

F. No.-J-11011/493/2009- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

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Dated 25th August, 2011

To, ✓
Shri K.B. Maheshwari, Sr. Vice President
M/s Intas Pharmaceuticals Limited.
Survey no. 191, Village Chacharwadi, Vasana
Taluka Sanand, District Ahmedabad, Gujarat

E-mail: kmaheshwari@intaspharma.com ; Fax :079-26578862

Subject: Bulk Drugs Manufacturing Unit at Sy. No. 191, Village Chacharwadi Vasana, Taluka Sanand, District Ahmedabad, Gujarat by M/s INTAS Pharmaceuticals Ltd. – Environmental Clearance reg.

Ref. : Your letter no. nil dated 24th June, 2010.

Sir,

Kindly refer your letter dated 24th June, 2010 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report alongwith Public Hearing Report and additional information submitted on 8th September, 2010 and 21st February, 2011 as well as submission of resolution of the Board of Directors duly signed by the Managing Director vide dated 9th June, 2011 for no repetition of violation in the future regarding above mentioned project.

2.0 The Ministry of Environment and Forests has examined the application. It is noted that the proposal is for setting up of Bulk Drugs Manufacturing Unit at Sy. No. 191, Village Chacharwadi Vasana, Taluka Sanand, District Ahmedabad, Gujarat by M/s INTAS Pharmaceuticals Ltd. No eco-sensitive area is located within 10 km. The total land acquired for the project is 50,000 m². Total project cost is Rs. 14.00 Crores. Following products will be manufactured:

| S. N. | Products* | Quantity (Kg/Month) |
|--------------|--------------------------|---------------------|
| 1 | Aripiprazole | 25.00 |
| 2 | Metoprolol Succinate | 425.00 |
| 3 | Pregabalin | 150.00 |
| 4 | Rabeprazole | 50.00 |
| 5 | Telmisartan | 425.00 |
| 6 | Paliperidone | 25.00 |
| 7 | Paclitaxel | 2.50 |
| 8 | Desvenlafaxine Succinate | 50.00 |
| 9 | Fesoterodine Fumarate | 50.00 |
| Total | | 1202.50 |

* At a time, only two products will be manufactured.

3.0 Packed column scrubber consisting of venturi followed by alkali scrubber will be provided to control HCl emissions. Primary condenser with chilled water and secondary condenser with chilled brine of -10 °C will be provided to the all reactors to control fugitive

emissions from process. Packed column type scrubber consisting venturi followed by water scrubber will be provided to control solvent vapour emissions. Total fresh water requirement from ground water source will be 46 m³/day. Total industrial effluent generation will be 14.65 m³/day. Industrial effluent will be segregated into High COD and low COD effluent streams. High COD streams will be evaporated in multi effect evaporator (MEE). Low COD effluent stream will be treated in ETP and treated effluent will be recycled and reused within the factory premises. ETP sludge will be sent to hazardous waste treatment storage disposal facility (TSDF). Process residue (organic), solvent residue and spent carbon will be sent to the cement plant. Used oil will be sold to the authorized re-processor.

4.0 Public hearing of the project was held on 11th June, 2010.

5.0 All synthetic organic chemical industries (bulk drugs & intermediates) located outside the notified industrial estate/area are listed at S.N. 5(f) under category 'A' and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry-2) in its 3rd, 14th and 21st meeting held during 15th-16th September, 2009, 16th-17th September, 2010 and 23rd-24th March, 2011 respectively. The Committee recommended the proposal for environmental clearance.

7.0 Based on the information submitted by the project proponent, 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) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.
- ii) As proposed, packed column scrubber consisting of venturi followed by alkali scrubber shall be provided to process vents to control HCl emissions within the limit prescribed by CPCB/GPCB. Packed column scrubber consisting of venturi followed by water scrubber shall be provided to control solvent vapours. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards. In the event of failure of any pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- iii) No steam boiler shall be installed for the proposed project as steam shall be made available for process from the existing adjoining plant of M/s INTAS Pharmaceuticals Ltd.
- iv) Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM₁₀, SO₂, NO_x, CO, VOC and HCl shall be monitored in the ambient air and emissions from the stacks shall be monitored and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and Gujarat Pollution Control Board (GPCB). On-line VOC analyzer shall be installed for monitoring of VOCs in the ambient air. ✓

- v) In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the GPCB.
- vi) For further control of fugitive emissions, following steps shall be followed :
1. Closed handling system shall be provided for chemicals.
 2. Reflux condenser shall be provided over reactor.
 3. System of leak detection and repair of pump/pipeline based on preventive maintenance.
 4. The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
 5. Cathodic protection shall be provided to the underground solvent storage tanks.
- vii) The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- viii) Solvent management shall be carried out as follows :
- i. Reactor shall be connected to chilled brine condenser system
 - ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - iv. Solvents shall be stored in a separate space specified with all safety measures.
 - v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- ix) Total fresh water requirement from ground water source shall not exceed 45 m³/day and prior permission shall be obtained from the Central Ground Water Authority/State Ground Water Board.
- x) Industrial effluent generation shall not exceed 14.65 m³/day. Industrial effluent shall be segregated into high COD and low COD effluent streams. High COD effluent stream shall be treated in MEE. Low COD effluent stream shall be treated in ETP and treated effluent shall be recycled and reused within the factory premises after achieving desirable water quality for various purposes. Sewage shall be disposed through septic tank followed by soak pit.
- xi) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
- xii) The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from GPCB shall be obtained for disposal of

solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.

- xiii) As proposed, ETP sludge shall be sent to the TSDF. Process residue (organic), solvent residue and spent carbon will be sent to the cement plant.
- xiv) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All Transportation of Hazardous Chemicals shall be *as per* the Motor Vehicle Act (MVA), 1989.
- xv) Entire plant where solvents are used shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- xvi) The company shall undertake following waste minimization measures :-
 - a. Metering and control of quantities of active ingredients to minimize waste.
 - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - c. Use of automated filling to minimize spillage.
 - d. Use of Close Feed system into batch reactors.
 - e. Venting equipment through vapour recovery system.
 - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- xvii) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the OISD 117 norms
- xviii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xix) Green belt shall be developed in 16,500 m² out of total plot area 50,000 m². Selection of plant species shall be as per the CPCB guidelines.
- xx) Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile sewage treatment plant, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.

B. GENERAL CONDITIONS:

- i. The project authorities shall strictly adhere to the stipulations made by the Gujarat 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. 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 upwind and downwind direction as well as where maximum ground level concentrations are anticipated.

- iv. 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).
- v. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.
- vi. 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. Training to all employees on handling of chemicals shall be imparted.
- vii. Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.
- viii. The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
- ix. The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.
- x. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xi. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xii. As proposed, the company shall earmark sufficient funds towards capital cost and recurring cost per annum 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 earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
- xiii. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.
- xiv. The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the Gujarat Pollution

Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

- xv. The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.
- xvi. 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.
- xvii. 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.

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

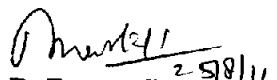
9.0 The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

10.0 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, 1989/2003/ 2008 and the Public Liability Insurance Act, 1991 alongwith their amendments and rules.


(Dr. P. B. Rastogi)
Director

Copy to:

1. The Principal Secretary, Forests & Environment Department, Government of Gujarat, Sachivalaya, 8th Floor, Gandhi Nagar - 382 010, Gujarat.
2. The Chief Conservator of Forests (Western Zone), Ministry of Environment & Forests, Regional Office, E-5, Arera Colony, Link Road -3, 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 State Pollution Control Board, Paryavaran Bhawan, Sector 10 A, Gandhi Nagar-382 043, Gujarat.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Scientist 'G', IA II(I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
7. Guard File/Monitoring File/Record File.


(Dr. P. B. Rastogi) 2-5/8/11
Director