

F. No. J-11011/8/2013- IA II (I)
Government of India
Ministry of Environment, Forest & Climate Change
(I.A. Division)

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Dated: 28th October, 2015

To,

Shri Manish Dhanuka (Managing Director)
M/s Dhanuka Laboratories Ltd.
7 Km, Old Manesar Road, Village Mohamadpur,
Gurgaon- 122002

E-mail: manishdhanuka@dhanuka.com ; Fax No.: +91-124-3938908

Subject: Bulk Drugs Manufacturing Unit at SP-4-4, RIICO Industrial Area Keshwana, Tehsil Kotputli, District Jaipur, Rajasthan by M/s Dhanuka Laboratories Ltd. – Environmental Clearance reg.

Ref. : Your online proposal no. IA/RJ/IND/6486/2012 dated 25th May, 2015.

Sir,

This has reference to your online proposal no. IA/RJ/IND/6486/2012 dated 25th May, 2015 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report alongwith Public Hearing Report regarding above mentioned project and subsequent submission of additional information vide letter dated 23rd June, 2015.

2.0 The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that proposal is for setting up of bulk drugs manufacturing unit at SP-4-4, RIICO Industrial Area Keshwana, Tehsil Kotputli, District Jaipur, Rajasthan by M/s Dhanuka Laboratories Ltd. Total plant area is 32800 m² of which greenbelt will be developed in 10824 m². Total project cost is Rs. 70.00 Crore. Out of which Rs. 5 Crore and Rs. 60 Lakh are earmarked towards capital cost and recurring cost per annum of implementation of environmental management plan. No forest land is involved. Interstate boundary of Haryana is located within 5 Km distance. It is reported that no national park/wildlife sanctuary/reserve forest is located within 10 km distance. Following products will be manufactured:

S.N	Products	Capacity (kg/month)
1	7 –ACCA	3000
2	Cefaclor	3000
3	Cefixime	12000
4	Cefdinir	1000
5	Cefuroxime Axetil	4000
6	Cefprozil	1000
7	CefditorenPivoxil	1000
8	Cefcapene	225
9	Ceftibuten	200
10	Pregabaline	3000
11	Sertraline Hydrochloride	2000

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12	Ondansetron	2000
13	Clopidogrel	5000
14	Gabapentin	4000
15	R&D products	5000
16	CefpodoximeProxtil	4000
	Total	50425

3.0 Bagfilter will be provided to the coal fired boiler to control particulate emissions. Scrubber will be provided to control process emissions viz. HCl, HBr and Ammonia. Scrubber will be provided to the vent of incinerator. Adequate stack height and acoustic enclosure will be provided to DG set (6 x 500 KVA. Total water requirement will be 160 m³/day of which fresh water requirement will be 150 m³/day and remaining 10 m³/day will be met from treated effluent. Industrial effluent and domestic effluent generation will be 154 m³/day. Effluent will be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD will be passed through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS effluent stream will be treated in the effluent treatment plant (ETP) and then passed through reverse osmosis (RO). Condensate and recover water will be recycled/reused within factory premises as cooling tower make up and horticulture purpose. 'Zero' effluent discharge will be adopted and no effluent will be discharged outside the premises. ETP sludge and MEE salt will be sent to TSDF. Spent oil will be sent to the authorized recycler/re-processors.

4.0 Public hearing as per Section 7 (i), III Stage (3), Para (i) (b) of EIA Notification 2006 as project is located in the notified industrial area.

5.0 All the synthetic organic chemicals industry (Bulk Drugs Manufacturing Unit) located inside the notified industrial area are listed at S.N. 5(f) under Category 'B'. However, due to applicability of general condition i.e. interstate boundary within 5 km (i.e. 4 Km Rajasthan-Haryana), project is treated as Category 'A' project and appraised at the Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry-2) in its 6th, 42nd and 46th meetings held during 5th -7th March, 2013, 16th -17th June, 2015 and 20th - 21st August, 2015 respectively. Project Proponent and the EIA Consultant namely (M/s EQMS India Pvt. Ltd.), have presented EIA / EMP report as per the TOR. EAC has found the EIA Study / EMP Report to be adequate and in full consonance with the presented TORs. 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) Bagfilter 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/SPCB guidelines.
- iii) Ambient air quality data shall be collected as per NAAEQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM_{2.5}, PM₁₀, SO₂, NO_x, VOC, CO, HBr, HCl and NH₃ 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 the Rajasthan State Pollution Control Board (RSPCB).

- iv) 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. Odour management plan shall be implemented. The emissions shall conform to the limits stipulated by the RSPCB.
- v) 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.
- vi) 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.
- vii) 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.
 - vii. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- viii) Total fresh water requirement from ground water source shall not exceed 150 m³/day and prior permission shall be obtained from the CGWA/SGWA.
- ix) Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/reused within factory premises.
- x) 'Zero' effluent discharge should be adopted and no effluent will be discharged outside the premises.

- xi) 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.
- xii) 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.
- xiii) As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/cement industry.
- xiv) 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 RSPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xv) 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.
- xvi) 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.
- xvii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xviii) 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 along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
- xix) At least 2.5 % of the total cost of the project shall be earmarked towards the Enterprise social responsibility and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office Lucknow. Implementation of such program shall be ensured accordingly in a time bound manner.
- xx) As proposed, green belt of 10824 m² shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.
- xxi) 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, 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 State Government and Rajasthan State Pollution Control Board (RSPCB).
- 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.

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- iii. The locations of ambient air quality monitoring stations shall be decided in consultation with the RSPCB 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. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic wastewater and storm water drains.
- vii. Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.
- viii. 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.
- ix. 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.
- x. The company shall undertake CSR activities and all relevant measures for improving the socio-economic conditions of the surrounding area.
- xi. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xiii. The company shall earmark sufficient funds for recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change 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.
- xiv. 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.
- xv. The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored

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data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal Office of CPCB and the Rajasthan State Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

- xvi. The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the Rajasthan 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 Lucknow Regional Offices of MoEF&CC by e-mail.
- xvii. 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 www.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.
- xviii. 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.


(Lalit Bokolia)
Additional Director

Copy to :-

1. Secretary, Department of Environment and Forests, Government of Rajasthan, Jaipur, Rajasthan.
2. Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi -110032.
3. Chairman, Rajasthan State Pollution Control Board, 4, Institutional area, Jhalana, Doongri, Jaipur, Rajasthan.
4. Chief Conservator of Forests (Central), Ministry of Environment and Forests, Region Office (Central), Kendriya Bhawan, 5th Floor, Sector-H, Aliganj, Lucknow – 226 024, U.P.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, Jorbagh Road, New Delhi.
6. Guard File/Monitoring File/Record File.


(Lalit Bokolia)
Additional Director