

08/04

F. No. J-11011/1188/2007- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

Paryavaran Bhawan
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New Delhi - 110 003
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Telefax: 011 - 2436 3973
Dated: 9th April, 2008

To,
M/s Lupin Pharmacare Ltd.
159, CST Road, Kalina, Santacruz (East)
Mumbai- 400 098
Maharashtra

Sub: Bulk Drug unit at Plot No. 2, Special Economic Zone, Phase-II, Near Pithampur, District Indore in Madhya Pradesh by M/s Lupin Pharmacare Ltd. - reg environmental clearance.

Sir,

This has reference to your letter no. Nil dated 25th October, 2007 on the above-mentioned project.

2. The Ministry of Environment and Forests has examined your application. It is noted that the proposal is for manufacturing bulk drugs in the unit in Special Economic Zone, in district Indore in Madhya Pradesh. Area of the project is 10.80 Ha. Total Cost of the project is Rs. 5.50 Crore. Following products will be manufactured.

Sl. No.	Product proposed	Production capacity (kg/month)
1.	Ethinyl Estradiol	50
2.	Norgestimate	35
3.	Norgestrel	13.8
4.	Desogestrel	12.6
5.	Norethindrone	5.4
6.	Levonorgestrel	3.7

Out of Six products, only one product will be manufactured at a time. The raw materials required would be Estrone, Sodamide, Acetic Acid, Methanol, Acetone, N-Hexane, Ethanol, Methylene Chloride, Ethyl Acetate, Sodium Hydride and Methoxydienone etc. It is noted that no boiler will be installed and boiler facilities from adjacent formulation unit will be used. Solvent recovery facility and chilled brine plant (-20 °C) will be provided. Total water requirement of 3.00 m³/d will be met from MP AICVN. About 2.55 m³/d of waste water will be generated of which 1.0 m³/d will be the domestic effluent, 1.0 m³/d, the industrial effluent and 0.5 m³/d process effluent. The effluent will be passed through a stripper and the striped effluent will be fed into the forced circulation type evaporator for concentration. The water will be recovered as condensate. The reject will undergo further concentration in an agitated thin film dryer. The solid waste will be generated in the form of process waste (16.5 kg/m), Distillation Residues (260 kg/m) and Spent Carbon (40 kg/m) which will be disposed of to CHW-TSDF of Madhya Pradesh Waste Management Project. Spent catalyst (0.8kg/m) will be disposed of to the manufacturer for recycling or to CHW-TSDF in Madhya Pradesh. The spent solvent (6500 kg/m) will be sent to Common incinerator facility for incineration or sold to the authorized recyclers. The discarded containers /barrels after decontamination will be sold or returned to supplier.

4. Since, the unit is located in the Notified Industrial area, public hearing is not required as per para 7 (i) III (b) Stage (3) –public consultation. The project is listed at Sl. No. 5(f) in the Schedule of EIA Notification, 2006. This is a 'B' Category project. Since SEIAA/SEAC was not constituted at the time of receipt of proposal, the project has been appraised at the Centre.

5. Based on the information submitted by you, the Ministry of Environment and Forests hereby accords environmental clearance to above project under the provisions of EIA Notification, dated 14th September 2006 subject to the compliance of the following Specific and General Conditions:

A. SPECIFIC CONDITIONS:

- i. There shall be no installation of boiler. The DG sets will be provided with acoustic arrangements to attenuate the noise pollution. The emissions from the DG sets shall be dispersed as per the CPCB/State Pollution Control Board standards.
- ii. The solid waste generated in the form of process waste, Distillation Residues and Spent Carbon shall be disposed of to CHW-TSDF of Madhya Pradesh Waste Management Project. Spent catalyst shall be disposed of to the manufacturer for recycling or to CHW-TSDF. The spent solvent shall be sent to Common incinerator facility for incineration or sold to the authorized recyclers. The discarded containers /barrels after decontamination will be sold or returned to supplier.
- iii. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
- iv. The company shall undertake measures for solvent recovery and Chilled Brine Secondary Condensers shall be provided for control of evaporation of low boiling solvents. 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.
- v. Regular monitoring of HC and VOC shall be carried out at all vents, in work zone area and in the ambient air at probable locations in and around the plant.
- vi. An plant area of 33% shall be developed as green belt. Selection of plants species shall be as per the Guidelines of CPCB.

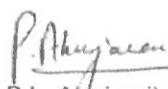
B. GENERAL CONDITIONS:

- (i) The project authorities shall strictly adhere to the stipulations made by the State Pollution Control Board.

- (ii) 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.
- (iii) 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.
- (iv) The gaseous emissions (NO_x , SO_2 , CO , VOC and HC) and 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.
- (v) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one station is installed in the up wind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (vi) 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.
- (vii) All the storage tanks will be under negative pressure to avoid any leakages. Breather valves, N_2 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. 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.
- (viii) 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.
- (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 cleaning to reduce wastewater generation.
- (x) 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 State Pollution Control Boards/Central Pollution Control Board.
- (xi) 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 Waste (Management and Handling) Rules, 1989, as amended from time to time. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes. All Transportation of Hazardous Chemicals shall be as per the MVA, 1989.
- (xii) 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).
- (xiii) Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act.
- (xiv) 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.
- (xv) Usage of PPEs by all employees/ workers shall be ensured.
- (xvi) The company shall strictly follow all the recommendations mentioned in the Charter on Corporate Responsibility for Environmental Protection (CREP).
- (xvii) 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.
- (xviii) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the project report submitted to the Ministry. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.
- (xix) The company will undertake all relevant measures for improving the Socio-economic conditions of the surrounding area. CSR activities will be undertaken by involving local villages and administration
- (xx) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.

- (xxi) A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
 - (xxii) The project authorities shall earmark adequate 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.
 - (xxiii) The implementation of the project vis-a-vis environmental action plans shall be monitored by the concerned Regional Office of the Ministry/SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies and shall be posted on the website of the Company.
 - (xxiv) 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 concerned Regional Office of the Ministry.
 - (xxv) 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.
6. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
7. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
8. Any appeal against this environmental clearance shall lie with the National Appellate Authority, if preferred, within a period of 30 days as prescribed under section 11 of the National Environment Appellate Authority Act, 1997.
9. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water 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. Ahujara)
Director

Copy to:

1. Secretary, Department of Forests, Government of Madhya Pradesh, Bhopal.
2. Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office, E - 3 / 240, Arera Colony Bhopal - 462 016.
3. Chairman, Madhya Pradesh Pollution Control Board, E-5, Arera colony, Paryavaran Parisar, Bhopal 463016, Madhya Pradesh.
4. Chairman, Central Pollution Control Board, CBD-Cum-Office Complex, East Arjun Nagar, New Delhi-110 032.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Guard File/Monitoring File/Record File.

(Dr. P. L. Ahujarai)
Director