State Level Environment Impact Assessment Authority

Madhya Pradesh
Government of India
Ministry of Environment & Forests

Madhya Pradesh Pollution Control Board
E-5. Arera Colony
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No:145 /EPCO-SEIAA/10
Date:28-05-10

To,

M/s Lupin Ltd
198-202 Industrial Area
Mandideep
Raisen M.P.

Sub:- Prior Environmental Clearance to capacity enhancement of existing products and addition of new products at 198-202, New Industrial Area No.2, Mandideep, Raisen M.P. ***Case no.148/2008***

This has reference to your letter no. LL/VSS/F-542/01-07 dated 20/11/2007 along with Application in Form-1, project report, list of products, manufacturing process details, raw materials, air and water pollution control details and project feasibility report for seeking environmental clearance for the above project under the Environment Impact Assessment Notification, 2006 and subsequent correspondence vide letter nos. LL/RKK/F-42/09 dt 05/12/09 and LL/RKK/F-42/09 dt 09/09/09.

2. The State Level Environment Impact Assessment Authority has examined the proposal and noted that the proposal is for prior environmental clearance for M/s Lupin Ltd., Bulk drug manufacturing unit at 198-202 New Industrial Area No.2, Mandideep, Distt- Raisen-(M.P.) Total land acquired by the plant is 58 acres. The cost of the project is Rs.2895 lakhs. The capital cost earmarked for environmental protection measures will be 470 lakhs. The plant is located within the notified new industrial area no.2, Mandideep, Distt-Raisen-(M.P).

The production profiles of the existing and proposed enhancement of pharmaceutical product along with additional new product are given below.

S.No.	Name of Product	Production Capacity (TPA)		
		Existing	Proposed enhancement and additional new product	Total
1.	Cephalexin	600	400	1000
2.	Cefaclor	50	70	120
3.	Lisinopril	35	65	100
4.	Cefdinir	12	12	24
5.	Cefipime	-	10	10
6.	Perindopril	-	10	10
7.	Trandipril	-	5	5
8.	Quinapril	-	20	20
9.	Ramipril	-	15	15
10	Recovered Solvent	-	7000	7000

3. The additional water required i.e. 200 KLD will be supplied by MPAKVN. The waste water 190 KLD generated from various activities due to proposed expansion will be treated in the effluent treatment plant having double stage activated sludge process along with tertiary treatment, reverse osmosis unit and multiple effect evaporator. Alkali based PP/FRP wet scrubber systems with activated carbon based high adsorbent tower will be installed to control the emissions. Fume extraction system along with adsorbent tower of activated carbon will be installed in technical section, raw material handling unit, product handling unit and packing area to remove chemical fumes from work place environment. Dust collection system with wet scrubber will be installed in all critical area and section to remove dust from the work place environment.

4. Since the unit is located in a notified industrial area, public hearing is not required as per para 7(i) III (b) stage (3). Based on the information submitted by the Project Authorities, State Level Environment Impact Assessment Authority considered the proposal in its 35th meeting held on 12/05/10 and hereby accords environmental clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 subject to compliance of the following specific and general conditions:

5. SPECIFIC CONDITIONS:

(i) The company shall enhance the capacity of effluent treatment plant from 200 KLD to 400 KLD to treat the additional effluent generated due to proposed activity. The treated water shall be utilized within the plant for gardening, washing, cooling purposes etc. to achieve zero discharge.

(ii) The hazardous wastes and other wastes generated from the process and treatment facilities should be disposed off as follows:-

S.No	Name of wastes	Mode of Disposal
1.	Used/Spent Oil	To be sold to authorized re-processors recyclers registered with CPCB.
2.	Process Residues/Wastes	Till the incinerator at CTSDF become operational, should be incinerated in captive incinerator in the plant and ash be disposed off at Common Treatment, Storage and Disposal Facility (CTSDF) of M.P. As and when the incinerator becomes operational, the incineration should also be taken place at CTSDF of M.P.
3.	Off Specification products/Date expired/ Discarded Drugs/Medicines.	- do-
4.	Spent Catalyst/Spent Carbon/Exchange Materials/Filter and Filter Materials.	- do-
5.	Spent Organic Solvent/Mother Liquor	- do-
6.	Chemical (ETP) Sludge	Should be disposed off at Common Treatment, Storage and Disposal Facility (CTSDF) of M.P.
7.	Spent Solvent	Should be reused after recovery or be disposed off through sale of recovery.
8.	Incinerated Ash	Should be disposed off at Common Treatment Storage and Disposal Facility (STSDF) of M.P.
9.	Discard Containers/Barrels used for hazardous wastes/chemicals	After cleaning and decontamination, should be disposed off through sale to authorized vendors.

(iii) The project authority shall obtain the membership of CTSDF for disposal of solid and hazardous waste and copy of the same shall be submitted to the Ministry's Regional Office at Bhopal. The company shall maintain the valid membership of CTSDF.

(iv) The company shall install scrubbers/Bag filters and dust collection system for control of emissions to achieve the norms prescribed by MPPCB or under EP Act, 1986. The higher standard/norms shall be applicable in case of overlapping between the aforesaid regulations.

(v) The project authority shall ensure that the solvent recovery shall not be less than 95% and provide the condensers with solvent storage tanks to achieve solvent recovery more than 95% and all the solvent storage shall be provided with breather valves to prevent solvent losses. The monitoring arrangement for solvent with the vents shall be provided. Solvent management shall be as follows:-

A. Reactor shall be connected to chilled brine condenser system
B. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
C. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
D. Proper earthling shall be provided in all the electrical equipment wherever there is solvent handling.
E. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

(vi) The company shall provide the monitoring arrangement with vents and regular monitoring shall be carried out and reports submitted to the MPPCB,CPCB and Ministry's Regional Office at Bhopal.

(vii) The project authorities shall provide the chilled brine solution in secondary condenser for condensation of VOCs. The process emissions, VOCs and particulate matter form various units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission level shall go beyond the stipulated standards.

(viii) Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits

imposed by MPPCB. For control of fugitive emission and VOCs following steps shall be followed:-

A. Closed handling system shall be provided for chemicals
B. Reflux condenser shall be provided over reducer
C. Solvent handling pump shall be provided with mechanical seals to prevent leakages
D. System of leak detection and repair of pump/pipeline based on preventive maintenance.
E. Solvent shall be taken from underground storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.

(ix) The company shall carry out the HAZOP study and the report shall be submitted to Ministry's Regional Office at Bhopal.

(x) The company shall comply with the CREP guidelines prepared by MPPCB for Bulk Drug Plants.

(xi) The company shall develop greenbelt in 33% of the project area as per the guidelines of CPCB to mitigate the effect of fugitive emission.

(xii) Requisite financial provision shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Fund so earmarked shall not be diverted for any other purposes.

(xiii) During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixings of accidental spillages with domestic waste and storm drains.

(xiv) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

(xv) The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.

(xvi) The DG set will be provided with acoustic arrangements to attenuate the noise pollution. The emission from DG set shall be dispersed as per the CPCB/MPPCB standards.

(xvii) Industry has proposed to utilized the captive incinerator for the incineration of hazardous waste generated due to proposed expansion. Incinerator specifications should be as per CPCB norms and should strictly follow the monitoring protocol as per CPCB guidelines. As a when, the common incinerator at CTSDF of M .P. becomes operational all the incinerable wastes be incinerated at there only.

6. GENERAL CONDITIONS

(i) The project authorities shall strictly adhere to the stipulations of the MPPCB. State government or any statutory body.

(ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests or State Level Impact Assessment Authority as the case may be. In case of deviations or alternations in the project proposal from those submitted to this State Level Impact Assessment Authority for clearance, a fresh reference shall be made to the State Level Impact Assessment Authority to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

(iii) The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemical Rules, 1989 as amended.

(iv) 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 M.P. State Pollution Control Board. Atleast one station should also be installed in the upwind direction

(v) For control of process emissions, stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided. The scrubbed water shall be sent to ETP for further treatment.

(vi) The company shall undertake following Waste Minimizations measures:-

- Metering quantities of active ingredients to minimize waste.
- Reuse of by-products from the process as raw materials as raw materials or as raw material substitutes in other processes.
- Maximizing recoveries.
- Use of automated material transfer system to minimize spillage.
- Use of "Closed Feed" system into batch reactors.

(vii) 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, Handling and Transboundary movement) Rules, 2003. Authorization from the MPPCB shall be obtained for collections/treatment/storage/disposal of hazardous wastes.

(viii) 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. 75 dBA (day time) and 70 dBA (night time).

(ix) A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the environmental management and monitoring functions.

(x) The project authorities shall provide rainwater harvesting system and ground water recharge.

(xi) The implementation of the project vis-a-vis environmental action plans shall be monitored by Ministry's Regional Office/MPPCB/CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.

(xii) The project proponent shall inform the public that the project has been accorded environmental clearance by the SEIAA and copies of the clearance letter are available with the MPPCB and may also be seen at Website of SEIAA www.mpseiaa.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 Bhopal.

(xiii) The project authority has to submit half yearly compliance report of the stipulated prior environmental clearance terms and conditions in hard and soft copy to the SEIAA of M.P. on 1st June and 1st December of each calendar year.

(xiv) The project authorities shall inform the Regional Office of 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.

(xv) All the storage tanks should be under negative pressure to avoid any leakages. Breather valves, N2 blanketing and secondary condensers with chilled brine chilling system shall be provided for all the storage tanks to minimize vapor losses. All the liquid raw materials shall be stored in storage tanks and drums. Closed handling systems for chemicals and solvents should be provided. Magnetic seals should be provided for pumps/agitators for reactors for reduction of fugitive emissions. Solvent traps shall be installed where ever necessary. Reactor generating solvent vapors will be converted to condenser with receivers.

(xvi) All venting equipments shall have vapor recovery system. All the pumps and other equipment's where there is a likelihood of HC leakages shall be provided with LDAR system, LEL indicators and HC detectors. Provision for immediate isolation of such equipments in case of leakage should also be made. The company should implement well defined LDAR programme for quantification and control of fugitive emissions.

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

8. The SEIAA reserves the right to stipulate additional conditions, if found necessary.

9. Any appeal against this environmental clearance shall lie with the National Environment Appellate Authority, if preferred within a period of 30 days as prescribed under Section 11 of the National Environment Appellate Authority Act, 1997.

10. The above conditions shall be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention and 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.

Sd/-
(**Ashok Shah**)
Member Secretary, SEIAA

Endt No. 146/SEIAA/EPCO/10 Dated:-28-05-10

Copy to:-

1. The Secretary, Department of Environment, Government of Madhya Pradesh, Bhopal
2. The Member Secretary, Madhya Pradesh State Pollution Control Board, Paryavarn Parisar, E-5, Arera Colony, Bhopal-462016
3. The Collector, Distt-Raisen-M.P.
4. Division, Monitoring Cell, MoEF, New Delhi- 110 003
5. The Regional Officer, MOEF, Bhopal
6. Guard file.

Sd/-
(**Ashok Shah**)
Member Secretary, SEIAA