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application Viz., the Application Form-I, REIA-EMP report and additional particulars.

It is noted, interalia that the project proposal, involves change of products, located at Plot No. B2, SIPCOT Industrial Complex, Kudikadu village, Cuddalore District. No ecologically sensitive area exists within 10 Km periphery of the project site. The project does not involve any Rehabilitation & Resettlement. The cost of the project is Rs. 12 Crores. The proposal involves manufacturing of the various new products as follows using the machineries vide Annexure.

| <b>S.No</b>  | <b>Name of the Proposed Products</b> | <b>Qty (T / Month)</b> |
|--------------|--------------------------------------|------------------------|
| 01           | Cefazolin Acid                       | 4.00                   |
| 02           | Chloramphenicol Hemisuccinate        | 2.50                   |
| 03           | Cefditoren Pivoxil                   | 0.50                   |
| 04           | Cefuroxime Acid                      | 5.00                   |
| 05           | 7 - AVNA                             | 5.00                   |
| 06           | Cefoperazone acid                    | 2.50                   |
| <b>TOTAL</b> |                                      | 19.50                  |

The power requirement shall be met from TNEB grid and with backup D.G sets of 2 Nos of 500 KVA (1 no. proposed in addition to the existing one).The water requirement will be 71.6 KLD for the proposed change of products which will be met through SIPCOT vide letter dt.9.4.09. Trade effluent of 56.52 KLD and domestic effluent of 5.6 KLD will be generated during operation.

The process effluent from the plant will be sent to the Effluent treatment plant. The treated effluent will be discharged into CUSECS line for Marine Disposal. Domestic effluent will be disposed into septic tank and dispersion trench. The hazardous solid waste viz sludge from ETP, discarded containers and barrels, process organic residues, inorganic & evaporation salt waste and spent carbon will be sent to the treatment, storage and disposal facility by M/s Tamilnadu Waste Management Limited at Gummidipoondi. The Spent solvents will be sent to the authorized recyclers of TNPCB/CPCB. Primary & secondary condensers for the reactors, condensers to the tray / filter dryers & centrifuges, vent condensers, product cooler & heat exchanger to the fluid bed dryer, blender and distillation column are provided as APC measures to control the VOC emissions from the process. Column steam stripper has been proposed before the equalization tank to reduce the VOC emissions from the trade effluent stream. Mechanical cyclone with a stack has been proposed for the 4 T/hr boiler.

The project activity is listed as 5 (f) and is of B1 Category project in the Schedule of EIA Notification, 2006. Public Hearing/consultation is not required for the

project as it is located in a notified industrial estate at SIPCOT Industrial Complex, Cuddalore District.

Based on the information submitted by you, the SEAC after due considerations of the relevant documents submitted by the Project Proponent have recommended to the SEIAA, Tamil Nadu to grant the Environmental Clearance to this project. The proposal was considered by the SEIAA, Tamil Nadu in its meeting held on 11.09.2009 and as the public consultation is not required for the project, the SEIAA hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 subject to the strict compliance of the terms and conditions as follows:

**A. SPECIFIC CONDITIONS - Environment Management Measures**

- i. The domestic effluent shall be disposed into septic tank and dispersion trench as stated.
- ii. The process effluent from the plant shall be treated in the ETP and the treated effluent shall be discharged into the CUSECS line for Marine Disposal after satisfying the standards prescribed by the Tamilnadu pollution Control Board.
- iii. A stack of adequate height shall be provided for control and dispersion of pollutants from the boiler. SPM emission in the flue gas shall be less than 100 mg/Nm<sup>3</sup>.
- iv. HCl, SO<sub>2</sub>, Nitrogen and Carbon Dioxide emissions from the process vents shall be scrubbed in water and Caustic lye solution scrubbers and dilute HCl so formed shall be reused. SO<sub>2</sub> shall be scrubbed in the scrubber using Caustic lye solution and the scrubbing liquid shall be sent to ETP for treatment. Scrubber efficiency shall be minimum 99%.
- v. Levels of HC and VOC at various probable locations in the ambient air in and around the plant shall be monitored through on line VOC monitors and the readings shall be submitted regularly.
- vi. Stringent odour control measures should be implemented to prevent totally odour nuisance to the neighbourhood population and industrial units in a complete and adequate manner.
- vii. The water requirement shall not exceed 71.60 KLD which shall be met from the SIPCOT.

- viii. Solid waste such as sludge from ETP, discarded containers and barrels, process organic residues, inorganic & evaporation salt waste and spent carbon shall be sent to TSDF, Gummidipoondi. The Spent solvents will be sent to the authorized recyclers of TNPCB/CPCB. The handling and disposal of hazardous waste should comply with TNPCB norms.
- ix. Spent solvents shall be recovered as far as possible & recovery shall not be less than 98 percent. Solvent vapours emitted during purification process from purification tanks as fugitive emissions shall be reduced as far as possible. All venting equipment shall have vapour recovery system.
- x. The proponent shall provide the APC measures as proposed operate and maintain the same efficiently and continuously such that no public complaints are received due to operation of the unit.
- xi. The Proponent shall furnish an undertaking that they will abide by the conditions / recommendations mentioned in the EIA report furnished by them.
- xii. 33 % of land shall be developed and maintained as Green Belt and selection of plant species shall be as per CPCB Guidelines.
- xiii. Proper safety and personal protective measures for the employees shall be implemented.

#### **B. GENERAL CONDITIONS:**

- i) It is mandatory for the project proponent to furnish to the SEIAA, Half yearly compliance report in hard and soft copies on 1<sup>st</sup> June and 1<sup>st</sup> December of each calendar year in respect of the conditions stipulated in the prior Environmental clearance.
- ii) The project authorities shall strictly adhere to the stipulations made by the Tamilnadu Pollution Control Board.
- iii) The Environmental Clearance does not relieve the applicant/proponent of his obligation/requirement to obtain other statutory and administrative clearance from other statutory and administrative authorities.
- iv) No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA. In case of deviations or alterations in the project proposal from those submitted for clearance, a fresh reference

shall be made to the SEIAA to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

- v) 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.
- vi) The gaseous emissions (SO<sub>2</sub>, NO<sub>x</sub>, HCl, CO, CO<sub>2</sub>, VOC and HC) and Particulate matter along with RSPM levels 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.
- vii) The locations of ambient air quality monitoring stations shall be decided in consultation with the Tamil Nadu Pollution Control Board and it shall be ensured that at least one station is installed in the up wind and another in the downwind direction as well as where maximum ground level concentrations are anticipated.
- viii) Dedicated scrubbers and stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided to control the emissions from various vents. The scrubbed water shall be sent to ETP for further treatment.
- ix) All the storage tanks will be under negative pressure to avoid any leakages. Breather valves, N<sub>2</sub> blanketing and secondary condensers with Chilled Brine chilling system shall be provided for all the storage tanks to minimize vapour losses. All liquid raw material shall be stored in storage Tanks and Drums. Closed handling systems for chemicals and solvents will be provided as committed. Magnetic seals will be provided for pumps/agitators for reactors for reduction of fugitive emissions. Solvent traps shall be installed wherever necessary. Reactor generating solvent vapors will be connected to condensers with receivers.

- x) All venting equipment shall have vapour recovery system. All the pumps and other equipment`s where there is a likelihood of HC leakages shall be provided with Leak Detection and Repair (LDAR) system and LEL indicators and Hydrocarbon detectors. Provision for immediate isolation of such equipment, in case of a leakage will also be made. The company shall provide a well defined Leak Detection and Repair (LDAR) programme for quantification and control of fugitive emissions. The detectors sensitivity will be in ppm levels.
- xi) 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 Closed Feed system into batch reactors.
  - Venting equipment through vapour recovery system.
  - Use of high pressure hoses for equipment cleaning to reduce wastewater generation.
- xii) Fugitive emissions in the work zone environment, product and raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by the Tamil Nadu Pollution Control Boards/Central Pollution Control Board.
- xiii) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000 and Hazardous Wastes (Management and Handling) Rules, 1989, as amended from time to time. Authorization from the TNPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes. All Transportation of Hazardous Chemicals shall be as per the MVA, 1989.
- xiv) The overall noise levels in and around the plant area shall be kept well within the standards 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. 75 dBA (day time) and 70 dBA (night time).

- xv) Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act.
- xvi) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis.
- xvii) Usage of PPEs by all employees/ workers shall be ensured.
- xviii) The company shall strictly follow all the recommendations mentioned in the Charter on Corporate Responsibility for Environmental Protection (CREP).
- xix) The Company shall harvest surface as well as rainwater from the rooftops of the buildings proposed in the expansion project and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.
- xx) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the EIA/EMP report. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.
- xxi) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xxii) A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xxiii) The project proponent shall advertise in at least two local newspapers widely circulated in the region, one of which shall be in the vernacular language informing the public that
  - i) The project has been accorded Environmental Clearance.
  - ii) Copies of clearance letters are available with the Tamil Nadu Pollution Control Board.
  - iii) Environmental Clearance may also be seen on the website of the SEIAA.

The advertisement should be made within 7 days from the date of issue of the clearance letter and a copy of the same shall be forwarded to the SEIAA.

- xxiv) The project authorities shall inform the Regional Office as well as the SEIAA, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
- xxv) The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- xxvi) The SEIAA reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
- xxvii) The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (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.
- xxviii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated EC conditions including results of monitored data (both in hard copies as well as by e-mail) to the Regional Office of MoEF, Bengaluru, the Zonal Office of CPCB, Bengaluru and the TNPCB. This shall also be put on the website of the Company by the proponent.
- xxix) The Environmental Statement for each financial year ending 31<sup>st</sup> March in Form-V which is mandated has to be submitted by the project proponent to the Tamil Nadu Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and shall also be put on the website of the company along with the status of compliance of EC conditions and shall also be sent to the Regional Office of MoEF, Bengaluru by e-mail.
- xxx) The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of MoEF, Bengaluru, the respective Zonal Office of CPCB,

Bengaluru and the TNPCB. The criteria pollutant levels namely; SPM, RSPM, SO<sub>2</sub>, NO<sub>x</sub> (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.

- xxxii) A copy of the clearance letter shall be sent by the proponent to the Commissioner, Cuddalore Panchayat Union, Cuddalore District and the Local NGO, if any, from whom suggestions /representations, if any, were received while processing the proposal. The clearance letter shall also be put on the website of the Company by the proponent

Member Secretary,  
State Level Environmental Impact  
Assessment Authority,  
Tamil Nadu.

Copy to:-

1. The Secretary to Government, Environment & Forests Dept, Govt.of Tamil Nadu, Fort St.George, Chennai-9.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD Cum-Office Complex, East Arjun Nagar, New Delhi 110032.
3. The Member Secretary, Tamil Nadu Pollution Control Board, 76, Mount Salai, Guindy, Chennai-600 032.
4. The CCF, Regional Office, Ministry of Environment & Forest (SZ), Kendriya Sadan, IV floor, E&F wings, 17th Main Road, Koramangala II Block, Bangalore - 560034.
5. Monitoring Cell, I A Division, Ministry of Environment & Forests, Paryavaran Bhavan, CGO Complex, New Delhi 110003.
6. The Chairman and Managing Director, SIPCOT, Chennai-600 008.
7. The Project Manager, SIPCOT Industrial Complex, Cuddalore.
8. The Commissioner, Cuddalore Panchayat Union, Cuddalore District.
9. Stock File.