

F. No. J-11011/169/2011 IA II (I)  
Government of India  
Ministry of Environment, Forest and Climate Change  
(I.A. Division)

Indira Paryavaran Bhawan  
Aliganj, Jorbagh Road,  
New Delhi -110003

E-mail : [lk.bokolia@nic.in](mailto:lk.bokolia@nic.in)  
Telefax: 011-24695313  
Dated 22<sup>nd</sup> June, 2015

To,

✓ Shri J. L. Nagori  
Vice Presidents (Bulk Drugs)  
M/s Ipca Laboratories Ltd.  
P.B. No.33, Sejavata  
Ratlam - 457002, Madhya Pradesh

E-mail: [ipcartm@ipca.co.in](mailto:ipcartm@ipca.co.in) / [jmenviro@gmail.com](mailto:jmenviro@gmail.com) ; Fax No. : 07412-279083

**Subject : Expansion of Bulk Drug Unit (2551.5 MTPA to 3322.0 MTPA) at Sejavta, Ratlam, Madhya Pradesh by M/s Ipca Laboratories Ltd. -Environmental Clearance reg.**

**Ref. : Your letter no. nil dated 21<sup>st</sup> July, 2014.**

Sir,

This has reference to your letter dated 21<sup>st</sup> July, 2014 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report on the above mentioned subject.

2.0 The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for expansion of Bulk Drug Unit (2551.5 MTPA to 3322.0 MTPA) at Sejavta, Ratlam, Madhya Pradesh by M/s Ipca Laboratories Ltd. Total existing plant area is 40.47 ha. and no additional land is required for the proposed expansion project. Out of which greenbelt will be developed in 14.76 ha. Total cost of project is Rs. 221.65 Crore. Rs. 16.0 Crore and Rs. 5.6 Crore are earmarked towards capital cost and recurring cost per annum for pollution control measures. Jamar River and Kurel River are flowing at a distance of 7.5 Km and 9.5 Km respectively. No reserve Forest/wildlife Sanctuary/protected Forest are located within 10 Km distance. Sambharkho protected forest is located at a distance of 9.5 Km. Following products will be manufactured:

S. N.	Products	Existing Capacity	Additional Capacity	Total
<b>Bulk Drugs</b>				
1	Synthetic Drug API	2551.5(TPA)	670.5(TPA)	3222(TPA)
<b>Formulations</b>				
2	Tablets (Million Nos. /Year)	800	1300	2100
3	Injections (Million Nos. /Year)	20	Nil	20
4	Liquid Orals (KL/Year)	2500	800	3300
5	Dry Syrup (Million Nos. /Year)	Nil	1.5	1.5
6	Ointment (TPA)	Nil	150	150
<b>R&amp;D Products</b>				
7	R & D Products (TPA)	Nil	05	05
<b>Steroids &amp; Hormones</b>				
8	Steroids & Hormonal products (TPA)	Nil	41.391	41.391

3.0 Multi-cyclone separator followed by bagfilter alongwith stacks of adequate height will be provided to coal fired boiler. Scrubber will be provided to the process vents to control process emissions viz. HCl and SO<sub>2</sub>. Total water requirement will be increased from 1050 m<sup>3</sup>/day to 1475 m<sup>3</sup>/day after expansion. Out of which, fresh water requirement from ground water source/ municipal supply will be 905 m<sup>3</sup>/day. And remaining water requirement (570 m<sup>3</sup>/day) will be fulfilled by recycled/treated effluent. Industrial wastewater generation will be increased from 525 m<sup>3</sup>/day to 620 m<sup>3</sup>/day after expansion. Industrial wastewater will be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS/COD effluent stream will be treated in effluent treatment plant (ETP) and then passed through Reverse Osmosis (RO). Treated effluent will be reused in cooling tower make up water and horticulture purpose. Sewage will be treated in sewage treatment plant (STP). No effluent will be discharged outside the premises and 'Zero' effluent discharge concept will be maintained. Inorganic & evaporation salt, ETP sludge and incineration ash will be sent to Treatment Storage and Disposal Facility (TSDf) for hazardous waste. Fly ash will be sold to brick manufacturers. Waste oil and used batteries will be sold to authorized recyclers/re-processors.

4.0 Public hearing was conducted on 20<sup>th</sup> February, 2014.

5.0 All the Synthetic Organic Chemicals located outside notified industrial area are listed at S.N. 5(f) under Category 'A' and appraised at the Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry) in its meetings held during 22<sup>nd</sup>-23<sup>rd</sup> June, 2011, 8<sup>th</sup>- 9<sup>th</sup> January, 2013, 16<sup>th</sup>-17<sup>th</sup> May, 2013 and 29<sup>th</sup> - 30<sup>th</sup> September, 2014 respectively. Project Proponent and their EIA Consultant namely M/s J M Environet Pvt. Ltd., have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be satisfactory and in full consonance with the presented TOR. The Committee recommended the proposal for environmental clearance.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment and Forest hereby accords environmental clearance to above project under the provisions of EIA Notification dated 14<sup>th</sup> September 2006, subject to the compliance of the following Specific and General Conditions:

**A. SPECIFIC CONDITIONS:**

- i) All pollution control and monitoring equipments shall be installed, tested and interlocked with the process. Company shall not start operation of the expansion unit unless the pollution control equipments are ready and running. SPCB shall grant 'Consent to Operate' after ensuring that all the mentioned pollution control equipments have been installed.
- ii) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21<sup>st</sup> July, 2010 and amended time to time shall be complied by the unit.
- iii) Multi-cyclone followed by bag filter shall be provided to the coal fired boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/MPPCB guidelines.
- iv) Two stage chilled water/caustic scrubber should be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution should be provided to process vents to control SO<sub>2</sub>. The scrubbing media should be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber should be monitored regularly and maintained properly. At no time, the emission levels should go beyond the prescribed

standards. Scrubbers vent shall be provided with on-line detection and alarm system to indicate higher than permissible value of controlled parameters.

- v) Ambient air quality data shall be collected as per NAAEQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> September, 2009. The levels of PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>, VOC, CO and HCl shall be monitored in the ambient air and emissions from the stacks 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 MP Pollution Control Board (MPPCB).
- vi) 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 MPPCB.
- vii) 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.
- viii) 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.
- ix) Solvent management shall be carried out 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 space 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.
  - g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- x) Fresh water requirement from ground water source shall not exceed 786 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA. Fresh water requirement from Municipal Supply shall not exceed 119 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA

- xi) Industrial wastewater generation shall not exceed 620 m<sup>3</sup>/day. Industrial wastewater/effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD effluent stream shall be passed through stripper followed by MEE and agitated thin film drier (ATFD). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Treated effluent shall be reused for cooling tower make up, utilities and horticulture. Sewage shall be treated in STP.
- xii) No effluent shall be discharged outside the plant premises and 'Zero' effluent discharge shall be maintained.
- xiii) Automatic /online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the respective SPCB and in the Company's website.
- xiv) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
- xv) 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.
- xvi) High calorific value waste viz. process organic residue and spent carbon shall be sent to cement industries. Inorganic & evaporation salt, ETP sludge and incineration ash shall be disposed off to the TSDF. The flyash from boiler shall be sold to brick manufacturers/cement industry. Waste oil and used batteries will be sold to authorized recyclers/re-processors.
- xvii) Till the remediation of the area is achieved, the Unit shall provide water supply to the affected villages under CSR programme.
- xviii) 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 MPPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xix) 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.
- xx) Fly ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing alongwith the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
- xxi) 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 vapor recovery system.
  - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- xxii) 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 norms.

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- xxiii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xxiv) As proposed, green belt shall be developed in 14.76 ha. out of total plant area of 40.47 ha. Selection of plant species shall be as per the CPCB guidelines.
- xxv) At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment based on earlier Public Hearing Issues, locals need and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office at Bhopal. Implementation of such program shall be ensured accordingly in a time bound manner.
- xxvi) The Company shall submit within three months their policy towards Corporate Environment Responsibility which should inter-alia address (i) Standard operating process/procedure to bring into focus any infringement/deviation/ violation of environmental or forest norms/conditions, (ii) Hierarchical system or Administrative order of the Company to deal with environmental issues and ensuring compliance to the environmental clearance conditions and (iii) System of reporting of non compliance/violation environmental norms to the Board of Directors of the company and/or stakeholders or shareholders.
- xxvii) 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 MP 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 Forest. 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 National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> November, 2009 shall be followed.
- iv. The locations of ambient air quality monitoring stations shall be decided in consultation with the MP State Pollution Control Board (MPPCB) 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.
- v. 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).
- vi. 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 its amendment time to time and prior

- permission from MPPCB shall be obtained for disposal of solid / hazardous waste including boiler ash.
- vii. During transfer of materials, spillages shall be avoided and gulland drains be constructed to avoid mixing of accidental spillages with domestic wastewater and storm water drains.
  - viii. Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.
  - ix. 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.
  - x. The company 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 the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
  - xi. The company shall undertake CSR activities and all relevant measures for improving the socio-economic conditions of the surrounding area.
  - xii. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
  - xiii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
  - xiv. As proposed, the company shall earmark Rs. 6.8 Crore and Rs. 19.22 Lakh towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment and Forest 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.
  - xv. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, ZilaParisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.
  - xvi. 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 MP Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
  - xvii. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the Madhya Pradesh 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 Bhopal Regional Offices of MoEF by e-mail.

- xviii. 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://moef.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.
- xix. 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 Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

11.0 Environmental Clearance is issued to M/s Ipca Laboratories Ltd for expansion of bulk drug unit (2551.5 MTPA to 3322.0 MTPA) at Sejavta, Ratlam, Madhya Pradesh.

  
(Lalit Bokolia)  
Additional Director

**Copy to :-**

1. The Secretary (Environment), Govt. of Madhya Pradesh, Mantralaya, Ballabh Bhavan, Bhopal, MP.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110032.
3. The Chairman, Madhya Pradesh Pollution Control Board, Paryavaran Parishar , E-5, Arera Colony, Bhopal - 462016
4. The Chief Conservator of Forest (Central), Ministry of Environment, Forest and Climate Change, Western Regional Office, Kendriya Paryavaran Bhavan, Link Road No. 3, Ravi Shankar Nagar, Bhopal - 462016
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, Jor Bagh, New Delhi-110003.
6. Guard file / Record file/ Notice Board.

  
(Lalit Bokolia)  
Additional Director