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F. No. J-11011/423/2006- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

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

E-mail : pb.rastogi@nic.in
Talefax : 011-24367668
Dated 15th June, 2007

To,

Shri H.D. Shah
Vice President (Manufacturing)
M/s INTAS Pharmaceuticals Ltd.
Plot No. 457 & 458, Sarkhej-Barla Highway
Maloda, Sanad, Ahmedabad
Gujarat.

E-mail : kmaheshwari@intaspharma.com / adbhimani@intaspharma.com
Fax No. : 079-6578862 / 02717-661106.

Subject : Expansion of Bulk Drug Unit at Plot No.457 & 458, Sarkhej-Barla Highway, Maloda, Sanad, Ahmedabad, Gujarat by M/s INTAS Pharmaceuticals Ltd.

Sir,

This has reference to your letter no. Intas/EC/2006-10-01 dated 31st October, 2006 on the above subject alongwith Application, Questionnaire and EIA/EMP report and subsequent communications dated 10th & 11th January, 2007 and 12th February, 2007 seeking environmental clearance for the above project under the Environmental Impact Assessment Notification, 2006.

2.0 The Ministry of Environment and Forests has examined your application alongwith EIA/EMP report. It is noted that the proposal is for expansion of bulk drug unit (API) at Plot No.457 & 458, Sarkhej – Barla Highway, Maloda, Sanad, Ahmedabad, Gujarat. Total land acquired is 94,213 m². No additional land will be required since the proposed API Unit will be set up in the existing premises only. Following drugs will be manufactured :

S.N.	Name of Product(s)	Products to be manufactured (kg / Year)
1	Gemcetabin	500
2	Capcitabene	5000
3	Exemestane	100
4	Imatinib Mesylate	750
5	Topotecan HCl	1
6	Docetexal	50
7	Timozolamide HCl	200
Total		6,601

3.0 Caustic scrubber and cyclone separator are provided to the existing incinerator for the control of air emissions. Solvent will be recovered after primary and secondary condensation using chilled water and reused in the reactor. Total water requirement from the bore well will be 159.40 m³/d and prior 'permission' from SGWB/CGWA will be obtained. All the treated water from the R.O. plant will be used in the process. Wastewater will be treated in ETP for primary, secondary and tertiary treatment. Finally treated wastewater will be used for land irrigation / green belt development within the plant premises. ETP sludge, process waste and incinerator ash will be disposed off at SLF site of M/s The Green Environment Services Co-operative Society Ltd. Incinerable waste and expired drugs will be incinerated in Company's own incinerator. Liquid expired drugs will be treated in ETP and sent to CBMWTF facility of M/s E-Coli Waste Management System.

4.0 Public hearing meeting was held on 4th October 2006. 'No Objection Certificate' has been accorded by the GPCB on Dated 8th February 2006. Total cost of the project is Rs. 8.00 Crores.

5.0 The Ministry of Environment and Forests hereby accord environmental clearance to the above project under EIA Notification dated 14th September, 2006 subject to strict compliance of the following conditions:

A SPECIFIC CONDITIONS :

- i) The gaseous emissions (SO₂, HCl & NO_x) 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. Inter-locking facility and on-line monitoring system shall also be provided and data shall be submitted to the Ministry's Regional Office at Bhopal / GPCB / CPCB regularly.
- ii) 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 GSPCB. Caustic scrubber and water scrubber shall be provided to control emissions.
- iii) Spent solvents shall be recovered as far as possible after primary and secondary condensation using chilled water and reused in the reactor. Action shall be taken to reduce the emissions as far as possible and recovery shall not be less than 95 percent. Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum. All venting equipments shall have vapour recovery system. Vapour arrestors shall be provided to drums while transferring solvents from tanks to the process system. Condensers / chilled brine shall be installed to reduce solvent vapours and ultimately quantity of use of solvents.
- iv) A time bound action plan for phasing out Methylene Chloride shall be prepared and submitted. Regular monitoring of the vents for Methylene Chloride, Toluene and other solvent shall be ensured.

- v) 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.
- vi) Total water requirement from the bore well and effluent generation shall not exceed 159.40 m³/day and 106.75 m³/day respectively. Prior 'permission' from SGWB/CGWA shall be obtained for the drawl of ground water. Low COD effluent shall be treated in ETP having primary, secondary and tertiary treatment facilities. High TDS and high COD effluent shall be segregated and treated. MEE shall be installed for the treatment of process effluent and rejects shall be sent to TSDF. Reverse Osmosis plant shall be installed to reduce water consumption by recycling and reusing treated wastewater. All the treated wastewater from the R.O. Plant shall be used in the process. Reject water shall be treated in tertiary ETP. Finally treated wastewater shall be used for land irrigation / green belt development within the plant premises. The domestic effluent shall be treated in septic tank and disposed off in a soak pit.
- vii) The solid/hazardous waste including ETP sludge, process waste and incinerator ash shall be stored in HDPE bags in secured landfill and sent to the TSDF site of M/s The Green Environment Services Co-operative Society Ltd. Spent activated charcoal shall not be disposed off in secured landfill (SLF). Instead, it shall be incinerated in the incinerator. Incinerable waste and expired drugs shall be incinerated in Company's own incinerator. Liquid expired drugs will be treated in ETP and sent to CBMWTF facility of M/s E-Coli Waste Management System. Spent/used oil will be sold to registered recyclers.
- viii) Incinerator installed shall be modified as per CPCB guidelines and shall meet the standards or otherwise solid/hazardous waste shall be sent to the TSDF.
- ix) Risk Assessment study shall be carried out and submitted to the Ministry, its Regional Office at Bhopal, CPCB and GPCB.
- x) The company shall develop rainwater harvesting structures to harvest the run off water for recharge of ground water.
- xi) Out of 94,219 m², green belt shall be developed in 42,370 m² (45%) to mitigate the effects of fugitive emissions all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.
- xii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

B. GENERAL CONDITIONS :

- i. The project authorities shall strictly adhere to the stipulations made by the Gujarat 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. 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 GSPCB.
- 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 GSPCB shall be obtained for collection, treatment, storage and 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 Gujarat State Pollution Control Board must be obtained for collection / 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. 75 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 EIA/EMP 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. As mentioned in the EIA/EMP, Rs. 10.00 Lakhs and Rs. 6.25 Lakhs earmarked towards capital cost and recurring cost/annum for environmental pollution control measures shall be judiciously used to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government. An implementation schedule for implementing all the conditions stipulated herein shall be submitted to the Ministry, its Regional Office at Bhopal / GPCB / CPCB. 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 the Ministry's Regional Office at Bhopal / GPCB / CPCB. 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 GPCB/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 Bhopal.
- 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.

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

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

8.0 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.B. RASTOGI)
Additional Director

Copy to : -

1. The Secretary, Department of environment and forests, Govt. of Gujarat, Gandhi Nagar, Gujarat.
2. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office, Link Road No.3, E - 5, Arera Colony, Bhopal - 462 016. M.P.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Gujarat Pollution Control Board, Paryavaran Bhawan, Sector 10-A, Gandhi Nagar - 382 010, Gujarat.
5. Joint Secretary (CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, New Delhi.
7. Guard File.
8. Monitoring File.
9. Record File.



(Dr. P.B. RASTOGI)
Additional Director