

भारत सरकार

पर्यावरण एवं वन मंत्रालय

By Speed Post

GOVERNMENT OF INDIA

MINISTRY OF ENVIRONMENT & FORESTS

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File No- J-11011/533/2007-IA II (I)

Date: 21st February, 2008

To,

M/s SVAKRM Laboratories (P) Ltd.
Sry. No. 405, Veleminedu Village
Chityal Mandal, Nalgonda District
Andhra Pradesh

Subject: New Bulk Drug Manufacturing Unit at Sry. No. 405, Veleminedu Village, Chityal Mandal, Nalgonda District, Andhra Pradesh by M/s SVAKRM Laboratories (P) Ltd. - Environmental Clearance regarding.

Sir,

This is with reference to your application No. SVAKRM LABORATORIES (P) LTD. dated 5th June 2007 seeking environment clearance for the above mentioned project.

2. The Ministry of Environment and Forests has examined the proposal. It is noted that the proposal is to set up a new Bulk Drug manufacturing unit at Survey No. 405, Veleminedu Village, Chityal in Nalgonda District of Andhra Pradesh. The cost of the project is Rs. 4.5 Crores. The total land area is 2.8834 ha out of which 2.1134 hectare will be developed as Green belt. River Musi is at 14 km from the industry. The following 9 products are proposed to be manufactured on campaign basis, making only three at a time with an overall tonnage of about 180 TPA-

S.No.	Name of Products	Quantity (TPA)
Bulk Drugs - Campaign Products		
1.	Tramadol Hydrochloride	60.0
2.	Ramipril	60.0
3.	Omeprazole	60.0
4.	Carvedilol	60.0
5.	Sertraline Hydrochloride	60.0
6.	Duloxetine Hydrochloride	36.0
7.	Sparfloxacin	48.0
8.	Drotaverine Hydrochloride	30.0
9.	Clopidogrel Hydrogen Bisulfate	60.0
By-Product		
10	Spent Sulfuric acid	364.8



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जहाँ है हरियाली।
वहाँ है खुशहाली।।

पर्यावरण भवन, सी.जी.ओ. कॉम्प्लेक्स, लोदी रोड, नई दिल्ली - 110 003
PARYAVARAN BHAWAN, C.G.O. COMPLEX, LODHI ROAD, NEW DELHI - 110 003

3. Power requirement of 520 HP will be met from AP Transco. Two Coal fired boilers of 5.0 and 3.0 TPH will be installed out of which one will be stand by. D.G. Sets of 250 & 125 KVA will be installed. The total water requirement will be about 107.06 KLD which will be met from the Ground water / Tankers. The waste water generation shall be 30.8 KLD which will be segregated in High TDS/Low TDS Streams. The High TDS Stream shall be sent to Multiple Effect Evaporation System and the 60% of condensate will be reused in cooling towers and the 40% of the condensate along with 7.0 KLD Low TDS effluent will be sent to ETP from where after primary treatment it will be sent to CETP, Patancheru till the commissioning of the proposed CETP in Nalgonda District. Domestic waste water of about 1.2 KLD will be sent to Septic Tank followed by Soakpit. Salts from the evaporation system will be sent to TSDF along with the ETP sludge. The solid waste of 1.168 TPD of salts from MEE and inorganic solid waste, 1.377 TPD of organic residue and process residue, 0.062 TPD of spent carbon, 0.025 TPD of ETP Sludge will be sent to TSDF at Dindigul. Boiler ash of 8.0 TPD will be sold to Brick Manufactures.

4. The project activity is listed at 5 (f) and is of 'A' Category under the Schedule of EIA Notification, 2006. The project was considered as per Para 2.2.1 (a) of the Interim Operation Guidelines dated 13th October 2006 issued by the Ministry. Public Hearing for the project was held on 10.05.2007

5. Based on the information submitted by you, the Ministry of Environment and Forests hereby accords environmental clearance to the above project under the provisions of EIA Notification dated 14th September 2006 subject to compliance of the following Specific and General conditions:

A. SPECIFIC CONDITIONS:

- i. The environmental clearance is subject to measures to be taken by the Industrial Associations as identified by the Andhra Pradesh Pollution Control Board vide its letter No. 45/PCB/CFE/BO/EC/2007 dated 15th June 2007.
- ii. Multicyclane Separator and wet scrubber followed by a stack of 30 m height shall be provided for control and dispersion of pollutants with coal fired boiler. Cyclane separator efficiency shall be minimum 90%.
- iii. CO₂, N₂, H₂, SO₂ Ammonia and Hal emissions from the process vents shall be scrubbed in water and Caustic lye solution scrubbers and Liquid Ammonia and dilute Hal so formed shall be reused. SO₂ shall be scrubbed in the scrubber using Caustic lye solution and the scrubbing liquid shall be sent to CETP, Patancheru, after primary treatment. Scrubber efficiency shall be minimum 95%. The gases containing traces of HCl gas shall be passed through Alkali Secondary Packed Tower, where gases shall be neutralized & clean air shall be vented through Blower stack. CO₂ formed shall be routed to atmosphere through vents and H₂ will be diffused with flame arrester.

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- iv. The waste water generation shall not exceed 30.8 KLD which shall be segregated in High/Low TDS Streams. The High TDS/High COD Stream shall be sent to Multiple Effect Evaporation System with Steam Stripper. The fore run shall be collected separately and sent with spent solvent for recovery. Final condensate shall be collected and 60% of condensate shall be reused in cooling towers and the 40% of the condensate along with 7.0 KLD of Low TDS effluents shall be sent to ETP from where, after primary treatment, it will be sent to CETP, Patancheru till the commissioning of the proposed CETP in Nalgonda District. 1.2 KLD of Domestic waste water will be sent to Septic Tank followed by Soak pit.
- v. 1.168 TPD of salts from MEE and inorganic solid waste, 1.577 TPD of Organic residue and process residue, 0.062 TPD of spent carbon, 0.025 TPD of ETP Sludge shall be sent to TSDF at Dindigal. Boiler ash of 8.0 TPD shall be sold to Brick Manufactures. The Company shall submit Membership documents of TSDF and CETP for record with in 15 days of issue of this letter.
- vi. Spent solvents shall be recovered as far as possible & recovery shall not be less than 98 percent. Solvent vapours emitted during purification process from purification tanks as fugitive emissions shall be reduced as far as possible. All venting equipment shall have vapour recovery system.
- vii. The Company shall implement various commitments made during the Public Hearing.
- viii. 2.1134 ha of land shall be developed as Green Belt and selection of plant species shall be as per CPCB Guidelines.

B. GENERAL CONDITIONS :

- (i) The project authorities shall strictly adhere to the stipulations made by the 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) 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.

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- (iv) The gaseous emissions (SO_2 , NO_x , HCl, CO, VOC and HC) 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.
- (v) Levels of HC and VOC at various probable locations in the ambient air in and around the plant will be monitored regularly.
- (vi) 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 up wind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (vii) Dedicated scrubbers and stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided to control the emissions from various vents. The scrubbed water shall be sent to ETP for further treatment.
- (viii) All the storage tanks will be under negative pressure to avoid any leakages. Breather valves, N_2 blanketing and secondary condensers with Chilled Brine chilling system shall be provided for all the storage tanks to minimize vapour losses. All liquid raw material shall be stored in storage Tanks and Drums. Closed handling systems for chemicals and solvents will be provided. Magnetic seals will be provided for pumps/agitators for reactors for reduction of fugitive emissions. Solvent traps shall be installed wherever necessary. Reactor generating solvent vapors will be connected to condensers with receivers.
- (ix) All venting equipment shall have vapour recovery system. All the pumps and other equipment's where there is a likelihood of HC leakages shall be provided with Leak Detection and Repair (LDAR) system and LEL indicators and Hydrocarbon detectors. Provision for immediate isolation of such equipment, in case of a leakage will also be made. The company shall provide a well defined Leak Detection and Repair (LDAR) programme for quantification and control of fugitive emissions. The detectors sensitivity will be in ppm levels.
- (x) 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.

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- 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 cleaning to reduce wastewater generation.
- (xi) Fugitive emissions in the work zone environment, product, and raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by the State Pollution Control Boards/Central Pollution Control Board.
- (xii) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000 and Hazardous Waste (Management and Handling) Rules, 1989, as amended from time to time. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes. All Transportation of Hazardous Chemicals shall be as per the MVA, 1989.
- (xiii) 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).
- (xiv) Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act.
- (xv) 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.
- (xvi) Usage of PPEs by all employees/ workers shall be ensured.
- (xvii) The company shall strictly follow all the recommendations mentioned in the Charter on Corporate Responsibility for Environmental Protection (CREP).
- (xviii) The Company shall harvest surface as well as rainwater from the rooftops of the buildings proposed in the expansion project 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.

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- (xix) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the EIA/EMP report. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.
- (xx) The company will undertake all relevant measures, as indicated during the Public Hearing for improving the Socio-economic conditions of the surrounding area. CSR activities will be undertaken by involving local villages and administration.
- (xxi) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- (xxii) A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- (xxiii) The project authorities shall earmark adequate funds 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 provided shall not be diverted for any other purpose.
- (xxiv) The implementation of the project vis-à-vis environmental action plans shall be monitored by the concerned Regional Office of the Ministry/SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies and shall be posted on the website of the Company.
- (xxv) 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 SPCC/Committee and may also be seen at Website of the Ministry at <http://emfoc.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.
- (xxvi) 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. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

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

8. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (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.


(Sanchita Jindal)
Additional Director

Copy to:

1. The Secretary, Department of Environment and Forests, Government of Andhra Pradesh, Secretariat, Hyderabad- 500 022, A.P.
2. The Chief Conservator of Forests, Regional Office (Southern Zone) , Ministry of Environment & Forests, Kendriya Sadan, 4th Floor , C& F Wing, 17 Main Road, II Block , Kormangla, Bangalore- 560 034, Karnataka .
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, A.P. Pollution Control Board, Paryavaran-Bhawan, A-3, Industrial Estate, Sanath Nagar, Hyderabad- 500 018, A.P.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Guard File
7. Monitoring File
8. Record File.

(Sanchita Jindal)
Additional Director