

F. No. J-11011/71/2007-IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

Paryavaran Bhawan
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Telefax: 011 - 2436 3973
Dated: March 12, 2008

To,

M/S Shilpa Medicare Limited
10/80, Rajendra Gunj
Raichur-584 102
Karnataka

Subject: **Expansion Project of Bulk Drug Unit at Raichur, Karnataka by M/s Shilpa Medicare Limited- Environmental Clearance regarding.**

Sir,

Kindly refer to your letter No. SML/24/06-07 dated 24th March 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 for expansion of the existing Bulk Drug Unit at Survey No. 33, 33 A, 40, 41-47, Chicksugur village in Raichur District of Karnataka. The capacity of the project, after expansion will be 126.75 TPA. Total cost of the existing project is Rs. 21.83 Crores out of which 0.86 Crores will be for environment protection and recurring cost for the same will be Rs. 0.24 Crores. The total land area required for the project is 08.38 ha. The site does not involve any Reserve Forests or Eco-sensitive area. No R & R is required. The following 13 Products shall be produced under the expansion project-

s. No.	Name of Products	Capacity (MTA)
1	Ambroxol HCl	47
2	Anastrozole	0.1
3	Bicalutamide	0.5
4	Carboplatin	0.35
5	Cisplatin	0.1
6	Coenzyme Q-10	18
7	Docetaxel	0.1
8	Gemcitabine HCl	0.3



9	Irinotecan HCl Trihydrate	0.1
10	Oxaliplatin	0.05
11	Paclitaxel	0.1
12	Temozolomide	0.1
13	3a, 7B-Dihydroxy Cholanic Acid	60
Total		126.8

3. Power Consumption will be 500 KVA which will be met from KPTCL. DG Sets of 500 KVA shall be provided as back up. Water requirement for the project shall be 13200 LTD. Waste water generation will be 8000-9000 LTD which will be treated in the ETP and used for gardening and landscaping.
4. The project activity is listed at 5 (f) and is of 'B' Category in the Schedule of EIA Notification, 2006. The Project was considered as per Para 2.1.1 (i) of the Interim Operational Guidelines dated 13th October 2006 issued by the Ministry as the Public Hearing for the project was held on 07.08.2006.
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. Emissions from the process vents shall be water/ alkali scrubbed & scrubbed water shall be treated in ETP. Scrubber efficiency shall be minimum 95%.
 - ii. Cyclone separator/ESP with a minimum stack height of 30 m shall be installed for dispersion of Particulate matter. Cyclone separator efficiency shall be minimum 90%.
 - iii. There shall be no odour *nuisance* from products & material used. Odour shall be controlled as per the Guidelines of CPCB.
 - iv. Regular monitoring of HC and VOC shall be carried out at various probable locations in the ambient air in and around the plant and in the work zone area.
 - v. Water withdrawal shall not exceed 13,200 LTD which shall be sourced from the Municipal supply.
 - vi. The waste water generation shall not exceed 8000 LTD which shall be treated in the ETP up to tertiary treatment and shall be used for gardening and landscaping, after meeting the discharge norms. Domestic water will be sent to septic tank followed by soak pit.



- (vi) 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.
- (vii) All the storage tanks will be under negative pressure to avoid any leakages. Breather valves, N₂ blanketing and secondary condensers with 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. Close 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.
- (viii) 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.
- (ix) 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.
 - > 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.
- (x) 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.
- (xi) 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



- vii. Process waste, ETP sludge and Organic residue shall be collected and packed in HOPE bags and stored temporarily in a separate leachate proof covered shed till disposal into TSDF. 200 kg of Coal Ash shall be sold to Brick manufacturers.
- viii. 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.
- ix. The Company shall implement various commitments made during the Public Hearing.

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.
- (iv) The gaseous emissions (SO₂, NO_x, 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) The locations of ambient air quality monitoring stations shall be reviewed in consultation with the State Pollution Control Board (SPCB) and additional stations shall be installed, if required, in the downwind direction as well as where maximum ground level concentrations are anticipated.



- (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-a-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 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.
- (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.
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.


(Dr.P.L. Ahujarai)
Director



- (xii) 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).
- (xiii) 25% of the total area shall be developed as green belt as per the CPCB guidelines.
- (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.
- (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. The eco-development plan should be submitted to the SPCB within three months of receipt of this letter for approval.
- (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.



Copy to:

1. The Principal Secretary, Department of Forests, Ecology & Environment, Government of Karnataka, room No. 404, 4th Floor, II Stage, Multi Storeyed Building, Bangalore- 560 001
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.

(Dr.P.L. Ahujara)
Director

