

Speed post



भारत सरकार  
पर्यावरण एवं वन मंत्रालय  
Government of India  
Ministry of Environment & Forests  
(IA Division)

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F. No. J-11011/470/2006-IA(II)

April 01, 2008

To

M/s AMI Life Science Pvt. Ltd.  
Block No. 82/B, ECP Road, Post Karakhadi,  
Tal. Padra,  
District Vadodara,  
Gujarat

**Sub: Expansion of existing Bulk Drug Manufacturing Facilities of Block No. 82/B, ECP Road, Post Karakhadi, Tal. Padra, District Vadodara, Gujarat by M/s AMI Life Science Pvt. Ltd. - Environmental Clearance reg.**

Sir,

This has reference to your letter no. nil dated October 2007 along with EIA/EMP and public hearing report seeking environmental clearance for the above project under the Environment Impact Assessment Notification, 2006.

2. The Ministry of Environment and Forests has examined the proposal and noted that the proposal is for environmental clearance for expansion of existing Bulk Drug Manufacturing Facilities of Block No. 82/B, ECP Road, Post Karakhadi, Tal. Padra, District Vadodara, Gujarat by M/s AMI Life Science Pvt. Ltd. The cost of the project is Rs. 2.49 Crores. The total area for the project is 10270 sq. m. No eco-sensitive zone exists within 10 km periphery of the site. The details of existing and proposed products are as follows:

S. No.	Products	Existing Capacity (TPM)	Capacity after Expansion (TPM)
1	1-Acetyl Naphthalene	2.0	2.0
2	2-Acetyl Naphthalene	1.0	1.0
3	Itopride HCl	0.0	6.0
4	Loxapine succinate	0.0	1.2
5	Amoxapine	0.0	0.3
6	Venlafaxine	0.0	6.0

7	Proguanil HCl	0.0	6.0
8	CBZ-L-VALINE	0.0	6.0
9	Nateglinide	0.0	0.6
10	Quetiapine	0.0	0.6
11	Carbamazepin	0.0	24.0
12	Oxcarbamazepin	0.0	12.0
<b>Total</b>		<b>3.0</b>	<b>65.7</b>

3. The total water requirement will be 33.74 KLD and met from the Ground water through Bore well at the site. The waste water generation would be 9.35 KLD which will be treated in Effluent Treatment Plant and sent to CETP. Industry has proposed to install Chillers with chilled brine circulation to reduce the solvent evaporation losses into the atmosphere. Two stage Alkali / water scrubber shall be provided to reaction vessel in addition to existing alkali scrubber. Hazardous wastes will be disposed of through TSDF.

4. The Public hearing was held on 12.10.2007.

5. The project activity is listed at S.N. 5(f) under Category 'A' and the proposal was considered and appraised at centre level in 77<sup>th</sup> meeting of the Expert Appraisal Committee (Industry) held during 21<sup>st</sup> - 24<sup>th</sup> January, 2008.

6. Based on the information submitted by the Project Authorities, the Ministry of Environment and Forests hereby accords the environmental clearance to the above project under the provisions of EIA Notification dated 14<sup>th</sup> September, 2006 subject to compliance of the following specific and general conditions:

**A SPECIFIC CONDITIONS:**

- i) The project authorities shall comply with the commitments made during public hearing held on 12<sup>th</sup> October 2007.
- ii) The project authorities shall provide the chilled brine solution in secondary condenser for condensation of the VOCs. The project authority shall ensure that the solvent recovery shall not be less than 95%.
- iii) The company shall provide the monitoring arrangement with vents and regular monitoring shall be carried out and reports submitted to the SPCB, CPCB and Ministry's Regional Office at Bhopal.
- iv) 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. Solvents shall be stored in a separate area specified with all safety measures.
  - E. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - F. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- v) The process emissions VOCs and particulate matter from various 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 unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.
- vi) 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 GPCB.
- vii) 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 provided over reducer
  - C. Solvent handling pump shall be provided 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.
- viii) The project authority shall install effluent treatment plant to treat the wastewater up to the inlet norms of the CETP and shall obtain the membership of CETP for disposal of treated effluent and copy of the same shall be submitted to the Ministry and Ministry's Regional Office at Bhopal. The company shall maintain the valid membership.
- ix) The project authorities shall obtain permission for drawl of ground water from Central Ground Water Authority or State Ground Water Board and copy of permission letter shall be submitted to the Ministry's Regional Office at Bhopal.
- x) Distillation residue (3.0 MTPA) and Chemical sludge from ETP (5.5 MTPA) shall be sent to TSDF for disposal. Used/spent oil (100 L/yr) and discarded barrels/containers/liners shall be sent to TSDF or sold to the approved recyclers. The project authorities shall maintain the valid membership of TSDF.



- xi) During transfer of materials spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.
- xii) As proposed the project authorities shall develop greenbelt in 27.21 % project area as per the guidelines of CPCB.
- xiii) Rs. 14 Lakhs shall be earmarked for the environmental protection measures. Adequate 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.
- 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.

#### **GENERAL CONDITIONS**

- i. The project authorities shall strictly adhere to the stipulations of the SPCB/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. 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. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- 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 State Pollution Control Board.
- 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 Minimization measures :-
  - Metering 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.
  - 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 and Handling) Rules, 2003. Authorization from the SPCB 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-à-vis environmental action plans shall be monitored by Ministry's Regional Office /SPCB / 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 Ministry and copies of the clearance letter are available with the SPCB 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.
- xiii. 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.

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



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

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 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, 1989 and the Public Liability Insurance Act, 1991 alongwith their amendments and rules.

  
(H.S. Malviya)  
Joint Director

Copy to :-

1. The Secretary, Department of Environment and Forests, Govt. of Gujarat, Secretariat Gandhinagar-382010
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110032.
3. The Chairman, Gujarat State Pollution Control Board, Paryavaran Bhavan, Sector-10A, Gandhinagar-382010.
4. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office (WZ), Ravishankar Nagar, Link Road-3, Bhopal- 462016, M.P.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
6. Guard file.
7. Record file

  
(H.S. Malviya)  
Joint Director