

Original

No. SEIAA: 29: IND: 2010

**STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT
AUTHORITY, KARNATAKA STATE**

(Constituted by Ministry of Environment & Forests, Government of India)

Department of Ecology and Environment
Room No.709, 7th Floor, IV-Gate,
M.S. Building, Bangalore-560 001,
Date: 3rd October 2013.

To

M/s. Kshatriya Laboratories Pvt. Ltd.,
Plot No. 28/1, Technocrat Industrial Estate,
Balanagar, Hyderabad- 500037.
Andhra Pradesh.

Phone No: 040-42016698

Email: kshatriyalaboratories@gmail.com

Sir,

Sub: Establishment of industry to manufacture bulk drugs and intermediates at Plot No. 106B & 107, Sy. No. 215, Gadvanthi Village, Humnabad Industrial Area, Humnabad, Bidar District of M/s. Kshatriya Laboratories Pvt. Ltd., - Issue of Environmental Clearance- reg.

This has reference to your applications received on 07.07.2010 addressed to SEIAA, Karnataka and subsequent letters addressed to SEIAA/SEAC, Karnataka seeking prior environmental clearance for the above project under the EIA Notification, 2006. The proposal has been appraised as per prescribed procedure in the light of the provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the Application in Form 1, Risk Assessment Report, material balance of each proposed drug, project report for manufacture of proposed drugs and the additional clarifications furnished in response to the observations of the SEAC, Karnataka.

The proposal is for manufacturing the following specialty chemicals:

Sl. No	Name of the Products	Quantity (TPM)
1	Rosuvastatin Calcium	0.5
2	Efavirenz	1.0
3	Eletriptan	1.0
4	Prasugrel	0.8
5	4-Chlorophenylboronic Acid	0.5
6	2-Indolecarboxylic Acid	0.5
7	5-Bromo Indole	2.0
8	2-Amino-3-Bromo-5-	0.5

	Chloropyridine	
9	N-phenyl piperazine	2.0
10	Tri-o-tolylphosphine	2.0
	Total	10.8

Group -2 -

Sl. No	Name of the Products	Quantity (TPM)
1	Pregabalin.....	1.0
2	Ritonavir	1.0
3	Telmisartan	1.0
4	Famcicovir	0.5
5	Methyl indole-4-carboxylate	1.0
6	7-Azaindole	0.5
7	2-Acetyl Pyridine	2.0
8	N-Methyl-3-phenyl piperazine	1.0
9	Methyl 4-(bromomethyl)benzoate	1.5
10	7-Chloro quinalidine	1.3
	Total	10.8

Group -3

Sl. No	Name of the Products	Quantity (TPM)
1	Ziprasidone	0.5
2	Imatinib	1.0
3	Febuxostat	0.5
4	Montelukast sodium	1.0
5	2-Mercapto-5-methoxybenzimidazole	1.0
6	Diethyl 5 - amino - 3 - methyl thiophene - 2, 4-dicarboxylate	0.5
7	2-Chloro-5-bromo pyrimidine	1.5
8	5-Methyl tetrazole	1.0
9	1-Benzyl-3-hydroxy-1H-indazole	1.8
10	1-Benzyl-3-hydroxy pyrrolidine	2.0
	Total	10.8

It is, inter-alia, noted that M/s. Kshatriya Laboratories Pvt. Ltd., have proposed for manufacture of specialty chemicals of total capacity 32.4 TPM. The total land area is 3 acres, out of which 1.23 acres is a built up area, 0.69 acre area is for road and 1.09 acres area is for green belt. Total water consumption is 63.48 KLD, out of which fresh water of 46.48 KLD will be source from KIADB / borewell within the plant. Out of which 63.48 KLD, 2.5 KLD is for domestic purpose, 3.98 KLD is for process, 4 KLD is for washings, 7.5 KLD is for boiler, 1.5 KLD is for R&D, 2 KLD is for scrubber, 20 KLD is for cooling tower and 5 KLD is for green belt. Power requirement of 600 HP will be sourced from industrial area supply/public supply. DG sets of 1 X 225 KVA will be installed for emergency power back-up. It is proposed to install coal fired boiler of capacity 3 TPA. The total cost of the project is ₹ 491.5 Lakhs.

The wastewater generation will be 18.81 KLD of which 2 KLD will be the domestic sewage and 16.81 KLD will be the industrial effluent. The domestic sewage will be treated in septic tank and discharged into soak pit. The industrial effluent will be treated in ETP followed by Multiple Effective Evaporator (MEE). The solid waste generated are ash from boiler of 1.3 TPD will be sold to brick manufactures, solvent residue of 0.1 TPA will be sent to TSDF/cement units, evaporation salts of 0.24 TPD will be sent to TSDF, process residue of 0.15 TPD will be sent to cement units, carbon of 19.17 Kg/day will be used for incineration in boiler, Catalyst of 6.67 Kg/day will be returned to manufacturer, ETP sludge of 20 KG/day will be sent to TSDF, municipal wastes of 30 Kg/day will be municipal solid waste disposal/vermin compost bed, detoxified containers of 750 Nos/year will be sent to authorized vendors, waste oil of 120 ltrs/year will be sent to authorized recyclers and used batteries of 1 Nos/year will be sent to Authorized recyclers.

The project proposal has been considered by SEAC and ToRs were issued on 19th July 2011 for conducting Environment Impact Assessment Study. The project is located within the notified industrial area and hence does not require public consultation. The EIA has been conducted by M/s. Team Labs and consultants, B-115 & 509, Annapurna Block, Aditya Enclave, Ameerpet, Hyderabad - 500 038 who is NABET, QCI accredited.

Based on the information submitted by you, presentation made by you and your consultants M/s. Team Labs and consultants, B-115 & 509, Annapurna Block, Aditya Enclave, Ameerpet, Hyderabad - 500 038 who is NABET, QCI accredited. The State Level Expert Appraisal Committee (SEAC) examined the proposal in the meeting held on 27th October 2010, 28th - 29th January 2011, 30th April 2011, 17th - 18th June 2011, 6th - 7th January 2012, 7th April 2012, 20th - 21st July 2012, 29th September 2012, 20th October 2012, 15th - 16th March 2013, 26th - 27th April 2013, 3rd June 2013, 28th - 29th June 2013 & 16th - 17th August 2013 and has recommended for issue of Environmental Clearance.

The SEIAA Karnataka has considered the project in its meeting held on 27th September 2013 and after due consideration of the relevant documents submitted by the project proponent and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC, have accorded environmental clearance as per the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the terms and conditions:-

Part A- SPECIFIC CONDITIONS

1. 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.
2. The industrial effluent generation shall not exceed 18.81 and it shall be treated in ETP followed by MEE. The domestic sewage shall be disposed through septic tank/soak pit.

3. Total water requirement from KIADB water supply shall not exceed 46.48 KLD and prior permission shall be obtained from the concerned Authority. No ground water is to be drawn without permission from the Central Ground Water Authority/Karnataka Ground Water Authority.
4. The process emissions from the boiler shall be dispersed through stack of adequate height as per CPCB /Karnataka State Pollution Control Board standards. The gaseous emissions from the DG set shall be dispersed through stack height as per CPCB standards shall be provided. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
5. 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, VOC 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, Bangalore, SEIAA, Karnataka, the respective Zonal office of CPCB and the Karnataka State Pollution Control Board.
6. The company shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF, Bangalore, SEIAA, Karnataka, the respective Zonal office of CPCB and the Karnataka State Pollution Control Board. The levels of SPM, RSPM, SO₂, NO_x and VOC (ambient levels) 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.
7. The Company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 for management of hazardous wastes and prior permission from KSPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. The concerned company shall undertake measures for fire fighting facilities in case of emergency.
8. 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 KSPCB.
9. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
10. 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.
11. For control of fugitive emission following steps shall be followed:
- a. Closed handling system shall be provided for chemicals.
 - b. Reflux condenser shall provided over reactor.
 - c. System of leak detection and repair of pump/pipeline based on preventive maintenance.
 - d. 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.
 - e. Cathodic protection shall be provided to the underground solvent storage tanks.
12. Solvent management shall be as follows:
- a. Solvent used in the process shall be completely recovered and reused as committed.
 - b. Reactor shall be connected to chilled brine condenser system.
 - c. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - d. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
 - e. Solvents shall be stored in a separate space specified with all safety measures.
 - f. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - g. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - h. 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 KSPCB.
13. No effluent shall be discharged outside the factory premises and "Zero" discharge concept shall be adopted.
14. Multi-cyclone followed by bag filter shall be provided to the boilers to control particulate emissions within 100 mg/Nm³. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
15. Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution shall be provided to process vents to control SO₂. 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.
16. 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.
17. Boiler 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.
 18. 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.
 19. The Company shall harvest surface as well as rainwater from the rooftops of the buildings and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.
 20. 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.
 21. 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.
 22. Usage of PPEs by all employees/ workers shall be ensured.
 23. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
 24. Green belt shall be developed in at least 33% of area with suitable species of the plants as per the CPCB guidelines to mitigate the effects of fugitive emissions. Selection of plant species shall be as per the CPCB guidelines.
 25. The adequate financial provisions 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.
 26. The company shall comply with the recommendations made in the EIA/EMP/Risk assessment report. Risk assessment shall be included in the safety Manual.
 27. 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.
 28. The coal to be stored in coal stockyard on impervious layer in a covered shed and along the boundary garland canal to be provided leading to a exit pond/tank to arrest coal dust run-off and to allow settling of coal fines. The coal fines to be removed periodically.
 29. The proponent shall adopt good management practices and implement all the measures proposed in the EMP.
 30. The project authorities shall spend ₹ 2 Lakhs towards the corporate social responsibility made during the SEAC meeting dated 16.08.2013 and submitted to the Authority.

31. The Project authorities also shall earmark at least 5 % of the total cost of the project towards the corporate social responsibility and item-wise details along with time bound action plan shall be prepared and submitted to the Authority.

B. GENERAL CONDITIONS:

1. The project authorities shall strictly adhere to the stipulations made by the Karnataka State Pollution Control Board (KSPCB).
2. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system 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.
3. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA/Ministry of Environment and Forests as the case may be. In case of deviations or alterations in the project proposal from those submitted to this Authority for clearance, a fresh reference shall be made to the Authority to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
4. The gaseous emissions (NO_x, SO₂ and SPM) and Particulate matter along with RSPM levels 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. Stack monitoring for SO₂, NO_x and SPM shall be carried.
5. 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. all transportation of Hazardous Chemicals shall be as per the MVA, 1989. Authorization from the KSPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
6. 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 KSPCB must be obtained for collection/treatment/storage/disposal of hazardous wastes.
7. Application of solar energy should be incorporated for illumination of common areas, lighting for gardens and street lighting in addition to provision for solar water heating. A hybrid system or fully solar system for lighting and heating should be provided. Details in this regard should be submitted to the SEIAA.
8. 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, Rules, 1989 viz. DBA (day time) and 70 dBA (night time).

9. The project proponent shall also comply with all the environmental protection measures and safeguards as per the information provided.
10. The implementation of the project vis-à-vis environmental action plans shall be monitored by MoEF, Regional Office at Bangalore / KSPCB/ CPCB and the Department of Environment & Ecology, Bangalore. A six monthly compliance status report shall be submitted to monitoring agencies.
11. The project proponent shall inform the public that the project has been accorded environmental clearance by the SEIAA and copies of the clearance letter are available with the KSPCB and may also be seen at Website of the Authority at <http://www.seiaa.kar.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 MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Department of Environment & Ecology, Bangalore.
12. The project authorities shall inform the MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Department of Ecology and Environment, Bangalore, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
13. The SEIAA, Karnataka may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
14. The SEIAA, Karnataka reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
15. 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.
16. The issue of Environment Clearance doesn't confer any right to the project proponent to operate / run the project without obtaining statutory clearances / sanctions from all other concerned Authorities.
17. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environmental (Protection) Act, 1986.
18. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
19. Officials from the Department of Environment and Ecology, Bangalore/ Regional Office of MoEF, Bangalore who would be monitoring the implementation of Environmental safeguards should be given full cooperation, facilities and documents/ data by the project proponents during their inspection. A complete set of all the documents submitted to MoEF / SEIAA should be forwarded to the CCF, Regional Office of MoEF, Bangalore/ Department of Ecology and Environment, Bangalore/ Regional Officer, KSPCB Bangalore.

20. In the case of any change(s) in the scope of the project, the project would require a fresh appraisal by this Authority.
21. The Authority reserves the right to add additional safeguard measures subsequently, if found necessary, and to take action including revoking of the environment clearance under the provisions of the Environment (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.
22. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained, as applicable by project proponents from the competent authorities.
23. These stipulations would be enforced among others under the provisions of water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) act 1981, the Environment (Protection) Act, 1986, the Public Liability (Insurance) Act, 1991 and EIA Notification, 2006.
24. Under the provisions of Environment (Protection) Act, 1986, legal action shall be initiated against the project proponent if it is found that construction of the project has been started without obtaining environmental clearance.

Yours Faithfully,


(RAMACHANDRA)

Member Secretary,
SEIAA.

Copy to:

- 1) The Secretary, Ministry of Environment & Forests, Government of India, Paryavaran Bhavan, CGO Complex, Lodi Road, New Delhi-110003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The CCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore-560 034.
- 4) Guard File.

