

PRE FEASIBILITY REPORT

of



EYTAN LABS LIMITED

Expansion of
Bulk Drug Manufacturing Unit
at

SY.NO:10 AND IT'S PARTS, GADDAPOTHARAM VILLAGE (V),
JINNARAM (MANDAL), MEDAK (DT), TELANGANA STATE.



EYTAN LABS LIMITED

No. 8-2-293/82/A/234 & 235, TF-1, 3rd floor, Empire square,
Road No: 36, Jubilee hills, Hyderabad-500033,

November, 2014

Contents

S. No.	Description	Page no.
1.0	Executive Summary	1
2.0	Introduction of The Proposed Project	2
2.1	Project Proponent	2
2.2	Brief description of nature of the project.	2
2.3	Need for the project and its importance to the country and or region	3 - 4
2.4	Demand-Supply Gap.	4
2.5	Employment Generation(Direct and Indirect) due to the project	4
3.0	Project description	5 - 7
3.1	Products and Production Capacity	8
3.2	Raw materials required and Quantities	8
3.3	Manufacturing Process	8
3.4	Resource – Utilize and Recycling	9
3.4.1	Water	9
3.4.2	Power Requirement	10
3.4.3	Fuel Requirement	10
3.5	Quantity of wastes to be generated	10
3.5.1	Waste Water Generation and utilization	10
3.5.2	Solid waste generation and Disposal	11
3.6	Schematic representations of the feasibility drawing which give information of EIA purpose.	11
4.0	Site Analysis	12
4.1	Connectivity	12
4.2	Land Form, Land use and Land ownership.	12
4.3	Existing Infrastructure	12
4.4	Soil classification	12
4.5	Climatic data from secondary sources.	12
4.6	Social Infrastructure available.	13
5.0	Planning brief	13
6.0	Proposed infrastructure	13
6.1	Industrial Area	13
6.2	Residential Area	13
6.3	Green Belt:	13
6.4	Social Infrastructure	13
6.5	Water management	14

6.6	Sewerage System	14
6.7	Industrial Waste Management	14
7.0	Rehabilitation and Resettlement (R&R) Plan	14
8.0	Project Schedule and Cost estimates	14
9.0	Analysis of project	14

LIST OF TABLES

Table No	Description	Page no.
2.1	Total Employment	4
3.1	Proposed Products and Quantities	8
3.2	Water Requirement Details	9
3.3	Wastewater generation and Treatment Method	10
3.3	Solid waste generation and Disposal	11

LIST OF FIGURES

Figure No	Description	Page no.
1.1	Location Map	6
1.2	Google Earth Map Showing Kanagala Plant	7

LIST OF FLOW CHART

Flow Chart No	Description	Page no.
3.1	Generalized Flow Chart for Bulk Drug Manufacturing	9

1.0 EXECUTIVE SUMMARY

Eytan Labs Limited is incorporated in the year of 2011 for producing quality Active Pharmaceutical Ingredients (**API'S**) and **intermediates** at affordable price as per procedures set by regulatory standards.

S. No	Parameter	Description
1	Project Location	Sy.No:10 and its Parts , Gaddapotharam Village (V), Jinnaram (Mandal), Medak (Dt), Telangana State
2	Category of Project as per EIA Notification & Amendments	5(f) "A"
3	Project cost	
4	Plot area	8.0 Acers
5	Proposed Products	Existing: 315.0 Kg/Day Proposed : 3501.50Kg/Day
6	Resources	
	(I)Electricity Requirement	2000 KVA
	Source of electricity	SPCPDCL
	D. G. Sets	Existing: 500 KVA X 2 No's (Continued) Proposed : 1000 KVA
	(II)Water consumption	Existing : 39.61 KLD Proposed : 324.79 KLD
	Source of water	Water supply by IDA
	Waste water generation	109. 84KLD
	Mode of disposal	Zero Liquid Discharge System
	(III)Boiler	Existing : 4.0 TPH Coal fired boiler (Continued) Proposed : 3 TPH & 5.0 TPH Boilers
	(V)Fuel	Coal – 30.0 MT / Day
7	Solid waste generation	Mentioned in Para 3.3 of report
8	Nearest Highway	State Highway 6 – (Hyderabad – Narsapur Road) – 2.8 KM National Highway No 9 -10.6 Kms
9	Nearest Railway Station	Bolarum Railway Station –16.0 KMs
10	Nearest Air Port	Rajiv Gandhi International Airport - 40.2 KMs

2.0 INTRODUCTION OF THE PROJECT

The objective of this pre- feasibility study is to provide information for the proposed expansion of Bulk Drug and intermediate unit of Eytan Labs Limited at Sy.No:10 and its Parts, Gaddapotharam Village (V),Jinnaram (Mandal), Medak (Dt), Telangana State

2.1 Project Proponent

Mr. Parvathaiah. B

Chairman

A post graduate with a specialization in organic chemistry. He possesses three plus decades of sound knowledge and experience about producing quality and cost effective API's and Intermediates as per both GMP and regulatory procedures. His expertise as a **technopreneur** has set new standards in **Production Process Technology (PPT)**. His continuous urge in achieving the excellence to have progress and development, is the true nomenclature of EYTAN.

Mrs. Anuradha. B

Managing director

A post graduate with a specialization in bio technology and medical-microbiology. Her endeavour in academics has achieved best performing scores in Micro biology, bio technology, bio chemistry and immunology as university topper. An enthusiastic entrepreneur of substance transforming EYTAN LABS “ A true global player” in producing quality API's and Intermediates' at affordable price.

Her management skills and involvement is the real asset for EYTAN to achieve its prime objective.

2.2 Brief description of nature of the project.

Eytan Labs Limited. is an existing unit and located at Sy.No:10 and its Parts, Gaddapotharam Village (V),Jinnaram (Mandal), Medak (Dt), Telangana State and proposed for expansion of existing production capacity by constructing additional buildings and adding additional facilities.

2.3 Need for the project and its importance to the country and or region

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organised sector, the Indian pharmaceutical industry is estimated to be worth \$ 4.5 billion, growing at about 8 to 9 percent annually. It ranks very high amongst all the third world countries, in terms of technology, quality and the vast range of medicines that are manufactured. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made in the Indian pharmaceutical industry.

The Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The Pharmaceutical and Chemical industry in India is an extremely fragmented market with severe price competition and government price control. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and injectibles. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units).

The Government has also played a vital role in the development of the India Software Industry. In 1986, the Indian government announced a new software policy which was designed to serve as a catalyst for the software industry. This was followed in 1988 with the World Market Policy and the establishment of the Software Technology Parks of India (STP) scheme. In addition, to attract foreign direct investment, the Indian Government permitted foreign equity of up to 100 percent and duty free import on all inputs and products.

L2 Current Scenario

Indian pharmaceutical industry is expected to grow at 19% in 2013. India is now among the top five pharmaceutical emerging markets. There will be new drug launches, new drug filings, and Phase II clinic trials throughout the year. On back of increasing sales of generic medicines, continued growth in chronic therapies and a greater penetration in rural markets, the domestic pharmaceutical market is expected to register a strong double-digit growth of 13-14 per cent in 2013.

Moreover, the increasing population of the higher-income group in the country will open a potential US\$ 8 billion market for multinational companies selling costly drugs by 2015. Besides, the domestic Pharma market is estimated to touch US\$ 20 billion by 2015, making India a lucrative destination for clinical trials for global giants.

Further estimates the healthcare market in India to reach US\$ 31.59 billion by 2020.

2.4 Demand-Supply Gap.

There is a quite considerable gap between supply and demand for bulk drugs and intermediates. Very few players are in the market who can offer continuous supply. The company wants to bridge this gap between demand and supply by expanding the production capacity and thereby, making good business. Company's marketing edge comes from its direct and close contact with the customers. Their products are major strength of their customers. Each stage of their product is been monitored /checked for their quality to ensure quality product reaches their customer. They plan to launch new products every year to satisfy the need of their customers as per the market demand.

2.5 Employment Generation (Direct and Indirect) due to the project

The unit has approximately 80 permanent and contractual employees. Apart from this there will be significant non estimated employment generation at the supplier firms and service industry providing services to the company. Company shall be giving preference to people from economically weaker sections for employment in various semi-skilled/unskilled jobs thereby contributing to their upliftment. The details of total employment in this unit shown in below Table2.1.

TABLE 2.1: TOTAL EMPLOYMENT

Particulars	No. of employees	Functional Area
Key managerial staff	15	Finance, Marketing, Production, Quality control, R&D, Logistics etc.
Administration	5	Office work
Skilled and semi skilled	50	Production Process, Maintenance, stores, Safety.& Un skilled workers
Total	70	

3.0 Project Description

Eytan Labs Limited is having existing production facility at Sy.No:10 and its Parts, Gaddapotharam Village (V),Jinnaram (Mandal), Medak (Dt), Telangana State. The company is presently into manufacturing of Bulk drugs and Intermediates. The present proposal is expansion of bulk drug and Intermediates from 315.0 Kg/Day to 3501.50 Kg/Day.

The Location map is shown at **Figure -3.1** and Google earth map showing Eytan labs Limited plant is shown at Figure -3.2 .

The site central coordinates are

Latitude: 17°35'44.35"N

Longitude: 78°22'45.97"E

There are no archaeological, historical sites located nearby. Therefore, the project site does not offer any negative impact on the local area, but rather has a positive impact on socio economic conditions of the habitants around it.

The Eytan labs limited is 10.6 Kms away from National Highway No– 9 & 2.8 Kms from Hyderabad – Narsapur Road (SH-6) and 16.0 Kms from Railway line at Bolarum Railway Station

The present expansion will not require any additional land and the unit is located in an area

FIGURE 1.1: LOCATION MAP



- **EYTAN LABS LIMITED**
Sy.No:10 and its Parts, Gaddapotharam Village (V),
Jinnaram (Mandal), Medak (Dt), Telangana State

FIGURE 1.2: GOOGLE EARTH MAP SHOWING EYTAN LABS LIMITED



3.1 Products and Production Capacity

M/s. Eytan Labs Limited is proposes to expand its Products and Manufacturing Capacity and the list of products are shown in Table3.1.

Table3.1: Proposed Expansion Products and Quantities

S. No	Product Name	CAS NO	Quantity in Kg/Month	Quantity in Kg/Day
1	Ciprofloxacin Hydrochloride	93107-08-5	10000.00	333.33
2	Ciprofloxacin Lactate	97867-33-9	5000.00	166.67
3	Efavirenz	154598-52-4	30000.00	1000.00
4	Emtricitabine	143491-57-0	10000.00	333.33
5	Febantel	58306-30-2	5000.00	166.67
6	Nadolol	42200-33-9	5000.00	166.67
7	Lamivudine	134678-17-4	15045.00	501.50
8	Levetiracetam	102767-28-2	10000.00	333.33
9	Zidovudine	30516-87-1	15000.00	500.00
	Total		105045.00	3501.50

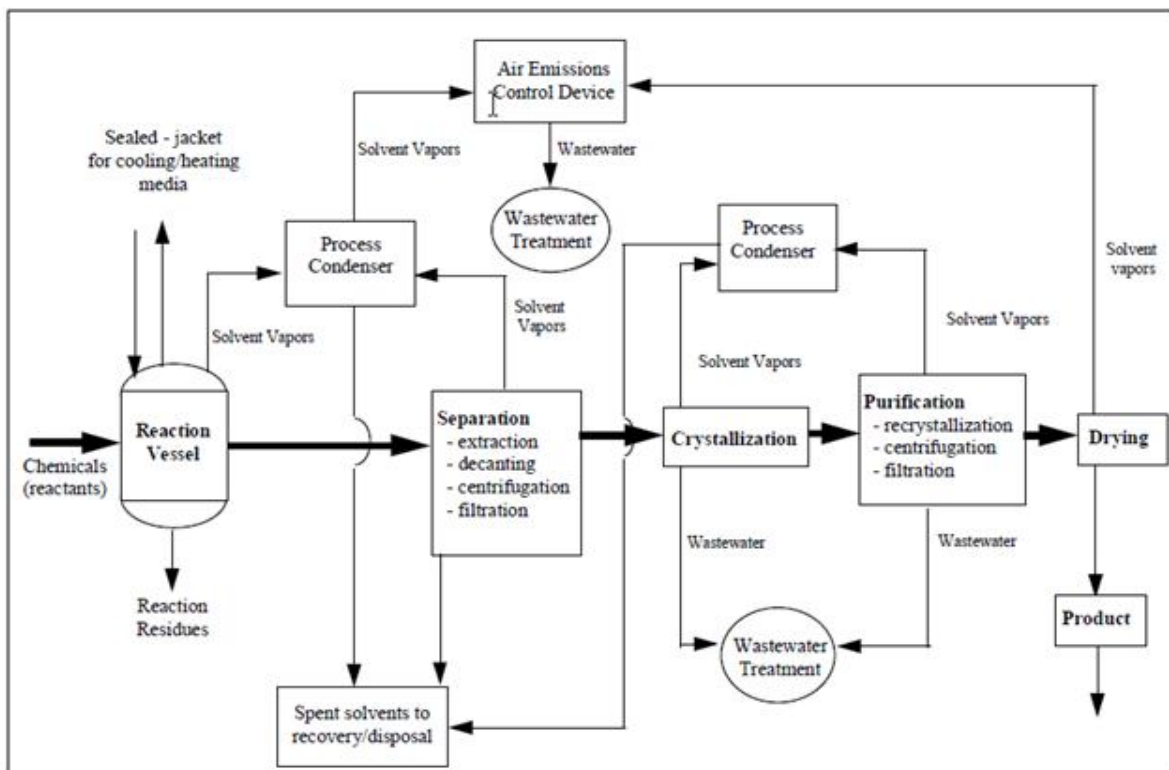
3.2 Raw materials required and Quantities

All the raw materials required for manufacturing of above products will be sourced from local market. The products wise required raw materials and quantities are enclosed in the annexure.

3.3 Manufacturing Process

The manufacturing process of bulk drugs consists of chemical synthesis extending to stages of processing involving different type of chemical reactions. The generalized Flow chart for bulk drug manufacturing is shown in **Flow chart 3.1**.

FLOW CHART 3.1: GENERALIZED FLOW CHART FOR CENTCHROMAN MANUFACTURING



3.4 Resource – Utilize & Recycling

3.4.1 Water

Water requirement of the project for domestic and industrial activity during operation phase will be 324.79 KLD. The water requirement will be met through IDA. The detailed water requirement shown in below Table3.2.

Table 3.2: WATER REQUIREMENT DETAILS

S. No	Purpose	Water Input in KLD
1	Process	50.79
2	Washings	3.00
3	Boiler Make up	70.00
4	Cooling towers Make up	189.00
5	Scrubbing system	2.00
6	DM Plant	2.00
7	Domestic	3.00
8	Gardening	5.00
	Total	324.79

3.4.2 Power Requirement

Power requirement of proposed expansion project will be made available through SPCPDCL. The total power requirement and Bulk drug unit power requirement are 2000 KVA respectively

Two No's of D. G. sets of 500 KVA & Additional 1000 KVA capacity of DG Sets are proposed installed to meet the emergency power requirement of the plant.

3.4.3 Fuel Requirement

Eytan Labs Limited has an existing coal fired boilers of 4 TPH capacities and in addition to that 3 TPH & 5 TPH capacity boilers are installed for the expansion purpose. Total fuel requirement will be around 30.0 TPD. Coal is procured from local sources.

3.5 Quantity of wastes to be generated

3.5.1 Waste Water Generation and utilization

Total effluent generated in the project is 109.84 KLD. The treated water 70.0 KLD will be reused for plant operations.

The process waste water from Process, floor Washes, scrubbers, QC and R&D are evaporated in MEE with stripper and ATFD after neutralization. The condensate from MEE and ATFD will be collected and treated in effluents treatment plant along with effluents from utilities followed by RO. RO rejects will be send back to MEE and RO Permeate will be re-used back.

To treat the sewage generated due to domestic activities will be disposed through septic tank following by soak pit.

Table3.3: Wastewater generation and Treatment Method

S. No.	Purpose	HTDS In KLD	LTDS In KLD	Effluent In KLD	Disposal Method
1	Process	56.81	0.53	57.34	HTDS Effluent sent to ETP with MEE system. LTDS effluents treated in ETP-RO Rejects to ME system and RO permeate to reuse, Condensate from MEE to reuse and MEE residue to AFTD.
2	Washings	0.00	3.00	3.00	
3	Boiler Blow Down	10.00	0.00	10.00	
4	Cooling towers Blow Down	0.00	33.00	33.00	
5	DM Plant	2.00	0.00	2.00	
6	Scrubbing system	2.00	0.00	2.00	

7	Domestic	0.00	2.50	2.50	Septic tank followed by Soak pit
	Total	70.81	39.03	109.84	

3.5.2 Solid waste generation and Disposal

The types of Hazardous and non Hazardous wastes generated from the project, method of disposal is shown in below table 3.4.

Table 3.4: Solid waste generation and Disposal

S. No	Name of the Solid Waste	Quantity Kg/Day	Disposal Method
1	Organic solid waste	2556.50	Sent to Cement Industries
2	Spent carbon	451.00	Sent to Cement Industries
3	ETP Sludge	50.00	Sent to TSDF
4	Coal ash from Boiler	14100.00	Sent to Brick Manufacturers
5	Distillation Bottom Residue	4946.50	Recovered & Reused
6	MEE salts	5820.50	Sent to TSDF
7	Waste Oils & Grease	700.0 Ltrs/Annum	SPCB Authorized Agencies for Reprocessing/Recycling
8	Detoxified Containers	300 No's / Month	After Detoxification sent back to suppliers/SPCB Authorized Parties
9	Used Lead Acid Batteries	6 No's/ Annum	Send back to suppliers for buyback of New Batteries

3.6 Schematic representations of the feasibility drawing which give information of EIA purpose.

The applicability of the S.O 1533 for the proposed project was explored by considering different possibilities & provision made in the said notification. Considering the products & project location of the proposed project it is noticed that the proposed project falls under Category 5 (f) "A" of the Schedule-I of EIA Notification SO 1533.

As per the provision of the SO 1533, it is necessary to get Environmental Clearance by applying to MoEF along with the Environmental Impacts Assessment Study Report for the proposed project prior to commissioning of the project activities. Therefore the EIA is required to conduct to comply with provisions of SO 1533 made for Category 5(f) "A" of schedule –I of the notification.

4.0 Site Analysis

4.1 Connectivity

M/s.Eytan Labs Limited is located at Sy.No:10 and its Parts, Gaddapotharam Village (V),Jinnaram (Mandal), Medak (Dt), Telangana State

- The nearest habitation from the site is Alinagar (Village) at a distance of 0.7 Km(N).
- The nearest railway station is Bolarum Railway Station at a distance of 16.0 KMs from the site (SE).
- The nearest airport is Rajiv Gandhi International Airport at a distance of 40.2 KMs
- The Nearest road ways

National Highway No.9 – 10.6 Meters

4.2 Land Form, Land use and Land ownership.

The unit is already an existing unit. There would be no any change in Land Use, Land Cover or Topography of plot. Dense green belt is already developed at plant.

4.3 Existing Infrastructure.

Proposed expansion project is a located in industrial Estate and the basic infrastructure is already there. The plant well connected with Road and Railway facilities

4.4 Soil classification

The district is mainly covered by two types of soils i.e Red soils and Black soils.

4.5 Climatic data from secondary sources.

Temperature Maximum: 44.4° C

Minimum: 6.9 ° C

Normal annual rainfall **873 mm**

4.6 Social Infrastructure available.

Well developed social infrastructure facilities are available at nearby Habitations.

5.0 Planning Brief

Proposed plant expansion activities will be started after getting statutory clearance from related authorities. The project will be completed within two years.

Further proposed project activities will take care of all the rules and regulation of statutory authority and provide the control measure and devices to achieve the standard norms

6.0 Proposed Infrastructure

6.1 Industrial Area

The present proposal is expansion of existing unit, the infrastructure and other facilities are already well developed and it is also located in Industrial Estate.

6.2 Residential Area

Staff Quarters are already there for employees who are working in the plant.

6.3 Green Belt:

Approximately 33 % of Green Belt is already developed and it will be maintained .

6.4 Social Infrastructure:

Facilities like road and communication are good..Banks, ATM's and medical facilities are also adequate.

Amenities:

Education- schools including middle, secondary and higher secondary schools, social welfare hostels.

Medical and Health- Community Health Centre, & Primary Health center Are available near villages

Power and water- All the villages are electrified and drinking water facilities are extended to all villages.

Rail and Road- The project site is very well connected by road through National Highway no. 9, Southern railways.

6.5 Water management

Water requirement will be met through ground water.

6.6 Sewerage System:

There will be no discharge of industrial effluent (**Zero Liquid Discharge**). The treated effluent will be reused. Domestic waste water will be disposed off through soak pit system.

6.7 Industrial Waste Management:

Due to proposed expansion, the effluent from cooling and Plant/Equipment washing will be generated and treated in the well designed Effluent Treatment Plant. The treated effluent will be reused.

7.0 Rehabilitation and Resettlement (R & R) Plan

Rehabilitation & Resettlement (R&R) plan is not applicable to proposed project.

8.0 Project Schedule & Cost Estimates

Proposed project activities will be started after getting statutory clearance form related authorities. The project will be completed within two years.

Proposed activity will provide benefits to the local people in terms of financial and social welfare.

The project cost for proposed expansion is 25.0 Crores will be used for constructing additional building , Equipments, Machinery and ZLD system.

9.0 Analysis of proposal (Final Recommendations)

- ❖ Local people will get direct financial benefit by way of employment.
- ❖ Local people will get some contracts of supply and services to get indirect income.
- ❖ Company will contribute in improving education and health facilities in nearby area