

Government of Maharashtra

No.: SEAC 2010/CR.407/TC-2
Environment department,
Room No. 217, 2nd floor,
Mantralaya Annexe,
Mumbai 400 032
Date: 15th October, 2011

To,
M/s. USV limited,
Plot No. B- 8/1 and B-9,
MIDC Lote Parshuram Industrial Area,
Dist - Ratnagiri.
E-mail: hoshi.edulji@usv.co.in
Telephone No. : 02356-227242/272701

Subject: Pharmaceutical project (expansion) at MIDC Industrial Area, Lote Parshuram, Taluka Khed, Ratnagiri District by M/s USV Ltd. - Environmental clearance regarding.

Sir,

This has reference to your communication dated 12th August, 2010 on the above mentioned subject. The proposal was considered as per the EIA Notification - 2006, by the State Level Expert Appraisal Committee, Maharashtra in its 39th meeting and decided to recommend the project for prior environmental clearance to SEIAA. Information submitted by you has been considered by State Level Environment Impact Assessment Authority in its 38th meeting held on 4th & 5th August, 2011.

2. It is noted that the proposal is for grant of Environmental Clearance for Pharmaceutical project (expansion) at MIDC Industrial Area, Lote Parshuram, Taluka Khed, Ratnagiri District by M/s USV Ltd. SEAC considered the project under screening category 5 (f) as per EIA Notification 2006.

Project information from documents submitted by you & considered by SEAC & SEIAA is summarized as below-

Name of the Project	:	Pharmaceutical project (expansion)
Type of Project	:	5 (f) - Bulk drugs and intermediates
Project Proponent	:	M/s. USV limited
Location of the project	:	Plot No. B- 8/1 and B-9, MIDC Lote Parshuram Industrial Area, Dist Ratnagiri.
Land	:	Total plot Area: 20,213 Sq.m.
Built up area	:	13,542 Sq. m.
Estimated cost of the project	:	Rs. 80 crores

-1-



Production capacity:

Sr. No	Product Name	Existing MT/M	Proposed Product	Qty MT/M
1	Glipizide Sulphonamide	0.5	Glipizide Sulphonamide	0.5
2	Glibenclamide Sulphonamide	0.5	Glibenclamide Sulphonamide	0.5
3	Glimipiride Sulphonamide	0.2	Glimipiride Sulphonamide	0.3
4	Pioimino Compound	0.2	Pioglitazone Hcl	0.5
5	Nimidipine Intermediates	0.1	Nimidipine	0.1
6	Nitrendipine Intermediate	0.1	Nitrendipine	0.1
7	Clopidogrel Intermediates	0.1	Clopidogrel Bisulphate	5.0
8	Carvedilol Intermediate	1.0	Ropinorole Hcl	0.1
9	Ticlopidine HCl Intermediate	1.0	Sevlamer Hcl, Colesevlem & Sevlamer Carbonate	20.0
10	Other Organic Intermediates Chemicals	1.3	Other Organic Intermediates Chemicals or Bulk drugs	5.0
11	.	.	Biotech products – Filgrastin, Peg-Filgrastin, Somatropin and other Biotech products	100 Kg/Year

Proposed by-products:

Sr. No.	Proposed by -Product	Quantity
1.	Clopidogrel Bisulphate- Potassium Carbonate Salt	18.40 MT/M
2.	Clopidogrel Bisulphate - Sodium Sulphate	21.20 MT/M
3.	Ropinorole Hcl Intermediate – Hydrazine Hydrate Salt	260 Kg/M

Fuel used:

- Fuel : 160 kg/hr of HSD for DG sets
- Furnace Oil: Not required, as existing boiler in B-1/8 facility will be used.
- Stand by Boiler 6 MT/hr will be erected in B-1/8 facility.

Total Water Requirement: 330 CMD; Source : MIDC

- Domestic: 30 CMD
- Gardening: 30 CMD
- Industrial process: 120 CMD
- Industrial cooling: 150CMD

Effluent generated:

- **Domestic Effluent:** 25 CMD;
- **Trade Effluent:** 235 CMD; Effluent will be treated in Effluent Treatment Plant. Secondary and tertiary treatment will be done in existing MFG location, Effluent will be carried through pipelines through corridor \
- **ETP – 360 CMD**



Power requirement: 1500 KVA; Source : MSEDCL.

- DG Set: 1 No. each of 1000 and 350 KVA capacity.

Solid Waste Management:

Sr. No.	Category of Haz. Waste	Type of Waste	Qty. Approx. MT/Month	Disposal
1	5.1	Used / Spent Oil	0.300	Sale to CPCB registered waste Oil Recycler
2	28.1	Residue and Waste (incl. Guinidine HCl)	1.801	TSDf, Taloja
3	28.2	Spent Carbon	0.579	
4	28.2	Spent catalyst	0.417	For recovery
5	28.5	Spent Solvents	622.00	Sale to MPCB authorized solvent recycler / reuser
6	33.3	Discarded Containers / Barrels / Liners used for Hazardous waste chemicals	05.00	Sale to MPCB Authorised parties, after decontamination within premises.
7	34.2	Toxic metal containing residue from used ion exchange materials in water purification	0.04	TSDf, Taloja
8	34.4	Chemical sludge / Oil & Grease skimming residue from industry specific ETP	2.50	
9	35.1	Filter and Filter Material	0.383	

- The solid wastes generated from the plant will be disposed off in an environmentally responsible manner in accordance with applicable regulations.
- Hazardous waste generation and its quantities are mentioned below along with its disposal pathways.
- All the hazardous waste will be disposed off at TSDf Taloja facility, including evaporator salts. Used oil will be given for CPCB approved recyclers and Spent solvent will be sold off to MPCB approved recyclers or given for approved parties for recovery and for reuse.

Green Belt Development: Green belt area: 6600 m²

Air pollution control measures:

- The Air pollution from the plant operations is mainly in the form of suspended particulate matter, Sulphur dioxide, Nitrogen oxides from point sources and HCl, from process. The main source of air pollutants are the furnace oil based boiler, stand by DG sets and process.
- **Emissions from the process and Utilities:** It is envisaged that during the manufacturing process, HCl emissions are likely to be generated. These emissions are scrubbed off in the well-designed scrubbers using appropriate media. In order to mitigate the impact of solvent emissions, the solvents are reused by redistillation and fractionation process. Besides these methods USV proposes the following in order to prevent the solvent leaks and recovery of solvents.
 1. Provide mechanical seals to prevent pump and gland leakages.



2. Choose equipments which avoid solvent loss to the atmosphere e.g. closed filters, closed centrifuge, closed driers, etc. and
3. Provide vent condensers to reduce solvents emissions in the work place.
 - The concentration of the air borne pollutants in the work place environment will be periodically monitored to detect and measure fugitive emissions if any, from the process. Corrective measures, if any, warranted will be promptly initiated.
 - **Boiler Emissions:** The other source of air pollution from the plant is the combustion of furnace oil in the 6 MT boilers. In the new plot there will not be any new boiler. 6 MT boiler already installed in existing MFG location will only be utilized, as it has enough steam producing capacity. Adequate stack height of 39 Mtrs and optimal flue gas velocity of 6.6 m/s are provided for better dispersion of gaseous pollutants like SPM, SO₂ and NO_x.
 - **Stack Gas monitoring:** The emissions from the stacks will be regularly monitored for exit concentration of SPM, SO₂, NO_x. Sampling ports are provided in the stacks as per the CPCB guidelines.
 - **Ambient Air quality monitoring:** The concentration of SPM, SO₂, NO_x and other nine parameters (total 12 parameters) in the ambient air inside the plant will be monitored, as per 2010 EPA guidelines and also as per state PCB guidelines.

Noise Pollution Control System:

- Effective enclosures will be constructed of heavy weight material and any air gaps in its construction are filled with master of other fillers.
- Usage of acoustic proof material for walls, ceiling and doors to absorb sound waves to reduce reverberations will result in significant noise reduction.
- All the openings like covers, partitions will be acoustically sealed.
- The use of damping materials such as thins rubber / sheet for insulating the noise generating sources.
- Shock absorbing techniques will be adopted to reduce impact.
- Inlet and outlet mufflers will be installed to the outlet of exhanusts.
- Provision of separate acoustic proof (Sound proof) cabins for workers and operators
- Hearing protectors such as ear plugs / muffs will be provided tot eh operators working int eh high noise areas.
- The green belt will be provided to the tune of 33% of total site, which acts as noise attenuator. No human population is nearby, as industry is situated in MIDC and no impact of noise is envisaged to be felt at this area.

EMP: Capital cost: Rs. 410 lakhs and annual O&M cost Rs. 100 lakhs.

3. The proposal has been considered by SEIAA in its 38th meeting & decided to accord environmental clearance to the said project under the provisions of Environment Impact Assessment Notification, 2006 subject to implementation of the following terms and conditions:

- (i) This environmental clearance is issued subject to land use verification. Local authority / planning authority should ensure this. This environmental clearance issued with respect to the environmental consideration and it does not mean that State Level Impact Assessment Authority (SEIAA) approved the proposed land use.
- (ii) "Consent for Establishment" shall be obtained from Maharashtra Pollution Control Board under Air and Water Act and a copy shall be submitted to the Environment department before start of any construction work at the site.
- (iii) No land development / construction work preliminary or otherwise relating to the project shall be taken up without obtaining due clearance from respective authorities.



- (iv) No additional land shall be used /acquired for any activity of the project without obtaining proper permission.
- (v) For controlling fugitive natural dust, regular sprinkling of water & wind shields at appropriate distances in vulnerable areas of the plant shall be ensured.
- (vi) Regular monitoring of the air quality, including SPM & SO₂ levels both in work zone and ambient air shall be carried out in and around the power plant and records shall be maintained. The location of monitoring stations and frequency of monitoring shall be decided in consultation with Maharashtra Pollution Control Board (MPCB) & submit report accordingly to MPCB.
- (vii) A detailed scheme for rainwater harvesting shall be prepared and implemented to recharge ground water.
- (viii) Arrangement shall be made that effluent and storm water do not get mixed.
- (ix) Periodic monitoring of ground water shall be undertaken and results analyzed to ascertain any change in the quality of water. Results shall be regularly submitted to the Maharashtra Pollution Control Board.
- (x) Leq. of Noise level shall be maintained as per standards. For people working in the high noise area, requisite personal protective equipment like earplugs etc. shall be provided.
- (xi) Proper House keeping programmes shall be implemented.
- (xii) The overall noise levels in and around the plant are 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 confirm to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989.
- (xiii) Green belt shall be developed & maintained around the plant periphery. Green Belt Development shall be carried out considering CPCB guidelines including selection of plant species and in consultation with the local DFO/ Agriculture Dept.
- (xiv) Adequate safety measures shall be provided to limit the risk zone within the plant boundary, in case of an accident. Leak detection devices shall also be installed at strategic places for early detection and warning.
- (xv) Occupational health surveillance of the workers shall be done on a regular basis and record maintained as per Factories Act.
- (xvi) The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.
- (xvii) 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 Waste (Management and Handling) Rules, 2003 (amended). Authorization from the MPCB shall be obtained for collections/treatment/storage/disposal of hazardous wastes.
- (xviii) The company shall undertake following Waste Minimization Measures :
 - a. Metering 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 process.
 - c. Maximizing Recoveries.
 - d. Use of automated material transfer system to minimize spillage.
 - e. Use of "Closed Feed" system into batch reactors.
- (xix) Regular mock drills for the on-site emergency management plan shall be carried out. Implementation of changes / improvements required, if any, in the on-site management plan shall be ensured.
- (xx) A separate environment management cell with qualified staff shall be set up for implementation of the stipulated environmental safeguards.
- (xxi) Transportation of ash will be through closed containers and all measures should be taken to prevent spilling of the ash.

- (xxii) Fly ash utilization as per Fly ash Notification no. SO763(E) dated 14.09.1999 (amended) and as per direction of MPCB.
- (xxiii) Separate silos will be provided for collecting and storing bottom ash and fly ash.
- (xxiv) Separate funds shall be allocated for implementation of environmental protection measures/EMP along with item-wise breaks-up. These cost shall be included as part of the project cost. The funds earmarked for the environment protection measures shall not be diverted for other purposes and year-wise expenditure should reported to the MPCB & this department
- (xxv) The project management shall advertise at least in two local newspapers widely circulated in the region around the project, one of which shall be in the marathi language of the local concerned within seven days of issue of this letter, informing that the project has been accorded environmental clearance and copies of clearance letter are available with the Maharashtra Pollution Control Board and may also be seen at Website at <http://envis.maharashtra.gov.in>
- (xxvi) Project management should submit half yearly compliance reports in respect of the stipulated prior environment clearance terms and conditions in hard & soft copies to the MPCB & this department, on 1st June & 1st December of each calendar year.
- (xxvii) A copy of the clearance letter shall be sent by proponent to the concerned Municipal Corporation and the local NGO, if any, from whom suggestions/representations, if any, were received while processing the proposal. The clearance letter shall also be put on the website of the Company by the proponent.
- (xxviii) The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their 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 SPCB. The criteria pollutant levels namely: SPM, RSPM, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectorai parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.
- (xxix) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated EC 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 SPCB.
- (xxx) The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent to the concerned 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 EC conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.
- (xxxi) The environmental clearance is being issued without prejudice to the court case pending in the court of law and it does not mean that project proponent has not violated any environmental laws in the past and whatever decision of the Hon'ble court will be binding on the project proponent. Hence this clearance does not give immunity to the project proponent in the case filed against him.
4. The Environment department reserves the right to revoke the clearance if conditions stipulated are not implemented to the satisfaction of the department or for that matter, for any other administrative reason.



5. **Validity of Environment Clearance:** The environmental clearance accorded shall be valid for a period of 5 years to start of production operations.
6. In case of any deviation or alteration in the project proposed from those submitted to this department for clearance, a fresh reference should be made to the department to assess the adequacy of the condition(s) imposed and to incorporate additional environmental protection measures required, if any.
7. The above stipulations would be enforced among others under the Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and rules there under, Hazardous Wastes (Management and Handling) Rules, 1989 and its amendments, the public Liability Insurance Act, 1991 and its amendments.
8. Any appeal against this environmental clearance shall lie with the National Green Tribunal , Van Vigyan Bhawan, Sec- 5, R.K. Puram, New Dehli – 110 022, if preferred, within 60 days as prescribed under Section 35 of the National Green Tribunal Act, 2010.


(Valsa R Nair Singh)
Secretary, Environment
department & MS, SEIAA

Copy to:

1. Shri. P.M.A Hakeem, IAS (Retd.), Chairman, SEIAA, 'Jugnu' Kottaram Road, Calicut- 673 006 Kerla.
2. Shri. Dr. S. Devotta, Chairman, SEAC, T2/302 Sky City, Vanagaram –Ambattur Road, Chennai – 600 095
3. Member Secretary, Maharashtra Pollution Control Board, with request to display a copy of the clearance.
4. The CCF, Regional Office, Ministry of Environment and Forest (Regional Office, Western Region, Kendriya Paryavaran Bhavan, Link Road No- 3, E-5, Ravi-Shankar Nagar, Bhopal- 462 016). (MP).
5. Regional Office, MPCB, Kolhapur.
6. Collector, Ratnagiri.
7. IA- Division, Monitoring Cell, MoEF, Paryavaran Bhavan, CGO Complex, Lodhi Road, New Delhi-110003.
8. Director(TC-1), Dy. Secretary(TC-2),Scientist-1,Environment department
9. Select file (TC-3).

Government of Maharashtra

No.EC-2008/1436/CR.2/TC1
Environment department,
Room No. 217, 2nd floor,
Mantralaya Annexe,
Mumbai 400 032
Date: 24th January, 2012

To,
M/s. USV limited,
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Dist - Ratnagiri.
E -mail: hoshi.edulji@usv.co.in
Telephone No. : 02356-227242/272701

Subject: Modification in Environmental clearance – Pharmaceutical project (expansion) at MIDC Industrial Area, Lote Parshuram, Taluka Khed, Ratnagiri District by M/s USV Ltd.

Reference- 1. Even number environment clearance letter dated 15th October, 2011
2. Minutes of 49th meeting of SEAC held on 18th to 21st January, 2012
3. Minutes of 44th meeting of SEIAA held on 23rd/24th February, 2012

Sir,

This has reference to your communication dated 21st November, 2011 on the above mentioned subject.

2. Project information from documents submitted by you & considered by SEAC & SEIAA was summarized in even number environment clearance letter dated 15th October, 2011

Information on following points are modified as-


- **Furnace Oil:** 3.5 MT/day, for the 6 MT/Hr boiler, which will be installed in B-8/1 and B-9. The FO based boiler will act as a stand by boiler.
- **Coal and Briquette:** Coal consumption: 8 – 9 MT/day and Briquette: 12 –1 4 MT/day. The Boiler is multifuel burning and will be installed in plot no's: B-8/1 and B-9. Boiler capacity is : 6 MT/hr
- **HSD:** 160 Kg/hr for DG sets.
- **Stand by Boiler:** 6 MT/hr will be installed in B-8/1 and B-9 facility with Furnace Oil as a fuel

3. This amendment is subject to condition that consent to operate may be issued to the unit only after the additional capacity of CETP becomes functional or the project proponent

- 1 -



sets up own ETP. Terms and conditions stipulated in even number environment clearance letter dated 15th October, 2011 remains the same.


(Valsa R Nair Singh)
Secretary, Environment
department &MS, SEIAA

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8. Director(TC-1), Dy. Secretary(TC-2),Scientist-1,Environment department
9. Select file (TC-3).