PRE FEASIBILITY REPORT

OF

M/S. OTIRA PHARMACEUTICALS PVT. LTD

FLAT NO: 203, JAMUNATIRTHA APARTMENTS, DHARAMKARAN ROAD, AMEERPET, HYDERABAD – 500 016. TELANGANA STATE.

EXPANSION OF BULK DRUGS UNIT

AT

SY.NO:637,660, BONTHAPALLY (V), JINNARAM (M),

MEDAK (DT), - 502313. TELANGANA STATE.

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1.0 EXECUTIVE SUMMARY

M/s Otira Pharmaceuticals Pvt. Ltd was incorporated to produce bulk drugs with registered address at Flat No: 203, Jamunatirtha Apartments, Dharamkaran Road, Ameerpet, Hyderabad – 500 016, Telangana State.

The company proposes for expansion of its bulk drug and intermediate manufacturing capacity at Sy.No:637,660, Bonthapally (V), Jinnaram (M), Medak (Dt), - 502313. Telangana State.

S. No	Parameter	Description
1.	Category of Project as per EIA Notification & Amendments	5(f) "A"
2.	Project cost for Expansion	12.05 Crores
3.	Plot area	8327.837 SQM
4.	Proposed Products	Existing: 135 TPA of Bulk Drugs Proposed : 540 TPA The details of products& Quantities are mentioned in Section 3.1
5.	Resources	
	(I)Electricity Requirement	600 KVA
	Source of electricity	SPDCL
	D. G. Sets	Existing :150 KVA (Dropped) Proposed: 250 KVA 380 KVA D.G Set
	(II) Water consumption	Existing : 0.75 KLD Proposed : 116.99 KLD
	Source of water	Bore well water
	Waste water generation	59.0 KLD
6.	Mode of disposal	Zero Liquid Discharge System
	(III)Boiler	Existing : 2x 4,00,000 kcal/hr Thermo pack boiler Proposed : 4.0 TPH Coal Fired Boiler
	(V)Fuel	Coal - 10 MT / Day
7.	Solid waste generation	Mentioned in Para 3.3 of report
8.	Nearest Highway	Highway No.6 (Hyderabad - Narsapur) - 2.2KMs
9.	Nearest Railway Station	Sanathnagar Railway Station – 35 KMs
10.	Nearest Air Port	Rajivgandhi International Air Port - 47 KMs

2.0 INTRODUCTION OF THE PROJECT

The objective of this pre- feasibility study is to provide information for the proposed expansion of Bulk Drugs and its Intermediates manufacturing unit by **M/s Otira Pharmaceuticals Pvt. Ltd.** at Sy. No: 637,660, Bonthapally (V), Jinnaram (M), Medak (Dt), -502313, Telangana State

2.1 Project Proponent

Sri. V. Vamsi Krishna a MBA graduate and having 25 years experience in the field of bulk drugs and pharmaceuticals. Under his able guidance, supervision and technological skills, successful implemented a unit in Hyderabad. A part from the above is also having enough innovating marketing experience in trading of Bulk Drugs Intermediates.

Smt. V. Swarna kumari is having a Bachelors Science Degree in Pharma.10 years experience in Manufacturing of Bulk Drug and Intermediates.

2.2 Brief description of nature of the project.

The **M/s Otira Pharmaceuticals Pvt. Ltd.** proposes to expand its manufacturing products and capacity of Bulk Drugs and its intermediates, to meet the increasing demand.

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

In the last few decades, India's population is skyrocketing and so is the demand for Drugs to support this population. In order to satisfy this need, more production of bulk drugs and active pharma ingredients is needed. The expansion of the industry will be beneficial to the region. The company will bring new job opportunities for the local people. They will, therefore, become economically stronger.

M/s Otira Pharmaceuticals Pvt. Ltd. is a manufacturer of Active Pharmaceutical Ingredients and drug intermediates, located in Hyderabad.

Our commitment lies in providing the required quality API's and Intermediates to our exacting customers worldwide. We cater to a cross section of clients in Asia, Europe, North and South America.

Our inherent strength lies in producing cutting edge intermediates, for new as well as off patent API's within the requisite time frame stipulated by our customers. Fifty percent of our business has evolved from custom synthesis projects, which start from gram level and rise to multi ton supplies.

Hyderabad has developed as a major production center for bulk drugs due to the location if the many major Pharmaceutical Industries such as Dr. Reddy's Laboratories, Aurobindo Pharma, Neuland Laboratories, Siris, Hetaro Drugs, Divis Labs, Natco Pharma Limited, Matrix Labs, Nicholas Piramal etc., besides a large number of medium and small industries manufacturing bulk drugs of all kinds.

In support of this growth in Hyderabad and Bangalore, many basic chemical units and drug intermediate units have also come up to meet the input requirements of Bulk Drug manufacturing Companies. Large numbers of these units are still dependent on supply of basic chemicals mainly from Mumbai, Gujarat and other parts of the country involving heavy expenditure on transport and transit risks.

2.4 Demand-Supply Gap.

The demand for APIs and API intermediates is a derived demand. It gets derived from the demand for various medicinal formulations (final administrable drugs) for the formulation industry.

- The APIs and API intermediates being manufactured by basic drug manufacturers are exported as such or used by domestic formulators in their production processes. The formulation firms further produce final medicines and export these as well as sell these in the domestic market.
- There is a wide gap in the demand and availability of cheap and quality medicines in India and the world over.
- Generic medicines and off patent drugs have significant potential to increase access to cheap and effective medicines to poor people and in general to bridge the demand supply gap.
- Indian basic drug manufacturers are playing a significant role in increasing access to affordable off patent drugs.

- The products envisaged include third generation antibiotics, anticancer, antipsychotic, etc drugs which address the problems associated with present day stressful lifestyles and demand for these outstrips their demand and is increasing by the day.

Pharmaceutical Industry – Domestic Scenario

The Indian Pharmaceutical Industry today is in the front rank of India's Science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. The Indian Pharmaceutical industry is estimated to be worth US $ 8.0 billions at present, growing at a CAGR of over 15 % annually. If India' s high Economic growth rate holds steady, the pharmaceuticals market will triple to $ 24 billion by 2015 and become one of the world` s top 10 markets according to a study by McKinsey and company ,a leading management consulting firm. At a compounded annual growth rate of 15.0 %, the absolute growth of $ 24 billion will be next to the growth potential of the US and China, and in the same league as the growth in Japan and Canada and the UK. Five factors will drive the growth of the Indian Pharmaceuticals market over the next decade; Doubling of disposable incomes and the increase in numbers of middle class households , significant expansion of medical infrastructure, greater penetration of health insurance, a gradual shift in disease profile and adoption of patented products, and finally population growth.

It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. Playing a key role in promoting and sustaining development in the vital field of medicines, the Indian Pharmaceutical Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK.

The Indian Pharmaceutical sector has more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical Companies control 70% of the market. The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drugs intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables.

There are about 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). These units produce the complete range of pharmaceutical formulations, i.e. medicines ready for consumption by patients and about 350 bulk drugs, i.e. chemicals having therapeutic value and used for production of pharmaceutical formulations.

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

At present the company has over 25 employees. We have a strong team of R&D, Manufacturing, Quality Control and Quality Assurance chemists with very pertinent skills in process development, manufacture and testing of our product range. The team comprises of Doctorates, Post Graduates, Graduates and Chemical Engineers from some of the premier institutes in India. Hyderabad has emerged as major drug manufacture city with a presence in global market. Pharma industry in the state contribute more than one third to the country's total production.

Most of the companies have set up their R&D facilities in the state, thus making the state the pharmaceutical capital of the country.

The Details of employment during operational phase in this unit shown in below Table.

TABLE 2.1: EMPLOYMENT REQUIREMENTS FOR EXPANSION

Particulars	**No. of employees**	**Functional Area**
Key managerial staff	5	Finance, Marketing, Production, Quality control, R&D, Logistics etc.
Administration	10	Office work
Skilled and semi skilled	20	Production Process, Maintenance, stores, Safety.& Un skilled workers
Total	**35**	

3.0 Project Description

M/s Otira Pharmaceuticals Pvt. Ltd.., proposes for expansion of its products and production quantities at manufacturing unit at Bonthapally. The Location map is shown at **Figure** – 1.

The site coordinates are

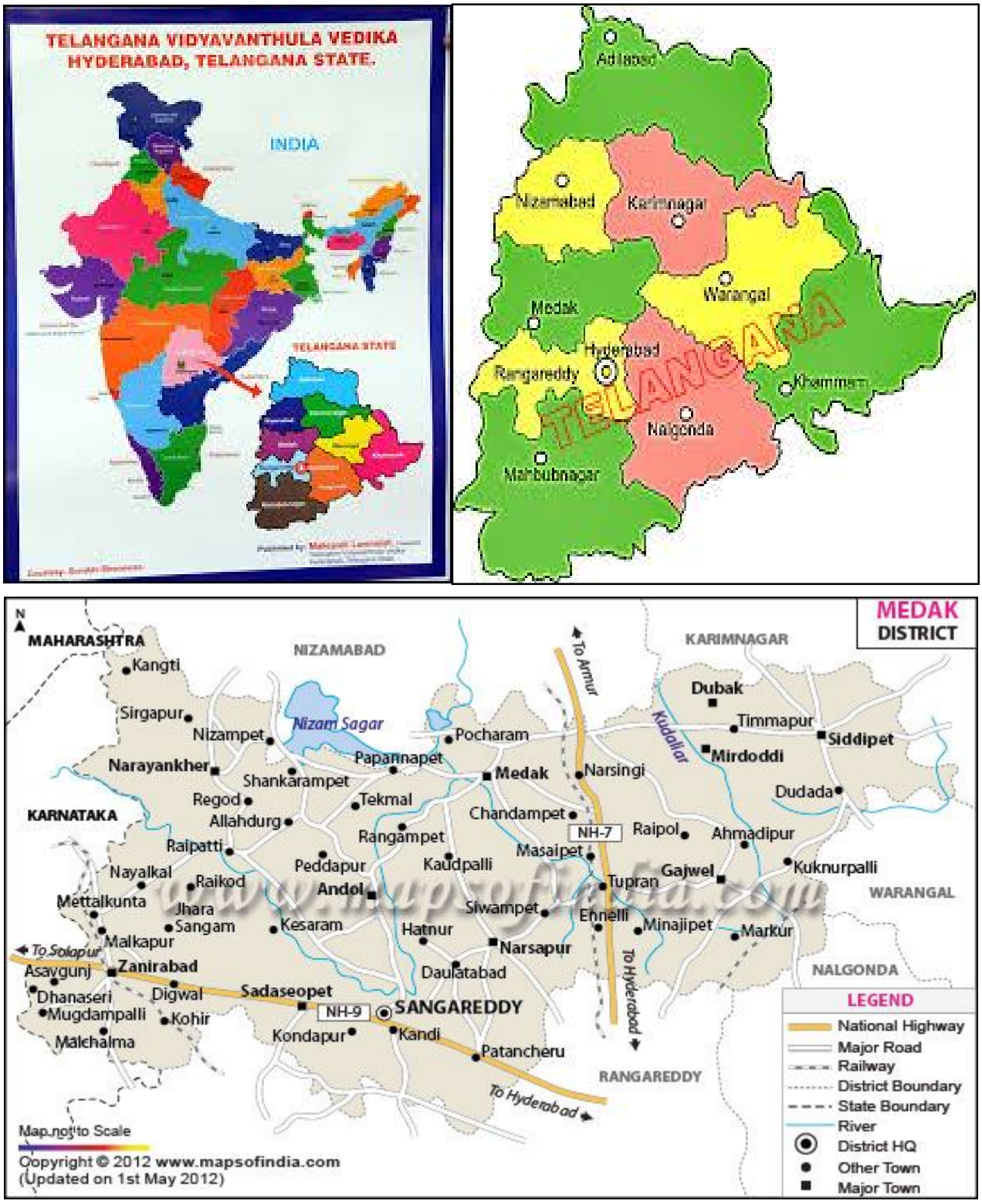
Latitude: 17°39'27.05" N

Longitude: 78°21'09.84" 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 proposed plant is well connected to Highway No-6 (Hyderabad - Narsapur) and Railway line at Sanathnagar Railway Station

FIGURE 1.1: LOCATION MAP



M/s Otira Pharmaceuticals Pvt. Ltd

Sy.no:637,660, Bonthapally (v), Jinnaram (m),
Medak (dt), - 502313, Telangana State.

3.1 Products and Production Capacity

M/s Otira Pharmaceuticals Pvt. Ltd. is proposes to produce the below mentioned shown in Table3.1.

Table3.1: Proposed Products and Quantities

S. No	Product Name	CAS No's	Quantity In Kg/Month	Quantity In Kg/Day
1	Ciprofloxacin Hydrochloride	85721-33-1	10000.00	333.33
2	Citalopram Hydrobromide	59729-32-7	3000.00	100.00
3	Domperidone	57808-66-9	5000.00	166.67
4	Esomeprazole Sodium	161796-78-7	1000.00	33.33
5	Esomeprazole Magnesium Trihydrate	217087-09-7	2000.00	66.67
6	Fexofenadine Hydrochloride	153439-40-8	5000.00	166.67
7	Omeprazole	73590-58-6	10000.00	333.33
8	Pantoprazole sodium	138786-67-1	2000.00	66.67
9	Sertraline Hydrochloride	79559-97-0	5000.00	166.67
10	Valsartan	137862-53-4	2000.00	66.67
			45000.00	**1500.00**

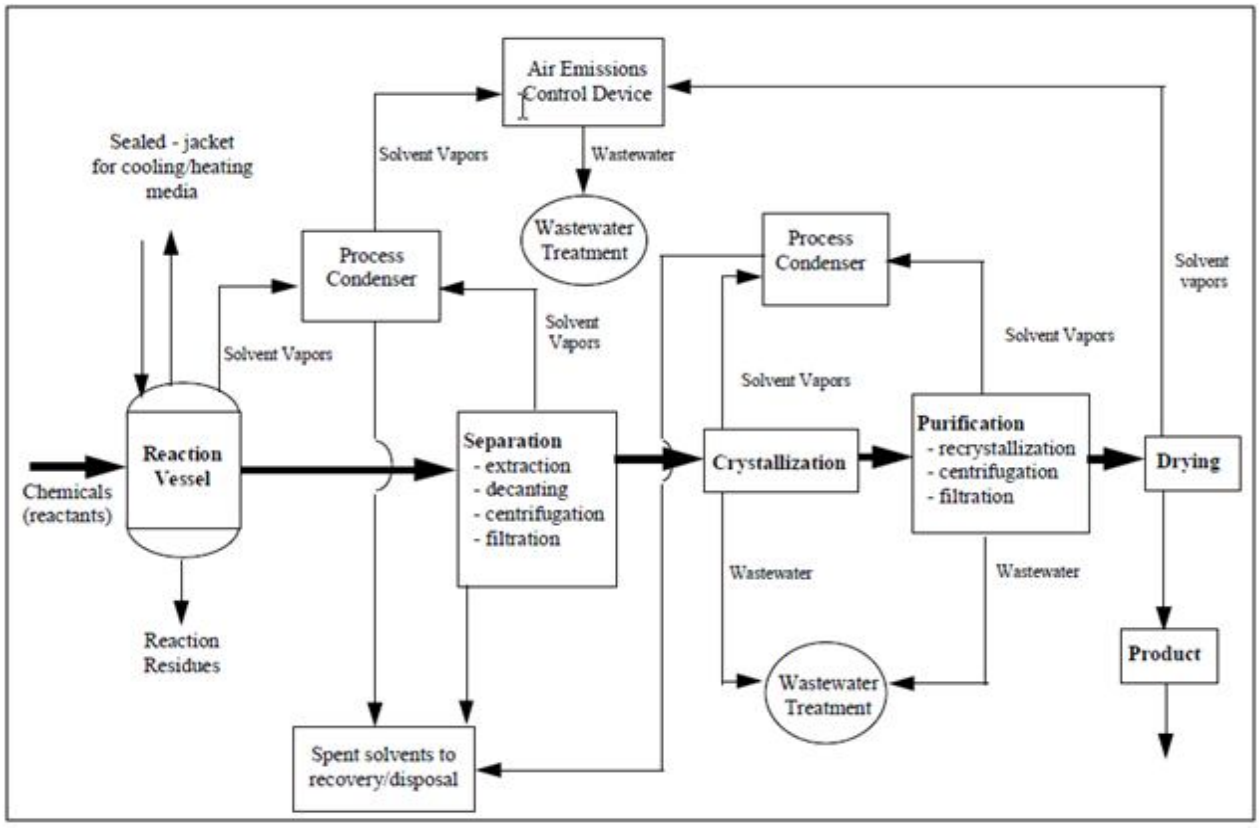
3.2 Raw materials required and Quantities

All the raw materials required for manufacturing of above products will be sourced from local market.

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 Bulk Drug 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 116.99 KLD. The water requirement will be met through Bore well. The detailed water requirement shown in below **Table3.2.**

Table 3.2: WATER REQUIREMENT DETAILS

S. No	Purpose	Water Requirement In KLD
1	Process	35.99
2	Washings	2.00
3	Boiler Make up	24.00
4	Cooling towers Makeup	44.00
5	DM Plant	2.00
6	Scrubber system	2.00
7	Domestic	2.00
8	Gardening	5.00
	Total	**116.99**

3.4.2 Power Requirement

Power requirement of proposed project will be made available through SPDCL. Total power requirement of proposed expansion is 600 KVA.

D. G. set of capacity 250 & 380 KVA will be installed to meet the emergency power requirement of the plant.

3.4.3 Fuel Requirement

M/s Otira Pharmaceuticals Pvt. Ltd. is proposes to install 4.0 TPH coal fired boiler in addition to the above existing 2 X4, 00,000 kcal/hr Thermo pack Boiler. Total fuel requirement will be around 10.0 TPD. Coal is procured form 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 59.0 KLD. The treated water 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	36.89	2.11	39.00	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	2.00	2.00	
3	Boiler Blow Down	4.00	0.00	4.00	
4	Cooling towers Blow Down	0.00	8.00	8.00	
5	DM Plant	2.00	0.00	2.00	
6	Scrubbing system	2.00	0.00	2.00	
7	Domestic	0.00	2.00	2.00	Septic tank followed by Soak pit
	Total	**44.89**	**14.11**	**59.00**	

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 table3.4.

Table 3.4: Solid waste generation and Disposal

S. No	Name of the Solid Waste	Quantity In Kg/Day	Disposal method
1	Organic Residue	862.70	Sent to Cement industries
2	Inorganic solid waste	247.20	Sent to TSDF
3	Spent carbon	130.67	Sent to Cement industries
4	ETP Sludge	50.00	Sent to TSDF
5	Coal ash from Boiler	4700.00	Sent to Brick Manufacturers
6	Solvents distillation residue	1068.00	Sent to Cement industries
7	MEE Salts	1938.00	Sent to TSDF
8	Waste Oils & Grease	150 Ltrs /Annum	APPCB Authorized Agencies for Reprocessing/Recycling
9	Detoxified Containers	150No's / Month	After Detoxification sent back to suppliers/APPCB Authorized Parties
10	Used Lead Acid Batteries	4 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 and its amendments.

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.

4.0Site Analysis

4.1 Connectivity

M/s Otira Pharmaceuticals Pvt. Ltd. is located at Sy.No:637,660, Bonthapally (V), Jinnaram (M), Medak (Dt), -502313, Telangana State

- The nearest habitation from the site is Bonthapally (Village) at a distance of 1.22 Km (ENE).
- The nearest railway station is Sanathnagar Railway station at a distance of 35 KMs from the site (SSE).
- The nearest airport is Rajiv Gandhi International Air port at a distance of 47 KMs (NNW)
- The Nearest Highway no.6 (Hyderabad - Narsapur) - 2.21kms (E)

4.2 Land Form, Land use and Land ownership.

The project site is located in Non Agricultural Land. There would be no change in Land Use, Land Cover or Topography of plot. After implementation of project a dense green belt would be developed. Total 33 % of Plant area will be allocated for green belt development.

4.3 Existing Infrastructure.

Proposed project in ptta land and the basic infrastructure is already there.

4.4 Soil classification

The district is mainly covered by three types of soils Sandy Loam, Black clay Loam, Laterate types of soil.

4.5 Climatic data from secondary sources.

Temperature Maximum: 44.4^{o} C
Minimum: 6.9 ^{o} C

Normal annual rainfall **1120 mm**

4.6 Social Infrastructure available.

Well developed social infrastructure facilities are available at nearby Habitations.

5.0 Planning Brief

Further proposed expansion 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. Only additional Building and Plant & machinery need to constructed and installed

6.2 Residential Area

No residential area is involved in the proposed project. The employs are accommodated in nearby Residential areas

6.3 Green Belt:

Approximately 33 % of Green Belt will be provided and 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 Highway no. 6 (Hyderabad - Narsapur) .

6.5 Water management

Water requirement will be fulfilled through Bore well water.

6.6 Sewerage System:

There will be no discharge of industrial effluent (**Z**ero **L**iquid **D**ischarge). 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 project, 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. Project cost for the proposed Expansion projects is Rs. 12.05 Crores which includes the cost of new Buildings and plant & machinery.

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.