Executive Summary of Environmental Impact Assessment Report

For

Establishment of Active Pharmaceutical Ingredients Manufacturing Facility

Project Proponents

M/s. Pegasus Lab Pvt. Ltd.

Survey No. 275/1 & 276/1, Village- Mann, Taluka- Mulshi, and District – Pune, Maharashtra

March – May 2013

EXECUTIVE SUMMARY

1.0 INTRODUCTION :-

This proposal is to set up a Synthetic Organic Chemicals (APIs i.e. Active Pharmaceutical Ingredients) kept at Entry 5(f) of the schedule in EIA notification promulgated in 2006. On the basis of pre-feasibility report submitted to the MOEF and a TOR presentation on 3rd December 2013 before the 3rd meeting of the expert committee M/s Pegasus Lab Pvt Ltd was issued a TOR on the basis of which this Environment Impact assessment report is being presented.

The proponents are M/s Pegasus Lab Pvt Ltd and with the vision of chairman, they are progressing well. The teams of scientist and management professionals have the appropriate experience, knowledge and initiative for this pharmaceutical division. With a collective foresight the project proponents has arrived at logic that the common synthetic routes will enable us to maintain inventories of common intermediate and a final few steps will enable to derive finished product just in time.

M/s Pegasus Lab Pvt Ltd has started R&D operations in May 2011 and has completed the synthetic R&D for development of these products. For commercial scale production, the project proponent proposes to set up USFDA cGmp complaint manufacturing facility near Pune.

Location of Project:-

#	Particulars	Details
1	Name of the Project	Active Pharmaceutical Ingredients Manufacturing Facility.
2	Latitude	18°35'49.91" N
	Longitude	73°41'55.68" E
3	Locations	Survey No. 275/1 & 276/1
	A. Village	Maan
	B. Taluka	Mulshi
	C. District	Pune
	D. State	Maharashtra
4	Nearest railway station	Chinchwad railway station around 12 km from the project site

5	Nearest airport	Pune airport at 30 km from the project site.
6	Nearest water body	The Kasar sai dam, which is approx. 9 km from the site. Mula river, around 6 km from the site in SE direction.
7	Nearest Town	Baner, 15 km in North direction.
8	Reserved forest/ Protected forest/Wild life sanctuary/Biosphere reserves.	No
9	Defense installations	One Army installation in Aundh which is 15 km from the site.

1.1 Nature of the Project

This project will be of a minuscule dimension with an aim to produce 35 kg/ year for ten molecules put together (though not all at the same time). The target will be achieved in small steps over the next five years. The required water, power and workforce are available. The total cost of the Project is Rs 24 crores and the village panchayat desires that such industry should come up here. We have purchased an already built-up construction, so that operation will commence promptly. The nature of the project is to produce Active Pharmaceutical Ingredients (APIs).

The manufacturing needs deep chemical engineering knowledge. The complexities of manufacturing of the product itself give a distinctive advantage to India as it has excellent intellectual and technical resources to manufacture good quality products.

1.2 Need of the Project:-

Due to the growing targeted therapy approach in the treatment of diseases, the demand for these APIs is increasing fast. These drug substances are either precursors or analogs of natural body hormones which have a vast application in modern medicines. As body generally develops bio chemistry molecules with multiple applications the use of this knowledge is growing to increase for treatment of various conditions. In minor modification in drug delivery systems as well as the structure these products are now being tried in different therapeutic segments.

The use of such active pharmaceutical ingredients is a comparatively new and growing concept in the global pharmaceutical industry. Though this market is dominated by the

innovators and branded sector, the generic sector has a small share, but it is set to grow as the branded drugs will go off patent in the years to come.

2.0 PROJECT DESCRIPTION:-

2.1 Product Detailing:-

In the total manufacturing capacity of 35 kg/year, the requirement of product (A-1) i.e. Misoprostol of our total capacity is 25 kg/year. The project is planned in a manner in which the final processing of two products, i.e. Misoprostol (A-1) and other any other product (B 2-10) can happen simultaneously.

List of product:

Sr.No.	**Product Name**
1	Misoprostol
2	Travoprost
3	Latanoprost
4	Bimatoprost
5	Unoprostone
6	Carboprost
7	Dinoprostone
8	Dinoprost
9	Alprostadil
10	Lubiprostone

3.0 DESCRIPTION OF THE ENVIRONMENT

The baseline status of environmental quality in the vicinity of project expansion site serves as a basis for identification and prediction of impact. The data were collected from both primary and secondary sources. Details of Attributes is as follows-

Sr. No.	Attributes	Parameters	Source	Data Procured from
1	Meteorology	Wind Speed, Wind direction, Relative humidity, and temperature	Secondary & Primary	Indian Meteorological Department, Pune
2	Water Environment	Physical, chemical and Parameters.	Primary	Monitored data

3	Ambient Air Environment	PM10, SO2, NOx, HC	Primary	Monitored data
4	Noise Environment	Noise levels in dBA	Primary	Monitored data
5	Land Use Pattern	Land use for different land use classifications	Primary	Based on Satellite Imagery for study area of 10 km
6	Socio-Economic Status	Socio-Economic characteristics, labor force characteristics, population statistics, Existing amenities in the study area and quality of life.	Secondary	Census Data of Pune District – 2001

As per TORs of the project issued by Ministry of Environment & Forest, New Delhi, the study area to be considered as 10 km from the project site. The baseline environmental quality has been assessed as per the TORs for the month of March 2013 to May 2013 in a study area of 5 km radial distance from the project site.

3.1 AIR ENVIRONMENT

The potential ambient air quality impacts arising from the proposed project would occur mainly during project construction phase. Suspended Particulate Matter size less than 2.5 (PM2.5) and Particulate Matter size less than 10 (PM10) would be the predominant pollutant generated from construction activities. The gaseous emissions such as SO2, NOx and CO would be generated from the construction equipments and vehicles. During operation phase, DG sets would be the only point source of emission.

The ambient air quality monitoring results show that the PM2.5 and PM10 concentrations at most of the locations within the core zone of the proposed project site are close to the norms prescribed for the residential areas. However, appropriate mitigation measures would still be employed during the construction stage to reduce any incremental rise in pollution level to an acceptable limit. Monitored values of SO2, NOx and CO in the ambient air are well within the limits indicating low pollution level (L) as per the CPCB criteria. Air quality was monitored and reported at surrounding villages.

3.2 NOISE ENVIRONMENT

Construction activities normally result in temporary and short duration increases in noise levels. The main sources of noise during construction period include movement of vehicles for loading and unloading of construction materials, fabrication, handling of

equipment and Materials, operation of power shovels, concrete mixing plants, generators etc. The areas affected are those close to the site.

Under the worst case scenario, considered for prediction of noise levels during construction phase, it has been assumed that all these equipments generate noise from a common point at an average noise level of 85 dB (A). Further to minimize these potential impacts, major construction activities would be scheduled during normal daylight working hours and would be implemented consistent with the applicable standards. The construction contractor will use equipments that are adapted to operate with appropriate noise muffling devices resulting in the least possible noise. Every effort would be taken to minimize the noise levels including the mandatory use of construction equipment with operable mufflers.

A preliminary reconnaissance survey has been undertaken to identify the major noise generating sources in the area. Noise at different noise generating sources has been identified based on the activities in the village area, ambient noise due to industries and traffic and the noise at sensitive areas like hospitals and schools. The noise monitoring has been conducted for determination of noise levels at select locations in the study area. Except for occasional time noise levels have been generally within limits.

3.3 WATER ENVIRONMENT

The proposed project does not have the potential of impacting the surface and ground water quality and quantity in a significant manner in the long term during the operation phase.

Project proposing to implement the rain water harvesting for ground water recharge, conservation through education to bring about greater water efficiency, and reuse of treated wastewater on the proposed site during operation of the project for use in horticulture and other auxiliary purposes, the effect would be minimized. The wastewater generated will be directly discharged to the sewer line without any treatment. Both these measures along with implementation of rainwater harvesting and conservation measures would have positive impact on the ground water quality and quantity.

Surface and Groundwater was tested at the project site and in study area for evaluation. Most of the parameters are observed to be within the limits prescribed by this standard. Since no wastewater from the complex will be discharged into the open, no impact on groundwater quality is envisaged.

3.4 LAND ENVIRONMENT

The project site lies in the Public / Semi-public land use category of the project area. The adjoining lands to the project site are essentially institutional. The proposed project site is a vacant land and does not involve activity of any type. It is anticipated that the construction activities of the proposed project would not have an adverse effect on the land use activities in the project area, and will not be encroached during the construction of the project.

Moreover, local land use planning will control the type, density and location of development in the future. Hence, the proposed new construction could be considered to comply with the present zoning classification of neighbourhood business.

Development of green belt and other landscape on the proposed site would enhance the visual aesthetics of the area.

3.5 BIOLOGICAL ENVIRONMENT

Baseline data for flora has been collected, which includes information on both plant species and plant communities. In the present study, information has been collected on existing plant species for site monitoring and management purposes. Information on distribution pattern of tree species has been collected to establish the interrelationship between species for prevailing environmental factors for post-development monitoring and management.

3.6 SOCIO ECONOMIC ENVIRONMENT

Socio-economic study of the area is a part of environmental impact assessment study for the proposed power project. Socio-economics, a component of environment includes description of demography, available basic amenities like housing, health care services, transportation, education and cultural activities. Information on the above said parameters has been collected to define the socio-economic profile of the study area (10-km radius).

4.0 TOPOGRAPHY AND HYDRO-GEOLOGY

The project site is located in Mann village, near to National Highway No.4 and 50. The Pawana River and Man River are located in the vicinity of 10 km from the proposed project site. The Kasarsai dam is located in North North West direction from the project site. The soils of Maharashtra are residual, derived from the underlying basalts. The area is covered by basaltic flows, which are commonly referred to as Deccan Traps (Geological Survey of India). The drainage pattern observed is dendritic to sub-

dendriticIn the semi-dry plateau, the regur (black-cotton soil) is clayey, rich in iron and the soil of the area is moisture-retentive. Mulshi Dam is the major producer of hydroelectricity in Pune. Water from the dam is used to irrigate paddies across the reign.

4.0 Environmental Impact Prediction

4.1 Impacts during Construction & operation Phase and Mitigation Measures

Probable environmental impacts during construction phase are typically due to activities related to clearing of vegetation, leveling of site, civil constructions erection of structures and installation of equipment. During the Operation Phase the establishment of the project, results in emissions, generation of wastewater and solid waste.

i) Impact on Air Quality

The main sources for impact of air quality during construction period is due to movement of vehicles and construction equipment at site, dust emitted during leveling, grading, earthmoving, foundation works, transportation of construction material etc.

Air Pollution Mitigation Measures

The dust generated will also be fugitive in nature, which can be controlled by sprinkling of water. Frequent water sprinkling in the vicinity of the construction sites would be undertaken and will be continued after the completion of plant construction as there is scope for heavy truck mobility. It will be ensured that diesel powered vehicles will be properly maintained to comply with exhaust emission requirements.

Well maintained equipment will be utilized to prevent Air pollution.Gas Detectors with Alarm system will be installed to detect any fugitive emission of Ammonia, HCl etc. Ensure usages of PPE's by workers.

ii) Impact on Noise Levels

The major sources of noise during the construction phase are vehicles and construction. The operation of the equipment can generate noise in the range 85-90 dB (A) near the source.

Noise Levels Mitigation Measures

The noise control measures during the construction phase include provision of caps on the construction equipment and regular maintenance of the equipment. High noise producing construction activities will be restricted to daytime only.

Well maintained equipment will be utilized to prevent noise generation. Ensure usages of PPE's by workers. Ensure proper maintenance of machinery to reduce noise level Ensure reprocessing of lube-oil and maintain records of the same.

iii) Impact on Water Resources and Quality

Impact on water quality during construction phase is due to non-point discharges of sewage generated from the construction work force stationed at the site. Runoffs from the construction yards and worker camps during monsoon could affect the quality of water bodies in the project area.

Water Pollution Mitigation Measures

Toilets with septic tanks will be constructed at site for workers. Construction yards will be constructed properly. Water usage will be strictly by putting water meter plant wise. Treated water shall be reused in process to minimize the fresh water requirement.

iv) Impact on Land use

Preparatory activities like construction of access roads, temporary offices, and go-downs, piling, storage of construction materials etc. will be confined within the project area. No forestland is involved. Therefore, impact will be negligible.

Impact on Topography

Most of the area forms plain land covered with mixed soil. Adequate storm water drains will be provided to collect and carry the surface runoff during monsoon to the natural drainage system of the project area.

v) Socio-economic Environment

The socio-economic impacts during the construction phase of the proposed Enhancement pharmaceutical plant could result due to migrant workers, worker camps, induced development etc. The local population will have employment opportunities in related service activities.

4.2 Facilities to be provided by Labour Contractor

The contractor will be made to provide the following facilities to construction work force:

First Aid

At work place, first aid facilities will be maintained at a readily accessible place where necessary appliances including sterilized cotton wool etc. Ambulance will be kept at the site and made available at workplace to take injured person to the nearest hospital.

Potable Water

Sufficient supply of water fit for drinking will be provided at suitable places.

Sanitary Facility

Sanitary facilities will be provided at accessible place within the work zone and kept in a good condition. The contractor will conform to requirement of local medical and health authorities at all times.

Canteen

The canteen will be provided for the benefit of workers.

Security

Pegasus will provide necessary security to work force in co-ordination with State authorities.

4.3 Waste water generation

The total waste water generation from the pharmaceutical plant will be sent to Effluent Treatment Plant (ETP) and the treated wastewater will be used for green belt development.

4.4 Impact on Ecology

The enhanced project will not have any significant impact on ecology as there are no reserve forests in the study area and in addition to that the project will implement an effective environmental management plan to control the emissions from the project.

4.6 Green belt development

33% of the total project area acquired for plant will be used for green belt development. Local species will be preferred for green belt development.

4.7 Impact on Health

Adequate air pollution and noise control measures will be provided. The environmental management and emergency preparedness plans will be prepared to ensure that the probability of undesired events and consequences would be reduced, and adequate mitigation measures will be provided in case of an emergency. The overall impact on Human health is negligible during operation of plant.

5.0 Environmental Monitoring Program

Pollution Monitoring and Surveillance Systems For Proposed Enhanced Sugar Plant and Cogeneration power plant, the Indian Emission Regulations stipulate the limits for particulate matter emissions and appropriate stack heights will be maintained for keeping the emission levels in the ambient within the air quality standards.

5.1 Air Quality monitoring programme

It is proposed to monitor particulate emission qualitatively and quantitatively in the stack and with the aid of a continuous particulate stack monitoring system. The stack monitoring data would be utilized to keep a continuous check on the performance of ECEs. Further it is proposed to monitor and record the weather parameters such as temperature (maximum & minimum), Relative humidity, wind direction, wind speed, rainfall etc. on daily basis, for this purpose, it is proposed to install Weather Monitoring Station with necessary gadgets.

5.2 Post Project Environmental Monitoring

Environmental monitoring will be conducted on regular basis to assess the pollution level in the plant as well in the surrounding area.

6.0 Risk Assessment and Disaster Management Plan

Rapid development has posed wide-ranging hazards threatening safety and health of people. Accidents may adversely affect the environment and the people living in the vicinity. These accidents can be minimized to a great extent by proper procedures, handling and training. EIA report also concluded following studies.

- Hazard Identification
- Risk Assessment
- Risk Analysis & Emergency Plan
- Risk Management & Insurance Planning
- Desaster Management Plan
- Onsite Emergency Plan

An emergency occurring in the proposed Enhancement plant is one that may affect several sections within it and/ or may cause serious injuries, loss of lives, extensive damage to environment or property or serious disruption outside the plant. It will require the best use of internal resources and the use of outside resources to handle it effectively. . It is imperative to conduct risk analysis for all the projects where hazardous materials, fuels are handled.

6.1 Methodology

The Risk Analysis Study carried out under the following task heads:-

System Study

The system description covers the plant description, storage & handling of fuels / chemicals, etc.

Hazard Identification

The hazards associated with the proposed Enhancement Project have been discussed in terms of material hazards due to fuel storage.

Frequency of Hazard Occurrence

Based on the available international statistics and in-house risk database, the frequencies of occurrence for the different accident scenarios were determined. The frequencies derived from the historical database have been checked with the possible hazard scenario identified during hazard identification.

Consequence Analysis

Based on the identified hazards, accident scenarios and the frequency of occurrence, consequence calculations were done for spreading distances (zone of influence) or risk distance for Pool fires.

Risk Reducing Measures

Necessary risk reducing measures have been suggested based on the consequence scenarios.

6.2 Remedial measures:

Storage in tightly closed containers in a cool, well-ventilated area away from WATER, HEAT, COMBUSTIBLES (such as WOOD, PAPER and OIL) and LIGHT.

- Storage away from incompatible materials such as flammable materials, oxidizing materials, reducing materials, strong bases.
- Use of corrosion-resistant structural materials and lighting and ventilation systems in the storage area.
- Wood and other organic/combustible materials will not be used on floors, structural materials and ventilation systems in the storage area.
- Use of airtight containers, kept well sealed, securely labelled and protected from damage
- Use of suitable, approved storage cabinets, tanks, rooms and buildings.
- Suitable storage will include glass bottles and containers.
- Storage tanks will be above ground and surrounded with dikes capable of holding entire contents.
- Limit quantity of material in storage. Restrict access to storage area.
- Post warning signs when appropriate. Keep storage area separate from populated work areas. Inspect periodically for deficiencies such as damage or leaks.
- Have appropriate fire extinguishers available in and near the storage area.

7.0 Project Benefits

This project development will give rise to social and economic development measures in the study area.

7.1 Improvement in Physical Infrastructure

- Road Transport facilities
- Educational facilities
- Water supply and sanitation

7.2 Improvement in Social Infrastructure

- Education facilities
- Banking facilities
- Post offices and Communication facilities
- Medical facilities
- Recreation facilities
- Business establishments
- Community facilities

8.0 ENVIRONMENTAL MANAGEMENT PLAN

Environmental Management Plan includes the protection, mitigation and environmental enhancement measures to be implemented to nullify the adverse impact on the environment. The management of the Pegasus Prvt.Ltd will take all the necessary steps to control and mitigate the environmental pollution in the designing stage of the project. While implementing the project Pegasus Prvt.Ltd will follow guidelines specified by CPCB under the Corporate Responsibility for Environmental Protection (CREP) Active Pharmaceutical Ingredients Manufacturing Facility. The EMP operation/implementation will be the responsibility of the "EHS Officer", who will be coordinating, arranging the collection and reporting of the results of all emissions, ambient air quality, noise and water quality monitoring

8.1 EMP for Construction phase

Activity	**Environmental Impacts**	**Mitigation Remarks**
Storage, Handling & Transportation of Raw materials and Products	• Air • Water • Land	• Chemical & Solvents to be stored in accordance with the rules and regulations of the Safety Department. • Separate storage area for solid/liquid raw materials. • Gas Detectors with alarm will be installed for detection of fugitive emission. • Install proper facilities to prevent rain/storm water contamination during the storage of solid raw materials. • Ensure disposal of used drums, bags as per the rules/regulations.

Transportation of all the raw materials, finished products & hazardous wastes.	Air • Water • Land	• Trained/Approved Transports will be given work for the transportation of the raw materials / products. • TERMCARD will be followed. • Ensure availability of MSDS of all the raw materials and finished products to the Off-
Development and maintenance of green belt	• Air. • Land	Ensure development and maintenance of proper green belt as proposed**.**
Direct / Indirect Employment	• Socioeconomic issue	Continue policy of local employment according to the skill and availability of the manpower

8.2 EMP for Operation phase

Activity	**Environmental Impacts**	**Mitigation Remarks**
Operation of Cooling Tower	• Air • Water • Noise	• Ensure proper maintenance of machinery to reduce noise level • Blow down is being sent in ETP provided within premises
Operation of Air Compressors	• Noise • Land	• Ensure proper maintenance of machinery to reduce noise level. • Ensure reprocessing of lube-oil and maintain records of the same

9.0 CONCLUSION

Overall, the proposed project will have positive impact on the Environment if the recommended Environmental Monitoring, mitigation & Management measures / aspects are fully implemented by the project proponents time to time.

The local people desire that this industry will be welcome in their area.

- The candidate site is suitable from general MoEF expectations.
- Water, power, Raw material and Market is assured and found available with ease.
- Full precautions will be taken for Pollution Control, Resource Conservation and Environmental Protection.
- This is cost effective and Sustainable Development.