

# **PRE FEASIBILITY REPORT**

## **FOR OBTAINING ENVIRONMENTAL CLEARANCE**

**For the Proposed Active Pharmaceutical Ingredients (APIs)**

**Manufacturing Project of**

## **M/s. SOLISOM HEALTHCARE LLP**

**Survey No.: 99/P1, Rajpar – Nashitpar Road,**

**Village: Nashitpar, Taluka: Tankara,**

**District: Morbi, Gujarat.**

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## 1. Introduction

**M/s. Solisom Healthcare LLP** is a partnership firm proposing to set up a Synthetic Organic Chemicals (Active Pharmaceutical Ingredients - APIs) manufacturing unit with total production capacity of 41.1 MT/month at Survey No.: 99/P1, Rajpar – Nashitpar Road, Village: Nashitpar, Taluka: Tankara, District: Morbi, Gujarat.

The proposed products falls under Category “5(f)” as stated in Environment Impact Assessment notification published on 14<sup>th</sup> September, 2006. Further, the location of the proposed project is outside the notified industrial estate and do not fall in ‘Small Scale Industrial Unit’ criteria as per the notification dated 25<sup>th</sup> June, 2014. Hence, the project proponent has to obtain the Environmental Clearance (EC) from the Ministry of Environment, Forest & Climate Change, New Delhi. M/s. T. R. Associates (NABET and NABL Accredited EIA consultants) has been appointed to carry out EIA/EMP studies for obtaining Environmental Clearance.

The total land area of company is 7,689 m<sup>2</sup> out of which 2545 m<sup>2</sup> (33.1 % of total land) area will be used for greenbelt development. The estimated cost of the proposed project is 400 Lakhs. Total budget allocation towards Environmental Management Facilities will be approx. Rs. 118 Lakhs. Total 30 persons will be employed including skilled persons, unskilled persons and office/administrative staff.

## 2. Project Proponent and their back ground

Details of Partners are as given below.

Sr. No.	Name of Partners	Background
1	Mr. Kirankumar G. Rangapadiya	<ul style="list-style-type: none"> <li>Education: Master of Pharmacy</li> <li>Experience: 6 years in R&amp;D</li> <li>Field: Pharmaceutical Industry</li> </ul>
2	Mr. Bhumini M. Patel	<ul style="list-style-type: none"> <li>Education: Master of Pharmacy</li> <li>Experience: 2 years in R&amp;D</li> <li>Field: Pharmaceutical Industry</li> </ul>
3	Mr. Gaurang J. Lakhtaria	<ul style="list-style-type: none"> <li>Education: Master of Pharmacy</li> <li>Experience: 1 years in Production</li> <li>Field: Pharmaceutical Industry</li> </ul>

## 3. Brief description of nature of the project:

M/s. Solisom Healthcare LLP is proposing to manufacture Synthetic Organic Chemicals (Active Pharmaceutical Ingredients) at Survey No.: 99/P1, Rajpar – Nashitpar Road, Village: Nashitpar, Taluka: Tankara, District: Morbi, Gujarat.

#### **A. Need for the project and its importance to the country and or region**

The pharmaceutical industry in India is in an urgent need for new scientific advances that would yield innovative and effective drugs and therapies. This need is an important factor driving the growth of the API industry in the country, which has led to the invention of a new generation of APIs.<sup>1</sup> In India, good quality raw materials are available at cheap rates, enabling the manufacturing at low cost. This increases the profit margin as compared to other players in the world. To meet the current and future market demand, the project proponent intends to start a new unit. Looking to the market demand, the proposed project is feasible at stated location.

#### **B. Imports v/s Indigenous production**

Indian market is open and big that is why every kind of import is booming. Of the total domestic consumption, approximately 32% was imported. Of the total imports, China alone accounts for 57-60% of the APIs imported by India. The remaining imports are from countries such as Italy, Germany, Malaysia, and others. These facts indicate that there is plentiful scope for the domestic API market to grow, if the manufacturers are able to produce the required amount of APIs on their own, rather than importing it from other countries.<sup>1</sup>

#### **C. Export Possibility**

More than 30% of the APIs manufactured in India are exported to countries such as US, UK, Japan, etc. The total production market of API in India was valued at approximately US\$ 11 Billion in FY 2016. This market is forecasted to grow at a CAGR of around 9% during the period of FY 2016–FY 2022.<sup>1</sup>

#### **D. Employment Generation (Direct and Indirect) due to the project**

This project will provide direct employment to 30 people whereas it will provide employment to many others indirectly.

### **4. Project Description**

#### **(i) Type of project including interlinked and interdependent projects**

The scientific research & development in API manufacturing is focused on increasing the yield, reducing the toxicity of waste and consumption of solvents, using alternative manufacturing method etc. In this context, the API manufacturing is viewed as an environmentally hazardous activity. According to MoEF&CC, GOI mandated prior Environmental Clearance for synthetic organic chemicals manufacturing units vide s.o. 1533 dated 14-09-2006. Active pharmaceutical ingredients are frequently used for curing the diseases. So it is an individual industry having no direct dependency on others.

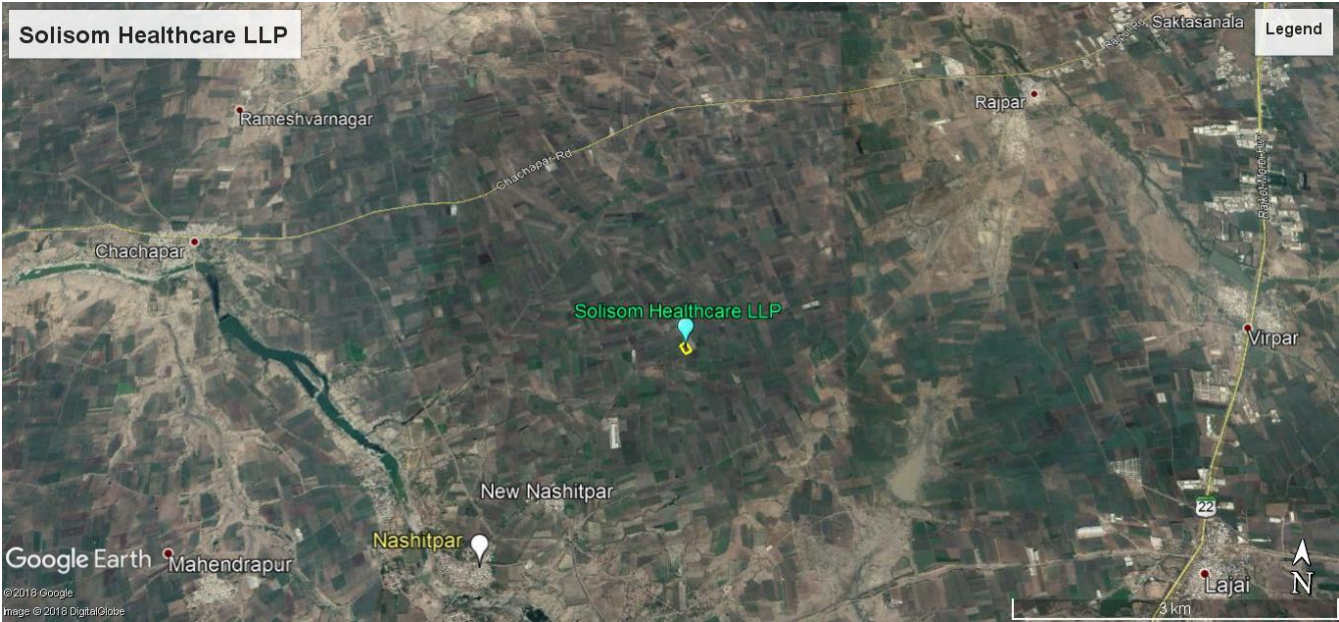
<sup>1</sup> <http://publication.assochem.tv/data/product-file/48%20-%20Indian%20API%20Market%20Outlook%202022.pdf>

**(ii) Location**

Proposed project is to be located at Survey No.: 99/P1, Rajpar – Nashitpar Road, Village: Nashitpar, Taluka: Tankara, District: Morbi, Gujarat.

Geographic Coordinates : Latitude: 22°44'12.53"N  
Longitude: 70°44'11.35"E

Google images showing proposed project site are given below:





Boundary Point	Geo Co-ordinates
Point 1	Latitude: 22°44'14.77"N Longitude: 70°44'11.23"E
Point 2	Latitude: 22°44'11.52"N Longitude: 70°44'13.47"E
Point 3	Latitude: 22°44'10.44"N Longitude: 70°44'11.28"E
Point 4	Latitude: 22°44'13.26"N Longitude: 70°44'9.43"E

Salient features in the surroundings area of the proposed site within 10 km radius are as follows:

Sr. No.	Important Features	Description
1	Location	Survey No.: 99/P1, Rajpar – Nashitpar Road, Village: Nashitpar, Taluka: Tankara, District: Morbi, Gujarat.
2	GPS Coordinates	Latitude: 22°44'12.53"N Longitude: 70°44'11.35"E
3	Temperature Range	12.8°C to 40.5°C
4	Mean Sea Level	61 m
5	Annual Rain Fall	676.1 mm (average)
6	Nearest Railway Station	Morbi Railway Station – 13.7 km in NE direction
7	Nearest Airport	Rajkot Airport – 47.5 km in South direction
8	Nearest Town	Morbi – 8 km in NE direction
9	Nearest Village	New Nashitpar – 1.85 km in SW direction
10	Nearest National Highway	NH 8A – 15.8 km in NE direction
11	Nearest State Highway	SH 24 – 5 km in SE direction
12	Nearest River/Water body	Demi River – 3 km in WSW direction Phulki River – 5.1 km in NE direction
13	National Parks / Sanctuary	None within 10 km radius.

### (iii) Alternative Sites considered

No other sites were selected.

**(iv) Size or magnitude of operation****List of Proposed Products**

Sr. No.	Name of the Product	Production Capacity (MT/Month)	CAS Number
1.	Deferasirox	4	201530-41-8
2.	Duloxetine Hydrochloride	3	136434-34-9
3.	Esomeprazole Magnesium Trihydrate	4	217087-09-7
4.	Gabapentin	5	60142-96-3
5.	Levocetirizine Dihydrochloride	3	130018-87-0
6.	Metaxalone	6	1665-48-1
7.	Pregabalin	6	148553-50-8
8.	Quetiapine Fumarate	2	111974-72-2
9.	Rabeprazole Sodium	3	117976-90-6
10.	Rivaroxaban	1.5	366789-02-8
11.	Rosuvastatin Calcium	1.6	147098-20-2
12.	R & D Activity	2	--
<b>Total</b>		<b>41.1</b>	

**(v) Project description with process details**

Details of manufacturing process are given in **Annexure- 4** of **Form- 1**.

**(vi) Raw material required along with estimated quantity**

Details of raw material and its consumption are given in **Annexure- 3** of **Form- 1**.

**(vii) Resource optimization/ recycling and reuse envisaged in the project, if any, should be briefly outlined.**

Latest process technology will be adopted as available in market with optimum resources requirement with highest yield and less waste and pollution generation. Treated industrial effluent will be reused. In addition to this, all the feasible cleaner production technologies will be adopted.

**(viii) Availability of water its source, Energy/ power requirement and source should be given.**

Energy/power requirement will be 200 kVA which will be procured through Paschim Gujarat Vij Corporation Ltd (PGVCL).

The total water requirement will be 119 kl/day, out of which 31 kl/day will be drawn through Borewell.

**(ix) Quantity of wastes to be generated (liquid and solid) and scheme for their Management/disposal**

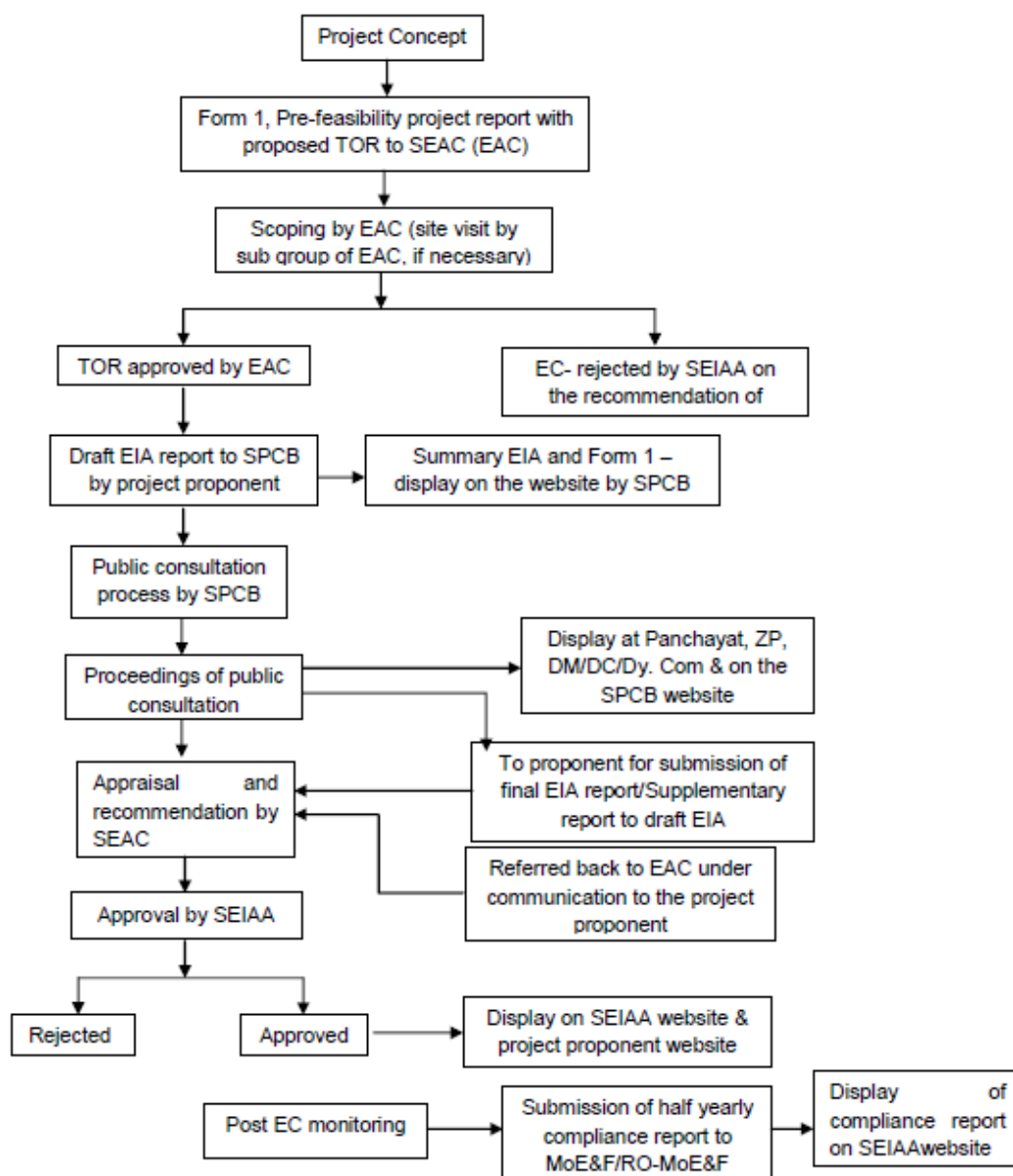
- **Hazardous Waste Generation and Disposal**

Details of hazardous waste generation and its disposal are given in ***Annexure- 5*** of **Form- 1**.

- **Wastewater Generation and Disposal Facility**

Details of domestic as well as industrial wastewater generation and its disposal are given in ***Annexure- 7*** of **Form- 1**.

(x) Schematic representations of the feasibility drawing which give information of EIA purpose



(xi) Site Analysis

a. Connectivity

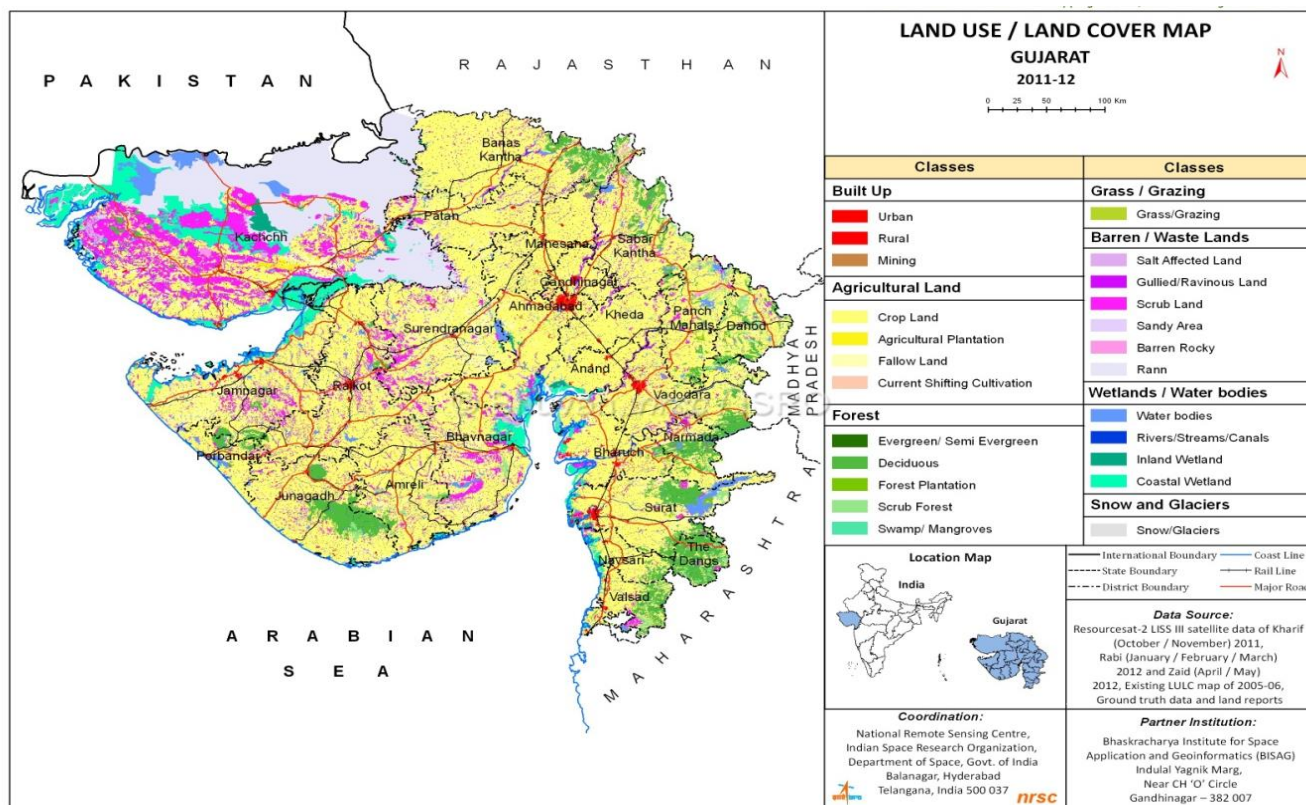
Nearest railway station	Morbi	13.7 km in NE direction
Nearest highway	SH 24	5 km in SE direction
Nearest airport	Rajkot Airport	47 km in South direction
Nearest City	Morbi	8 km in NE direction



**b. Land Form, Land use and Land ownership.**

Proposed project site has already been procured by proponent and it is an open area which is presently not being used for any purposes.

**(i) Existing Land Use Pattern**



## (ii) Topography Map

Project Site



**c. Existing Infrastructure**

- (1) Nearest railway station: Morbi railway station is 13.7 km away from the project site
- (2) Nearest highway: State Highway 24 is 5 km away from the project site.  
National Highway 8A is 15.8 km away from the project site.
- (3) Nearest airport: Rajkot Airport is 47.5 km from the project site.
- (4) Power: 200 kVA from Paschim Gujarat Vij Company Limited.
- (5) Water: Source of the water will be a Borewell.
- (6) Basic amenities: Good road connectivity with state and national highway.
- (7) Post Office: Nasitpar branch post office is 1.88 km away from Project Site.

**d. Soil classification of Morbi District**

The soils of Morbi district are of clayey loam to clay type. They vary in color from very dark brown to very dark greyish brown and reddish brown. The EC of the soil is generally less than 1.0 mmhos/cm and cation exchange capacity is between 40 and 60 me/100 gm of soil.

**e. Climate data from secondary source**

General climate of the district is sub-tropical and is characterized by three well-defined seasons, i.e. summer - from April to June, monsoon - from July to September, and winter - from October to March.

**Temperature:**

Highest temperature is 43 to 46 °C in summer and lowest temperature comes down to 7 to 15 °C in winter season.

**Relative Humidity:**

The relative humidity is generally over 75 % in the south west monsoon. In the rest of the year the air is comparatively dry, especially in the afternoons. During the period of November to May the relative humidity varies between 40% and 50%.

**Wind:**

In the south west monsoon season, the wind direction is westerly to south westerly. In the post monsoon/cold season, wind blows from the north-north east direction. In summer seasons the direction of the wind is mainly between north west and south west. The wind speed gradually increases from February and reaches the peak in July when the south west monsoon is most active. It again decreases from August and becomes low.

**Rainfall:**

More than 90% of the rainfall occurs during the monsoon. Rainfall during the winter and summer months is negligible. The average annual rainfall of the district is 592 mm.



#### **f. Social Infrastructure available.**

Availability of resources in huge quantity and suitable climatic conditions has induced the growth of Ceramic industries hugely in Morbi taluka. At present, more than 700 enterprises in around Morbi are manufacturing Ceramic Tiles, Floor Tiles, Luster Wall Tiles, Glazed Wall Tiles, Vitrified Tiles, Porcelain Tiles, 2D, 4D Tiles, Spartek, Roofing and Mosaic Tiles. More than 100 enterprises are manufacturing specialized Vitrified Tiles which has great demand in the region as well as all over the country.

Morbi is also hub of digital and other types of watches and clocks manufacturing enterprises such as Ajanta, Samay, Sonera and Sonam which are World leaders in this sector. After 2002, Paper industries have grown rapidly as ancillary sector due to need of high quality craft grade papers which are very suitable for packing of goods. There are number of export-import houses working in this district.

Besides, many enterprises deal in consumer durables and engineering goods. Tourism also fetches significant income to the economy of the district as many visitors visit the district having historic values. Though the concept of avoiding risk factor for the Governmental regulations and process causes adverse effect and resulted in weakened industrial growth.

Industrial Training Institutes, Productivity Development Centers, Small Scale Enterprises Development Institute- Ahmedabad, District Industries Center- Morbi and other Nongovernmental organizations must come forward to promote more and more training programs to increase and motivate the productivity of the labor force available in the district.

### **5. Planning Brief**

#### **(i) Planning Concept (type of industries, facilities transportation, etc) Town and Country Planning/Development authority Classification.**

Infrastructure facilities are pre-perquisite for industrial development. The industrialization cannot take place in the absence of infrastructural facilities. The infrastructural facilities include availability of developed roads, power, railway, water, communication, transport, technical institutions, industrial estates, banking facilities, container depot, industrial clusters and other auxiliary services. In Morbi district, the existing facilities are elaborated as under:

- Land is the basic requirement to establish industry. Availability of suitable land at reasonable price facilitates industrial development of an area. The uncultivable, barren and non-agricultural land can be utilized for establishing industrial sector.
- Availability of sufficient water is also pre-requisite for any industry. Through discussion with local authorities, we will use ground water as our source of water.
- Sufficient power supply is the main factor for running industries. The main source of supply is Paschim Gujarat Vij Co. Ltd., Morbi. Facility in respect of Electricity is

considerably increased in this district as now-a-days Government gives more stress on the development of Electricity network.

- Good roads are must for industrialization which in turn facilitates transportation and development of trade and commerce. The development of roads is looked after by different departments in the district. The National Highway is looked after by C.P.W.D., the state highways are looked after by the P.W.D. and roads in the other parts of the district by District Panchayat Office.
- Good and advance communication facilities help the functioning of industries and as a result economic development is achieved. Morbi District is having the capacity of 21,888 telephone connections and working connections are 8,405.
- In Morbi district, air transport facility is not available at present. However, the nearest Airport is Rajkot Airport which 65.20 km away from Project Site.

## (ii) Population

Population summary of the Morbi district is depicted in the following table.

Description	No.
Population	Total : 9,60,329 Person
	Male : 4,94,726 Person
	Female: : 4,65,603 Person
Population density	481 persons per sq. km.
Village Population	Total: 6,01,909 Person
Urbanised Population	Total: 3,58,420 Person
Population increase rate	N.A
Male- Female ratio	1000 : 961
Scheduled Caste population	49,902 persons
Scheduled Tribe population	4,036 persons

## (iii) Land use planning (breakup along with green belt etc).

Sr. No.	Particular	Area (m <sup>2</sup> )
1	Built Up area	2,921
2	Green belt area	2,545
3	Open/ Road area	2,223
<b>Total</b>		<b>7,689</b>

**(iv) Assessment of Infrastructure Demand (Physical & Social).**

Surrounded villages in 10 km area from the project site are having all the necessary physical and social infrastructure facilities due to agricultural activities, animal husbandry and industrial development within the area.

**(v) Amenities/Facilities.**

All the basic amenities/facilities such as power connection & power back-up, drinking water, internal roads, water & wastewater treatment plant etc. will be provided.

**6. Proposed Infrastructure**

**a. Industrial Area**

Industry has provided 2,921 m<sup>2</sup> built up area for industrial process/manufacturing activity which provides all needed facility including proper ventilation, safe handling system, etc.

**b. Residential Area**

Not Applicable

**c. Green Belt.**

2,545 m<sup>2</sup> area will be proposed for greenbelt development. In addition to this, project proponent will participate in greenbelt development programs in nearby areas under their CSR.

**d. Social Infrastructure**

The proponent will provide social infrastructure facilities within 10 km radius of the proposed project.

Education Facilities:-Many Facilities for village schools like game kits, drawing kits, table-chairs; school construction (classroom/toilet/school boundary), ceiling fans/ coolers or books for school library are proposed.

Health Facilities:-Assistance to existing health facilities in nearest Hospital, for improvement in health facilities or services.



**e. Connectivity (Traffic and Transportation Road / Rail / Metro / Water ways)**

Proposed project site is located near to State Highway 24 and well connected to the internal roads and highways. The site is well connected to Morbi Town and Rajkot City.

**f. Drinking Water Management**

In proposed project, out of 31 kl/day fresh water requirement, approx. 1.5 kl/day water will be consumed for domestic purpose.

**g. Sewerage System.**

Domestic wastewater 1.35 kl/day will be disposed off through Septic Tank/ Soak Pit System.

**h. Industrial Wastewater Management.**

Industrial wastewater will be generated from process, boiler (blow-down), cooling tower (blow-down), scrubber & washing. Industrial wastewater will be collected in collection cum neutralization tank. Separate collection tank will be provided for collection of w/w stream having ammoniacal nitrogen & it will be passed through ammonia stripper. Wastewater from ammonia stripper and other high COD w/w stream will be mixed in collection cum neutralization tank -1. After that it will be passed through solvent stripper. Solvents will be stripped and collected using condenser and w/w stream will be passed through MEE. MEE salt will be sent to approved TSDF site. W/W from boiler bow-down, cooling tower blow-down, MEE condensate and RO reject will be collected into collection tank -2 and after that it will be passed through primary clariflocculator, aeration tank, secondary clariflocculator, PSF and ACF. Sludge will be collected from the bottom of the primary & secondary clariflocculator and aeration tank. Dried sludge will be stored in bags and ultimately disposed off at TSDF site. Thus, unit will maintain Zero Effluent Discharge.

**i. Solid/Hazardous Waste Management**

ETP waste + evaporation residue, discarded bags/drums/barrels & used oil, distillation residues, spent carbon, spent solvents, date expired drugs and off-specification drugs are the main solid hazardous waste that will be generated from the proposed unit. Used oil will be reused as a lubricant within the factory premises/sold to registered recycler. ETP sludge will be collected, stored into solid waste storage area and disposed to authorized TSDF site. Discarded bags and containers will be sold to approve vendor. Distillation residues, spent carbon, spent solvents, process residues will be sent to approved CHWIF.

**j. Power Requirement & Supply / source**

Power requirement for the proposed project will be approx. 200 kVA which will be obtained from PGVCL.

**7. Rehabilitation and Resettlement (R & R) Plan**

Not applicable.

**8. Project Schedule & Cost Estimates****(i) Likely date of start of construction and likely date of completion**

Construction work is not yet started. Construction work for proposed manufacturing unit will be started only after obtaining EC.

**(ii) Estimated project cost along with analysis in terms of economic viability of the project**

Expected project cost is approximately Rs. 400 Lakhs.

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