PRE-FEASIBILITY REPORT

For Proposed

MANUFACTURING OF BULK DRUGS, INTERMEDIATES & ALLIED PRODUCTS

By

M/s. TETRAHEDRON LABORATORIES PVT LTD.

Plot No. F-25, MIDC Chincholi, Taluka: Mohol,
District: Solapur, Maharashtra, India.

Conducted & Prepared By

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TABLE OF CONTENTS

1. EXECUTIVE SUMMARY 3
2. INTRODUCTION OF THE PROJECT/BACKGROUND INFORMATION 3
3. PROJECT DESCRIPTION 5
4. SITE ANALYSIS 36
5. PLANNING BRIEF 38
6. PROPOSED INFRASTRUCTURE 39
7. REHABILITATION AND RESETTLEMENT (R & R) PLAN 40
8. PROJECT SCHEDULE & COST ESTIMATES 40
9. ANALYSIS OF PROPOSAL (FINAL RECOMMENDATIONS) 41

LIST OF TABLES

TABLE 1.1 PRODUCT DETAILS 10
TABLE 1.2 LIST OF RAW MATERIAL 28
TABLE 1.3 WATER REQUIREMENT & WASTEWATER GENERATION 31
TABLE 1.4 ELECTRICITY REQUIREMENT 32
TABLE 1.5 FUEL REQUIREMENT 32
TABLE 1.6 DETAILS OF FLUE GAS STACKS 33
TABLE 1.7 DETAILS OF PROCESS GAS STACKS 33
TABLE 1.8 DETAILS OF HAZARDOUS WASTE 34
TABLE 1.9 DETAILS OF NON-HAZARDOUS WASTE 34
TABLE 1.10 ENVIRONMENT SETTINGS 36
TABLE 1.11 AREA BREAK-UP 39

LIST OF FIGURES

FIGURE 1.1 LOCATION MAP OF PROPOSED PROJECT 6
FIGURE 1.2 PROJECT BOUNDARY OF PROPOSED PROJECT SITE 7
FIGURE 1.3 GOOGLE IMAGE OF THE PROJECT SITE (5 & 10 KM RADIUS) 8
FIGURE 1.4 PLANT LAYOUT FOR PROPOSED PROJECT 9
FIGURE 1.5 WATER BALANCE DIAGRAM 32

1. EXECUTIVE SUMMARY

M/s. Tetrahedron Laboratories Pvt Ltd. is located at Plot No. F-25, MIDC Chincholi, Taluka: Mohol, Distt.: Solapur, Maharashtra. M/s. Tetrahedron Laboratories Pvt Ltd. is promoted by Mr Nikunj Chitalia and Mr Sunil Makwana and plan for Manufacturing of Bulk Drugs, Intermediates & Allied Products @ 145.834 MT/Month.

As per the EIA Notification, 2006, the proposed project comes under category 'B' listed at item 5(f). The Great Indian Bustard Sanctuary is located within 5 km of the project area. Hence, the category of the proposed project will come under category 'A'.

The site is well connected with road and railway, nearest city Solapur located at distance of 13 km and Sina River passing SSW direction at distance at 6.73 km. There is no reserved forest, national park, eco sensitive areas in surrounding 10 km radius. The Great Indian Bustard sanctuary, Nannaj is located 3.5 Km from project site. The project doesn't fall under CRZ boundaries.

The detail related to the proposed project is discussed in the upcoming section.

2. INTRODUCTION OF THE PROJECT/BACKGROUND INFORMATION

2.1 Identification of project and project proponent

2.1.1 Identification of project

M/s. Tetrahedron Laboratories Pvt Ltd. is situated at Plot No. F-25, MIDC Chincholi, Taluka: Mohol, Distt.: Solapur, Maharashtra. Total 9 products are presently proposed with production capacity of 145.834 MT/M. The total area covered by the proposed project is 6000 square meter.

2.1.2 Project Proponent

M/s. Tetrahedron Laboratories Pvt Ltd. is promoted by Mr Nikunj Chitalia , 27 yrs, is young , dynamic , energetic and believer in Digitalization work and world . He is BCA graduate and promoter Director of the company. He has experience of 8 years in Pharma market. Mr Sunil Makwana is Independent professional director. He is B.Com graduate and had good knowledge of accounts.

2.2 Brief description of nature of project

As per the EIA Notification, 2006, the proposed project comes under category 'B' listed at item 5(f). The Great Indian Bustard Sanctuary is located within 5 km of the project area. Hence, the category of the proposed project will come under category 'A'. Hence Environment Clearance is applicable to the proposed project.

2.3 Need of project and its importance to the country and/or region

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume of late, consolidation has become an important characteristic of the Indian pharmaceutical

market as the industry is highly fragmented.

The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Further, the government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

The Government of India plans to incentivize bulk drug manufacturers, including both state-run and private companies, to encourage 'Make in India' programme and reduce dependence on imports of Active Pharmaceutical Ingredients (API), nearly 85 per cent of which come from China.

2.4 Demand Supply gap

Few countries are contributing to the growth of the pharma industry, resulting in a robust jump in exports of drugs. Pharma exports from India will be more than the size of the domestic sales by FY 2015, according to a report by India Ratings & Research. The country provides generic medicines to almost 200 countries. It is responsible for about 40 percent of the generic and over-the-counter drugs consumed in the US. Indian generics market is expected to grow to $ 26.1 billion by 2016 from $ 11.3 billion in 2011.

The export of bulk drugs continue to grow to regulated markets and is supported by India's existing foothold in semi-regulated market. Pharmaceutical exports grew at a compounded annual growth rate of 22 percent between 2007-08 and 2012-13 to US$ 14.6 billion.

The country's pharma industry accounts for about 1.4 percent of the global pharma industry in value terms and 10 percent in volume terms. India's pharmaceutical exports stood at US$ 14.84 billion in FY 2013 – 14. The United States is the country's biggest market for pharma exports accounting for about 25 percent, followed by the United Kingdom. The US accounts for nearly 28 percent of Indian pharmaceutical exports, followed by the European Union at 18 percent and Africa at over 17 percent.

M/s. Tetrahedron Laboratories Pvt Ltd is dealer of pharmaceuticals bulk drugs, intermediates, aromatic compound and allied products. Tetrahedron Laboratories trade in above segments and part of the qty get it manufactured on job work basis at Ambernath, Badlapur and Tarapur. Company is now entering into own manufacturing of above bulk drugs, intermediates and allied products. It is backward integration of the products in which company is dealing past 6 years. Hence companies have ready manufacturing experience technology and ready market for sale.

2.5 Imports v/s indigenous production

Raw materials purchase from indigenous production. This helps in the economic development of the country to a great level. Thus, to decrease the dependency on imports, the project can work in a positive manner.

2.6 Export Possibility

There is no proposal to export the Bulk Drugs & Intermediates.

2.7 Domestic/ export markets

Our products have good demand in national markets. We shall export theproducts in local market.

2.8 Employment Generation (Direct and Indirect) due to project

M/s. Tetrahedron Laboratories Pvt Ltd. will give direct employment to local people based onqualification and requirement. In addition to direct employment, indirect employment shallgenerate ancillary business to some extent for the local population.In operation phase, the proposed project would require significant workforce of non-technical and technical persons. Migration of highly education and skilled experience will result in increase of literacy in the surrounding villages.

3. PROJECT DESCRIPTION

3.1 Type of Project including interlinked and interdependent projects, if any.

M/s. Tetrahedron Laboratories Pvt Ltd.is proposing Manufacturing of Bulk Drugs, Intermediates & Allied Products. The project falls under category ‘A’, section 5(f) of EIA notification 2006 and amendment thereof. The proposed production is 145.834 MT/M. There is no interlinked project with this proposed project.

3.2 Location (map showing general location, specific location and project boundary & project site layout) with coordinates.

- Coordinates of project site: 17˚46’36.61” N and 75˚48’11.64” E

- **Map showing general location:**

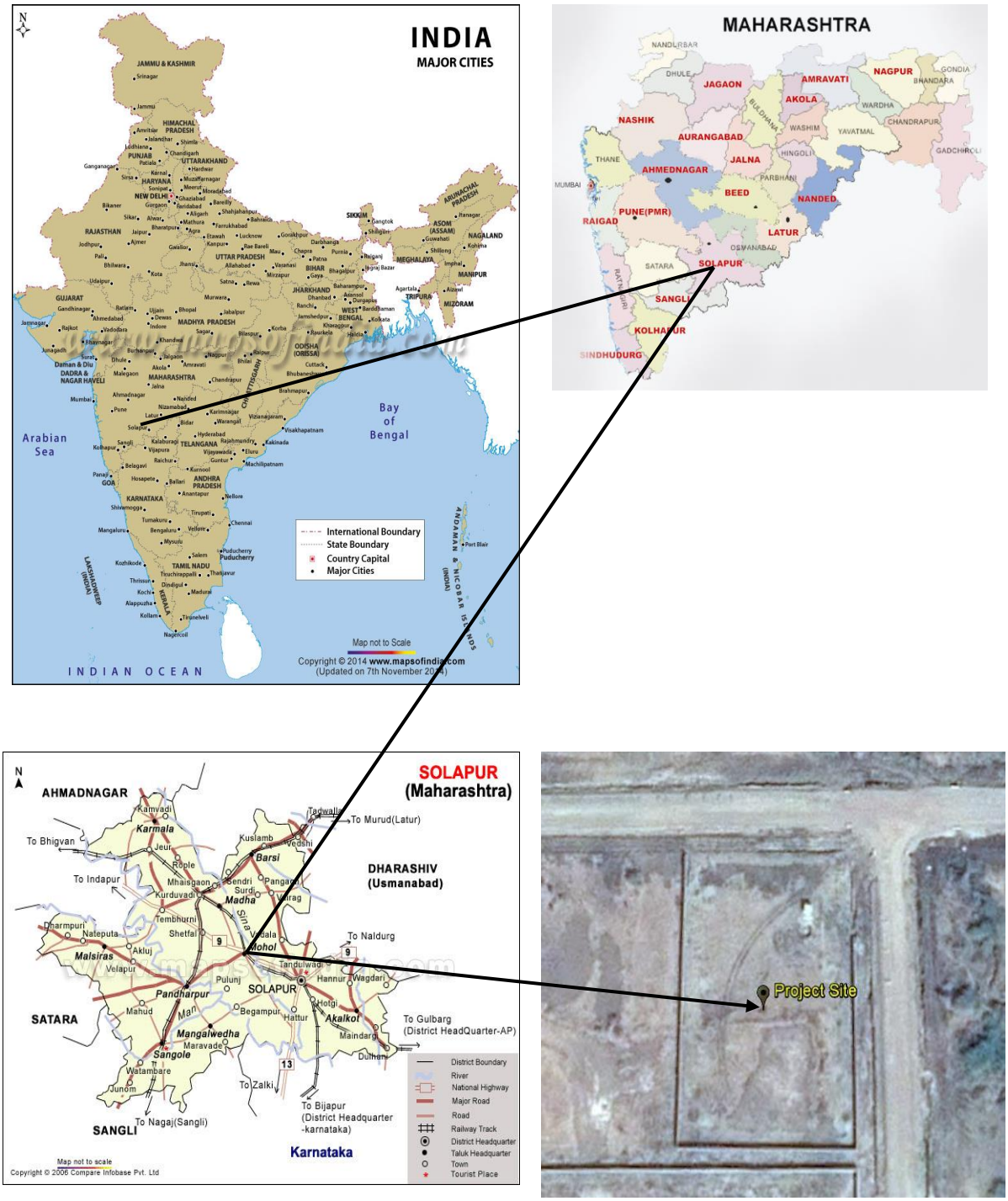


Figure 1.1 **Location Map of Proposed Project**

- **Project boundary of proposed site**

Figure 1.2 **Project Boundary of proposed project site**

- Co-ordinates of the corners of project site:

Corner	Coordinates
A	17°46'38.38"N, 75°48'10.63"E
B	17°46'35.24"N, 75°48'10.68"E
C	17°46'35.26"N, 75°48'12.73"E
D	17°46'38.39"N, 75°48'12.69"E

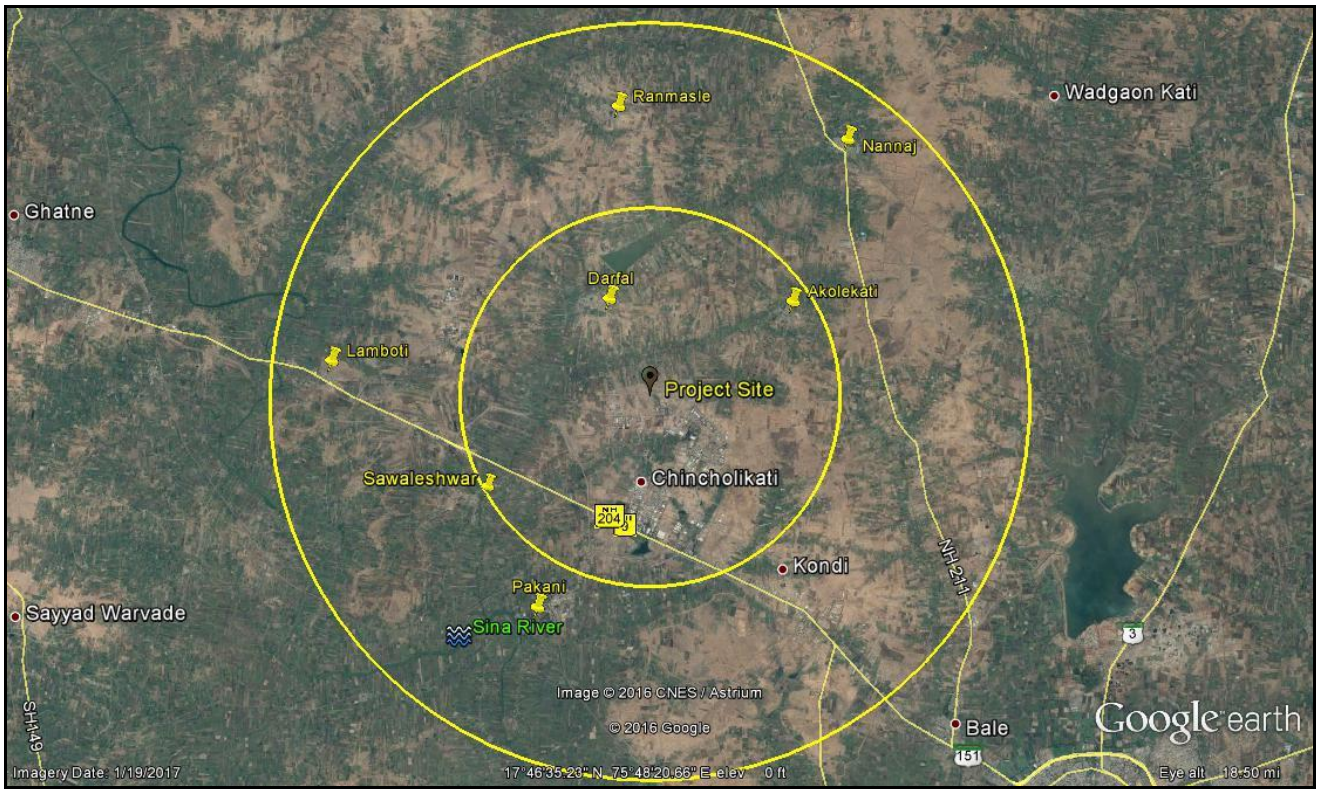


Figure 1.3 **Google Image of the project site (5 & 10 Km radius)**

➢ **Project site layout:**

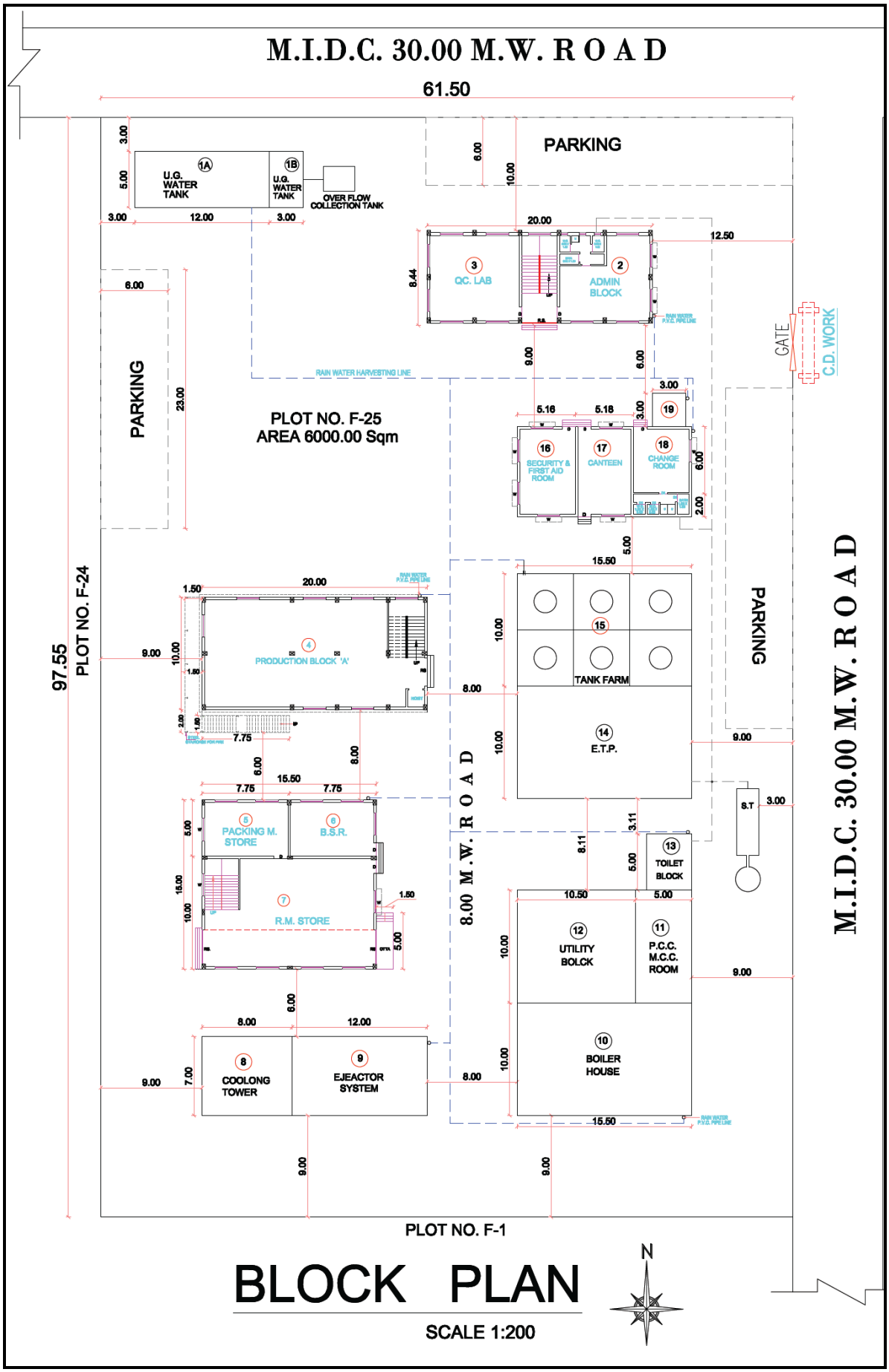


Figure 1.4 **Plant Layout for Proposed Project**

3.3 Details of alternate sites considered and the basis of selecting the proposed site, particularly the environmental considerations gone into should be highlighted.

No alternative site study will be carried out as proposed project will be located in a well developed industrial Area (MIDC Chincholi).

Major factors involved in the selection of site are listed below:

- Proposed project site is within the Chincholi MIDC, which on NH-13 has inherent properties of locational advantage of National Highway connecting to big Metros Mumbai, Pune and Hyderabad.
- The project site is located on level ground, which does not require any major land filling for area grading work.
- Proximity to Raw Material suppliers.
- Strategic location – proximity to Mumbai (396 kms), the commercial capital of India and well connected by rail and road. It has direct inter-city trains to Mumbai, Pune and Southern India. Its nature as a fast growing developing city, combined with its proximity to Mumbai and Pune, make ideal for sourcing human resources.
- Availability of Power, Water, etc.

3.4 Size or Magnitude of Operation

The proposed project is small scale industry and plan to establish Manufacturing of Bulk Drugs, Intermediates & Allied Products @ 145.834 MT/M.

Table 1.1 Product Details

Sr. No.	Product Name	Qty. (MT/M)
1	Cyano Acetic Acid	80.00
2	Cyclohexanyle Acetonitrile (Alkyl Nitrile)	30.00
3	Caffiene	3.00
4	Theophylline	3.00
5	Theobromine	5.00
6	Ethyl Cyano Acetate	6.50
7	Methyal Cyano Acetate	5.80
8	Cyano Acetamide	2.034
9	Metformin Hydrochloride	10.50
Total		**145.834**

3.5 Project Description with process details (a schematic diagram/flow chart showing the project layout, components of the project, etc. should be given)

3.5.1 Cyano acetic acid

Manufacturing Process:

Water is charged in M.S. Rubber lined reactor. Sodium salt of Sodium Monochloro Acetic Acid is charged.Sodium cyanide is added slowly & lot wise. After the completion of reaction the Sodium Salt of Cyano Acetic Acid is acidified with Sulphuric and this aqueous solution is extracted with MIBK (methyl iso butyl ketone) it is concentrated, cooled and centrifuged.

Reaction:

$$CH_2COOH + Na_2CO_3 \xrightarrow{2CL} CH_2COONa + H_2O + CO_2 \uparrow$$

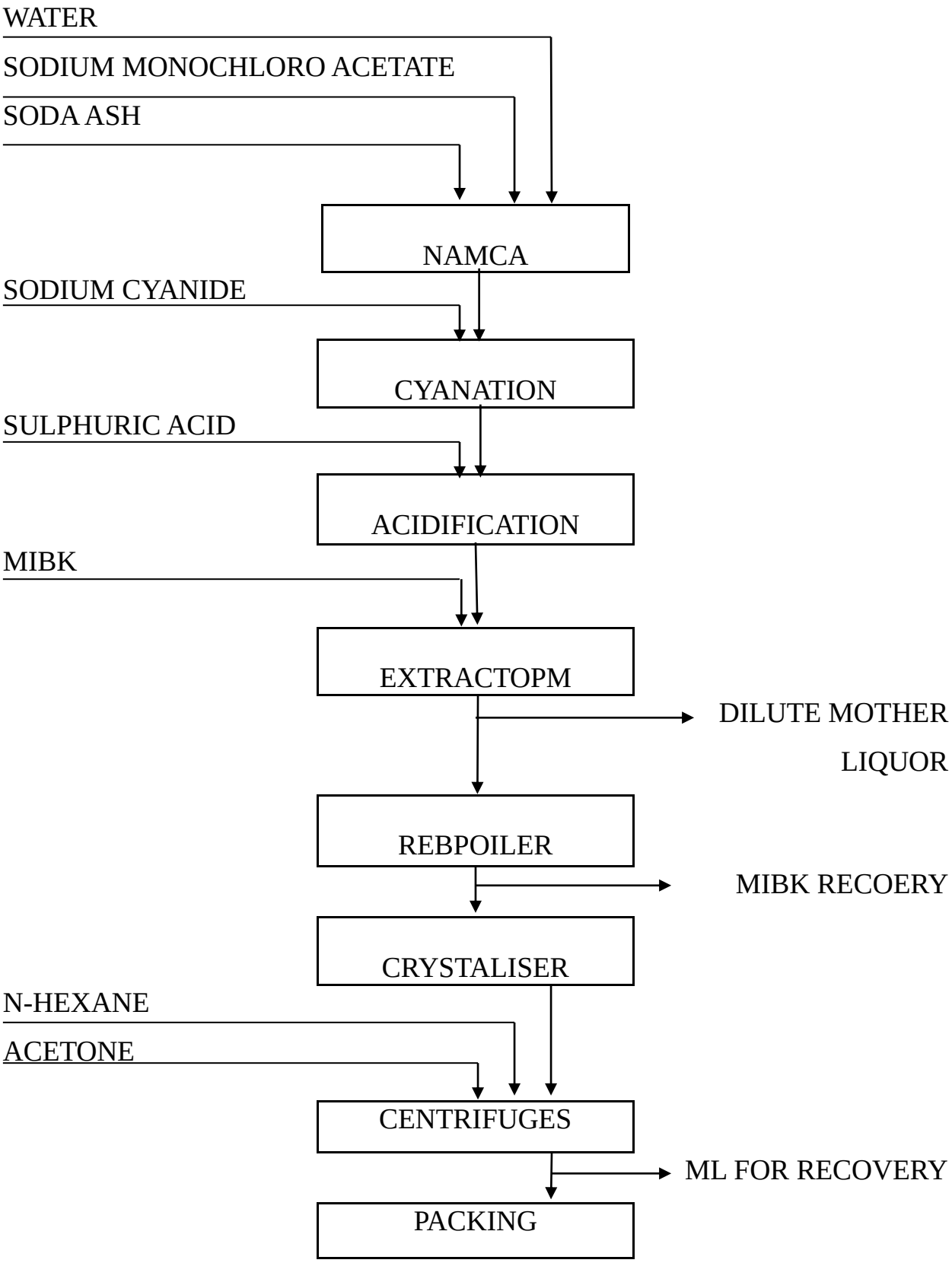
$$CL\text{-}CH_2COONa + NaCN \longrightarrow CN\text{-}CH_2COONA + NACl$$

$$CN\text{-}CH_2COONA + H_2SO_4 \longrightarrow H\ CN\text{-}CH_2COOH + Na_2SO_4$$

Material Balance:

Input	Kg per batch	Output	Kg per batch
Sodium Monochloro Acetate	2700	Product	1400
Water	6000	Liquid Effluent	10,042
Sodium Cyanide	1000	Solid Waste Carbon	08
Sulphuric Acid	1400	Solvent Losses	201.5
Carbon	8	Solvent Recovery For Recycle	11600
Sodium Hydrosulphite	8	.	
Ethylene Diamine Tetra Acetic Acid	0.500		
Mono Iso Butyl Ketone	12050		
Acetone	50		
n-Hexane	35		
Total	**23251**	**-**	**23251**

Process Flow Diagram:



3.5.2 Alkyl Nitrile

Manufacturing process:

In a SS reactor charge Cyano Acetic Acid. Add solvent Cyclohexanone and Ammonium Acetate at room temperature and heat the reaction to reflux and remove water by Azetrope. After complete removal water, maintain the reaction for 2 hrs. Fractionate the product by applying vaccum. Continuously give the sample to G.C. Till the product purity reaches to 0.98.5% after attaining its purity collect the main fraction and packed in 200 kegs HDPE drums.

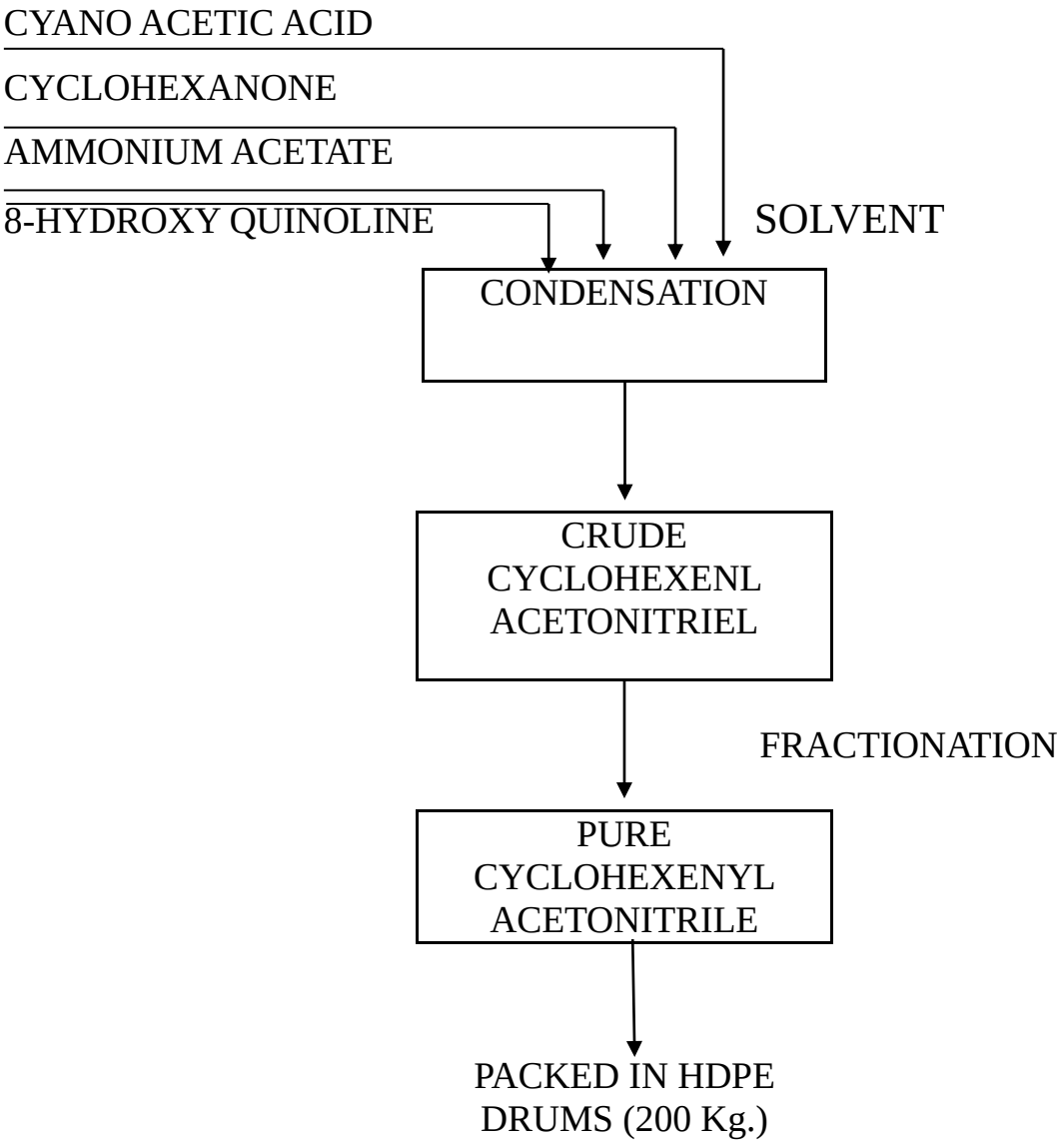
Reaction:

$$C_6H_{10}O + CN\text{-}CH_2COOH \longrightarrow C_8H_{11}N$$

Material Balance:

Input	**Kg per batch**	**Output**	**Kg per batch**
Cyclohexanone	1648	Product-Main Fraction	1400
Cyano Acetic Acid	1428	Liquid Effluent Water	300
Ammonium Acetate	50	Distillation Loss	26.3
8-Hydroxy Quinoline	0.30	I-Fraction	1000
Soda Ash	45	Bottom Fraction	445
Total	**3171.3**	**-**	**3171.3**

Process Flow Diagram:



3.5.3 Caffiene

Manufacturing process:

Charge wet cake of soda salt of state I under stirring. Wet cake 756.0 Kgs. Start heating by steam through jacket Heat to 50ºC-52ºC. Charge hydrochloric acid from dozer T503 to adjust pH to 11.5-11.7. Cool to 35oCStart addition of dimethyl sulphate in 1 ½hrs.keeping pH TP +ve by adding caustic soda lye in lots of one kg. Heat reaction mass to 85ºC - 88ºC Add 25Kgs. Act. Carbon Stir at 85ºC – 88ºC for one hour Filter the reaction mass in rector through the pp filter press to rector flush the line by air. Charge 300lts. DM water Heat to temp. 92ºC-94ºC Filter through pp filter press to rector Cool reaction mass in rector to 12ºC-15ºC. Centrifuge, spin dry wash each lot with 20lts. chilled ML of stage III from tank T509A Unload the wet cake in bags. Weigh & lable. Charge D.M.water 4.5 times the dry weight of crude Caffeine

Charge wet cake of crude Caffeine of stage II under stirring. Start heating by steam through jacket heat to 82ºC-84ºC. Check pH. Check clarity of soln. Charge 40kgs. fresh act. Carbon

Stir at 82ºC-84ºC for 1 hour. Filter the reaction mass in rector / 402B through the pp filter press to rector flush the line by air. Charge 200lts D.M.water. Heat to temp. 92ºC-94ºC Filter through

pp filter press to rector Cool reaction mass in rector to RT by jacket cooling water & then to 12°C-15°C by chilled water. Centrifuge, spin dry wash each lot with 20lts. chilled DM Water from tank T509B unload the wet cake in bags. Weigh & lable. Charge the wet cake in FBD/ TD & dry at 85oC till LOD is < 0.5%

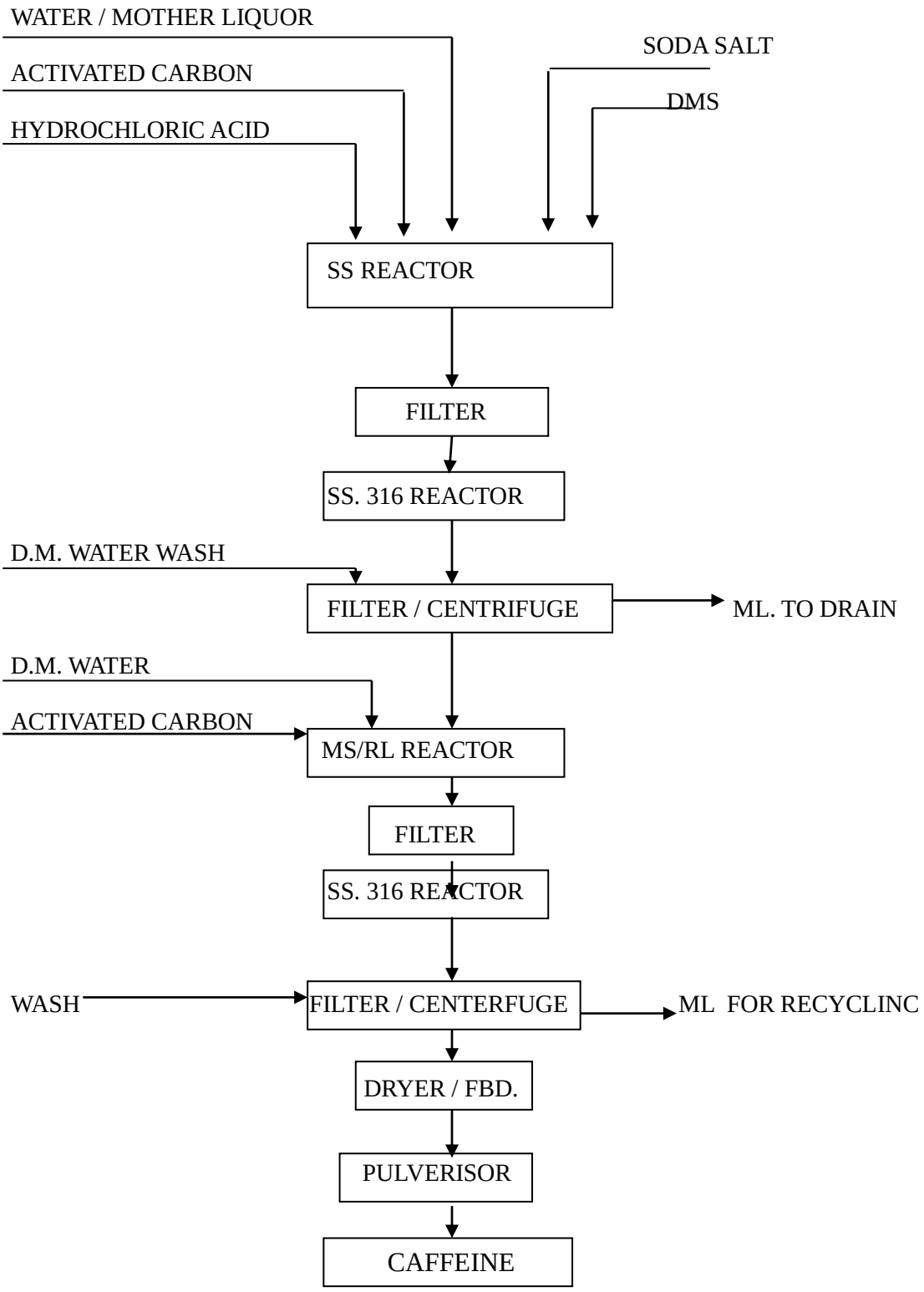
Reaction:

$$C_6H_{10}N_4O_2 \xrightarrow[\text{Methylation}]{\text{Dimethyl Sulphate}} C_8H_{10}N_4O_2$$

Material Balance:

Input	**Kg per batch**	**Output**	**Kg per batch**
Soda Salt	800	Wet Cake (Crude)	500
Water	2000	Solid Waste Carbon	10
Di-Methyl Sulphate	420	Liquid Effluent	2866
50% Caustic Solution	100	Product	500
Hydrochloric Acid 30%	16	Solid Waste Carbon	10
Activated Carbon	40	Liquid Effluent(ML)	2240
Water	2000		
Wet Cake (Crude)	500		
Activated Carbon	50		
Water Washing	200		
Total	**6126.0**	**-**	**6126.0**

Process Flow Diagram:



3.5.4 Theophylline

Manufacturing process:

Charge wet cake of soda salt of state I under stirring. Start heating by steam through jacket Heat to 92ºC-94ºC Charge hydrochloric acid from dozer T503 to adjust pH to 8.2-8.4 check clarity of soln. Charge 20kgs. fresh act. Carbon Stir at 92ºC -94ºC for 1 hour Filter the reaction mass in rector through the pp filter press to rector flush the line by air. Charge 300lts. ML of

stage III from T506A Heat to temp. 92ºC-94ºC Filter through PP Filter press to rector Charge 1.5kgs. Sod. Hydrosulphite Cool reaction mass in rector to 48ºC-50ºC. Adjust pH to 4.8-5.0 by hydrochloric acid at 48oC-50oC Stir at pH 4.8-5.0 & temp. 48ºC-50ºC. Cool to RT by jacket cooling water & then to 8oC-10oC by chilled water.Centrifuge, spin dry wash each lot with 20lts. chilled ML of stage III from tank T509A Unload the wet cake in bags. Weigh &lable.

Check clean & Dry Rector rector Charge D.M.water 6.8 times the dry weight of crude Theophylline Charge wet cake of crude Theophylline of stage II under stirring. Start heating by steam through jacket heat to 92ºC-94ºC. Check pH. Check clarity of soln.

Charge 40kgs. fresh act. Carbon Stir at 92ºC-94ºC for 1 hour Filter the reaction mass in rector through the pp filter press to rector flush the line by air. Charge 200lts D.M.water. Heat to temp. 92oC-94oCFilter through pp filter press to rector Charge 0.5kgs. Sod Hydrosulphite Cool reaction mass in rector to RT by jacket cooling water & then to 8ºC-10ºC by chilled water. Centrifuge, spin dry wash each lot with 20lts. chilled DM Water from tank T509B unload the wet cake in bags. Weigh &lable. Charge the wet cake in FBD/ TD & dry at 85oC till LOD is < 0.5%

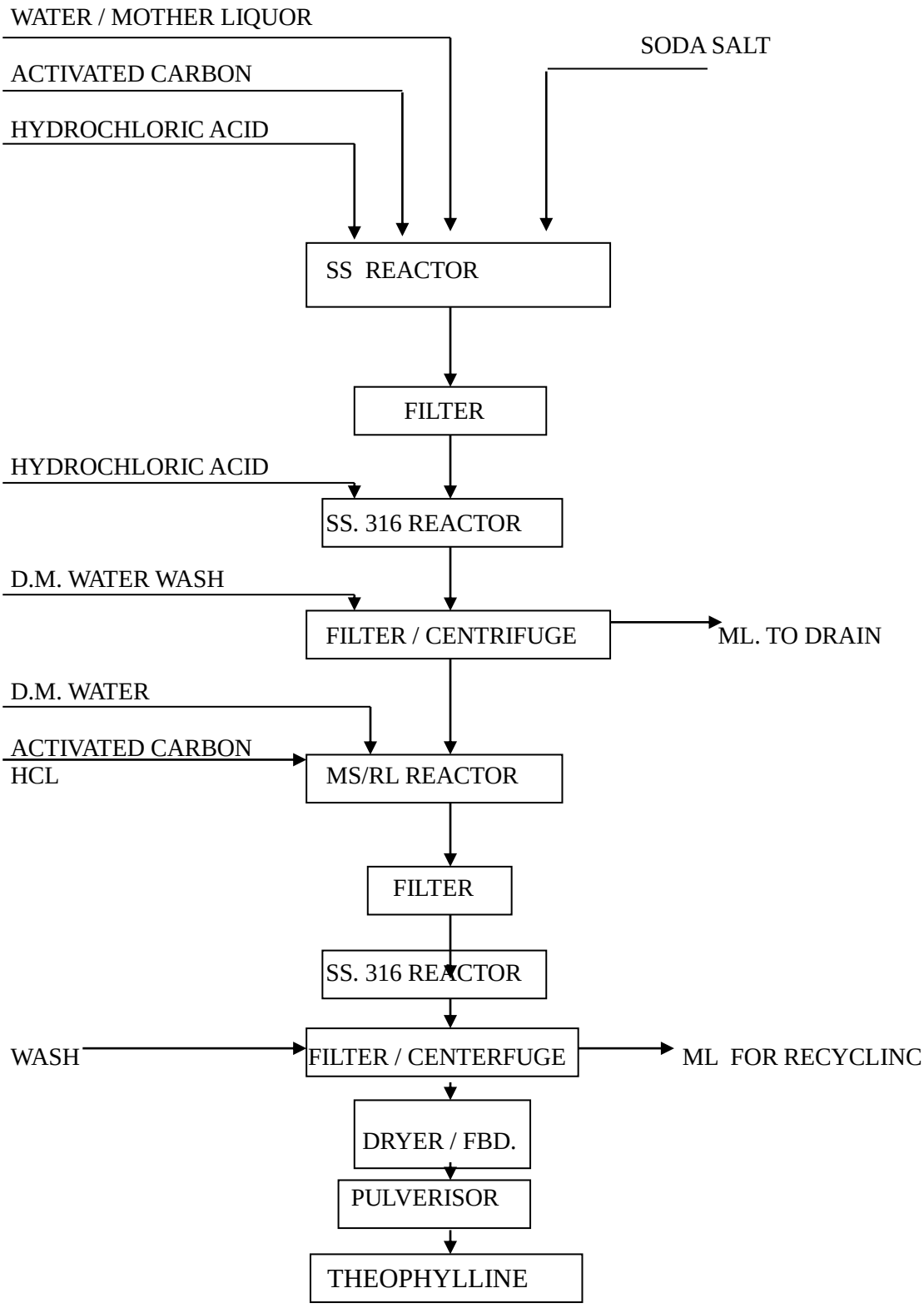
Reaction:

$$C_6H_{10}N_4O_2 \xrightarrow{\text{Ring closer}} C_7H_8N_4O_2$$

Material Balance:

Input	**Kg per batch**	**Output**	**Kg per batch**
Soda Salt	800	Wet Material(Crude)	500
Hydrochloric Acid 30%	500	Solid Waste(Carbon)	10
Activated Carbon	40	Effluent ML	2330
D.M. Water	1500	Product	500
Water	2000	Solid Waste	10
Wet Material (Crude)	500	Effluent ML	2030
Activated Carbon	40		
Total	**5380.0**		**5380.0**

Process Flow Diagram:



3.5.5 Theobromine

Manufacturing process:

Stage I: CAMU

Check the Rector, it should be clean & dry. Charge the cyano acetic acid at room temperature & give the sample to Q.C for M.C. Charge the Acetic anhydride at room temperature under stirring & give the sample to QC for MC. Slowly rise the temperature to 60 to 65 ºC. Start the

addition of mono methyl urea by scoop in 1-11/2 hr at 60 to 75 ºC. Caution :- Reaction is highly exothermic apply water in the jacket if temp rises more than 75 ºC. After addition of MMU rise the temperature to 88-90ºC & maintain the temperature 88-90ºC for 2 ½ hr

Cool the rector to 45-50ºC. Apply high vacuum & distilled out Acetic Acid completely below 80ºC. Charge the 2000 lits. Water in the rector .cool the reaction mass to 25- 30ºC & stir for 1 hr. Centrifuge /NF the material & check ML in lab for clarity & wash the cake perfectly with 200-300 lits of water for each lot. Spin / suck dry material for 1 hr Unload the material in to clean polythene bags & give the sample to QC for LOD & MR. Affix lables on each bag.

Stage II: AMU

Check the rector it should be clean & ready to use. Charge water by using water meter. Charge caustic lye / flakes. Cool the rector to 10-15ºC. Add CAMU slowly scoop wise between 10-25ºC. Maintain the reaction mass for 2 hrs at 25-28ºC temp. Charge water

8. Adjust PH of the reaction mass to 6.5 to7.5 with HCL Temperature should not go more than 45-50ºC apply cooling during HCL addition. Start the centrifuging Note:- Ensure that operator should wear safety Face shield, hand gloves & mask.

Check the centrifuge bag & fix it. It should be dry. Fill the lot & check ML it should be clear. Spin for 30-+10 min. Wash the cake with 200 lits of water. Spin for 1 hr. Stop centrifuge machine & give sample to QC for LOD & unload the product in dedicated HDPE bag & affix labels on each bag.

Stage III: ABMU

Check the rector it should be clean & ready to use. Charge DM water at room temperature & check pH. Charge AMU at RT & check pH. Charge Acetic Acid at RT & check pH. Cool the reaction mass to10-12ºC. Charge Bromine slowly between 10to 17ºC temperature & give sample to QC. Note:- Ensure that operator should wear safety Face shield, hand gloves& mask. Rise the temperature 18to 21ºC & maintain the reaction for 2hrs

Between 18 to 21ºC. Slowly add H2O2 by siphon between 20to 24ºC in 1-11/2hr. Maintain the reaction at 20 to 24ºC temp for 10-12hrs.&check TLC. Start the centrifuging.

Note:- Ensure that operator should wear safety Face shield, hand gloves & mask.

Check the centrifuge bag & fix it. It should be dry. Fill the lot & check ML it should be clear. Spin for 30-+10 min. Wash the cake with 200 lits of water. Spin for 1 hr. Stop centrifuge machine &give sample to QC for LOD & unload the product in dedicated HDPE bag & affix labels on each bag.

Stage IV: NMU

Note: ABMU is Purchased by Open Market

Check the rector it should be clean & ready for use. Charge MMA solution & give sample to QC for analysis. Charge ABMU wet material at RT & give sample to QC for MMA% Cool the reaction mass to 10ºC. Start MMA gas purging into the rector between 10 -20ºC at the rate of 10-15 kg per hr. Check the percentage of MMA. Heat to 105ºC distilled out water. Cool to 50ºC Chilled to 10ºC & Centrifuge. Spin dry the material & unload the material in HDPE bags. Weigh the material &give the composite sample to lab.

Stage V:Theobromine Crude

Check the rector. Charge water at 25 Deg. 750 Ltr. Charge NMU Wet. Material at 25 Deg. Charge Formic acid 25 to 30 Deg. Check pH 3 – 3.2. Raise the temp. To 92 –95 Deg. Maintain the temp for 2hrs at 92-95 Deg.Charge water 500 Ltrs. Charge Lye solution till clear solution is obtained check pH. It should be 12.5 to 12.8. Raise the temp to 92 –95 Deg. Maintain the temp for 2hrs at 92-95 Deg. Give the Sample to for TLC. Cool the reaction mass to 50-55 Deg. Add 10% H2SO4, pH 12– 12.2. Maintain the reaction for 60 mts. Charge EDTA & Carbon at 50-55 deg. Maintain the reaction for 45 mts. Filter the Reaction mass Intorector check for carbon particles. Charge 100 lts water +5 lts of C.S .lye in rector And filter the reaction mass in to the rector. Charge the Solution in rector. Prepare 15- 20% w/w H2SO4. Adjust the ph of the reaction mass to 10.0 –10.2 with the H2SO4.(DIL) Maintain the reaction mass for 1hrs And confirm the pH. Centrifuge the material and wash the cake with 200 lts of water. Spin dry the material & unload the material in HDPE bags. Weigh the material &give the composite sample to lab.

Stage VI: Theobromine Pure

Charge D.M. Water in rector. Charge Theobromine crude. Charge 48% Caustic Lye till solution is clear. Check the clarity and pH. Stir for 15 mts. Charge Activated Carbon. Maintain for 1 hour at 50 dig. Filter through F.P. and collect the filtrate in rector. Wash the leaf with 200 Ltrs. of water. Collect washing ML into Rector. Add 2.50 Kgs of Hydrose in 10 ltrs. Of water and EDTA to reaction mass. Maintain for ½ hour. Adjust the ph of the reaction mass with 10-15 % H2SO4 to 10.0 – 10.2. Stir for 30 mts and confirm the pH cool to RT. Centrifuge the material and wash the cake with DM water till sulphates Nil. Spin dry the material and Unload the material into Clean HDPE Bags. Load the material in a tray drier and dry the material till moisture content 0.05%

Reactions:

$C_5H_6BrN_3O_2$ (Aminobromo methyl uracil) $\xrightarrow{CH_3NH_2}$ (Methylation) $C_6H_{10}N_2O_2$ (N-Methyl uracil)

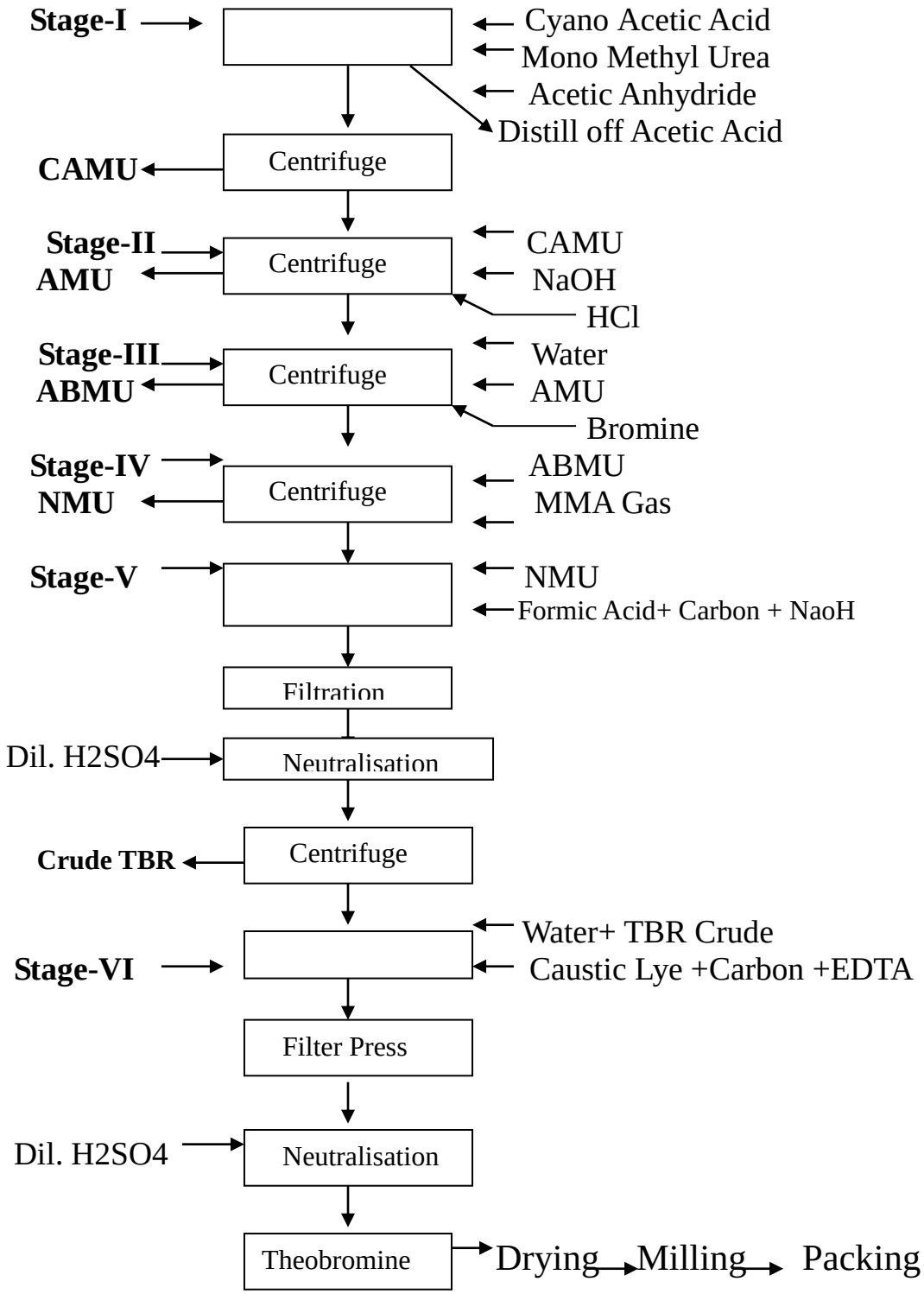
$C_6H_{10}N_2O_2$ (N-Methyl uracil) + HCOOH (Formic acid) + NaOH (caustic lye) $\longrightarrow$ $C_7H_7N_4O_2$ (Theobromine crude)

$C_7H_7N_4O_2$ (Theobromine crude) + HCL $\longrightarrow$ $C_7H_8N_4O_2$ (Theobromine Pure) + NaCl + H_2O

Material Balance:

Input	**Quantity per/batch (kg)**	**Output**	**Quantity per/batch (kg)**
ABMU	1100	N-MU Wet material	600
MMA solution	500	MMA Solution Recovery	900
MMA Gas	500	Centrifuge ml	600
Total	**2100**	**-**	**2100**
N-MU Wet material	600	Crude Material	800
Water	600	Cf effluent ml	1745
Formic Acid	250	Solid waste carbon	35
Caustic lye	200		
Act carbon	30		
Water washing	900		
Total	**2580**	**-**	**2580**
Water	2500	Wet Material(Pure)	550
Crude Material	800	Cf effluent ml	4546
Caustic lye	150	Solid waste carbon	35
Carbon	30		
Ethylene Diamine Tetra Acetic Acid	1		
Sulphuric acid	150		
Water washing	1500		
Total	**5131**	**-**	**5131**

Process Flow Diagram:



3.5.6 Ethyl Cyano Acetate

Manufacturing process:

In a Glass lined reactor Charge cyano acetic acid and add Ethanol, sulphuric acid at room temperature. Heat the reaction to reflux and remove water by azetrope . After complete removal water ,Maintain the reaction for 2 hrs at 74-70 Deg. After complete removal of water distil the product by applying low vacuum. Continuously give the sample to G.C till the product purity

reaches to 98%.After attaining its purity change the receiver and collect the main fraction and packed in 200 lts HDPE drums.

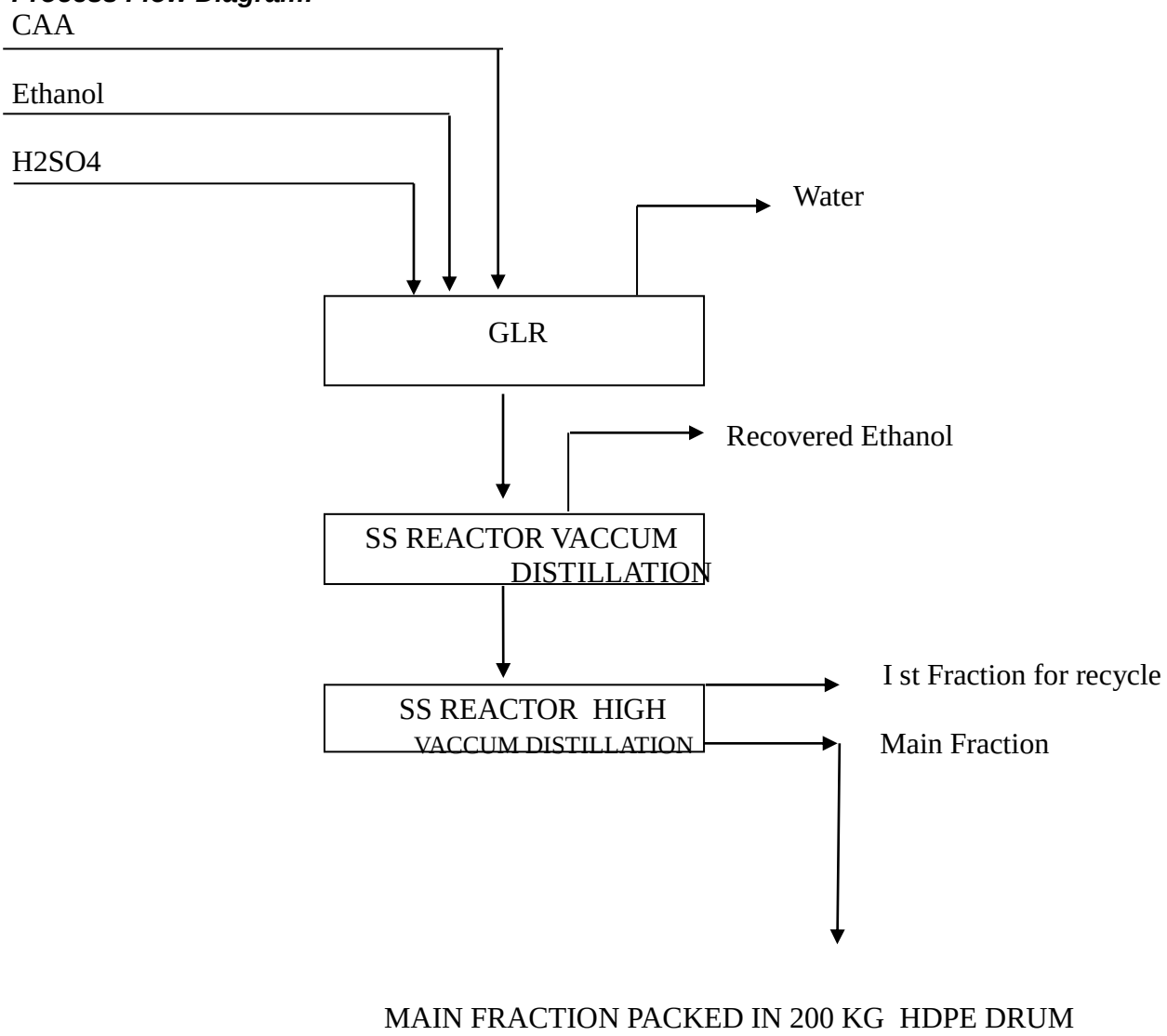
Reaction:

$$C_2H_5OH + CNCH_2COOH \longrightarrow CNCH_2COOC_2H_5 + H_2O$$

Material balance:

Input	Kg. per batch	Output	Kg. per batch
Cyano acetic acid	500.0	Product	650.0
Ethanol	600.0	Recoverd ethanol	276.0
Sulphuric acid	5.0	Fumigation loss	65.0
		Water	114.0
Total	**1105.0**		**1105.0**

Process Flow Diagram:



3.5.7 Methylcyano Atacete

Manufacturing process:

In a Glass lined reactor Charge cyano acetic acid solution and add Methanol , sulphuric acid at room temperature. Heat the reaction to reflux and remove water by azetrope. After complete removal of water, maintain the reaction for 2 hrs at 68-70 Deg. After complete removal of water distil the product by applying low vacuum. Continuously give the sample to G.C till the product purity reaches to 98%.After attaining its purity change the receiver and collect the main fraction and packed in 200 lts HDPE drums.

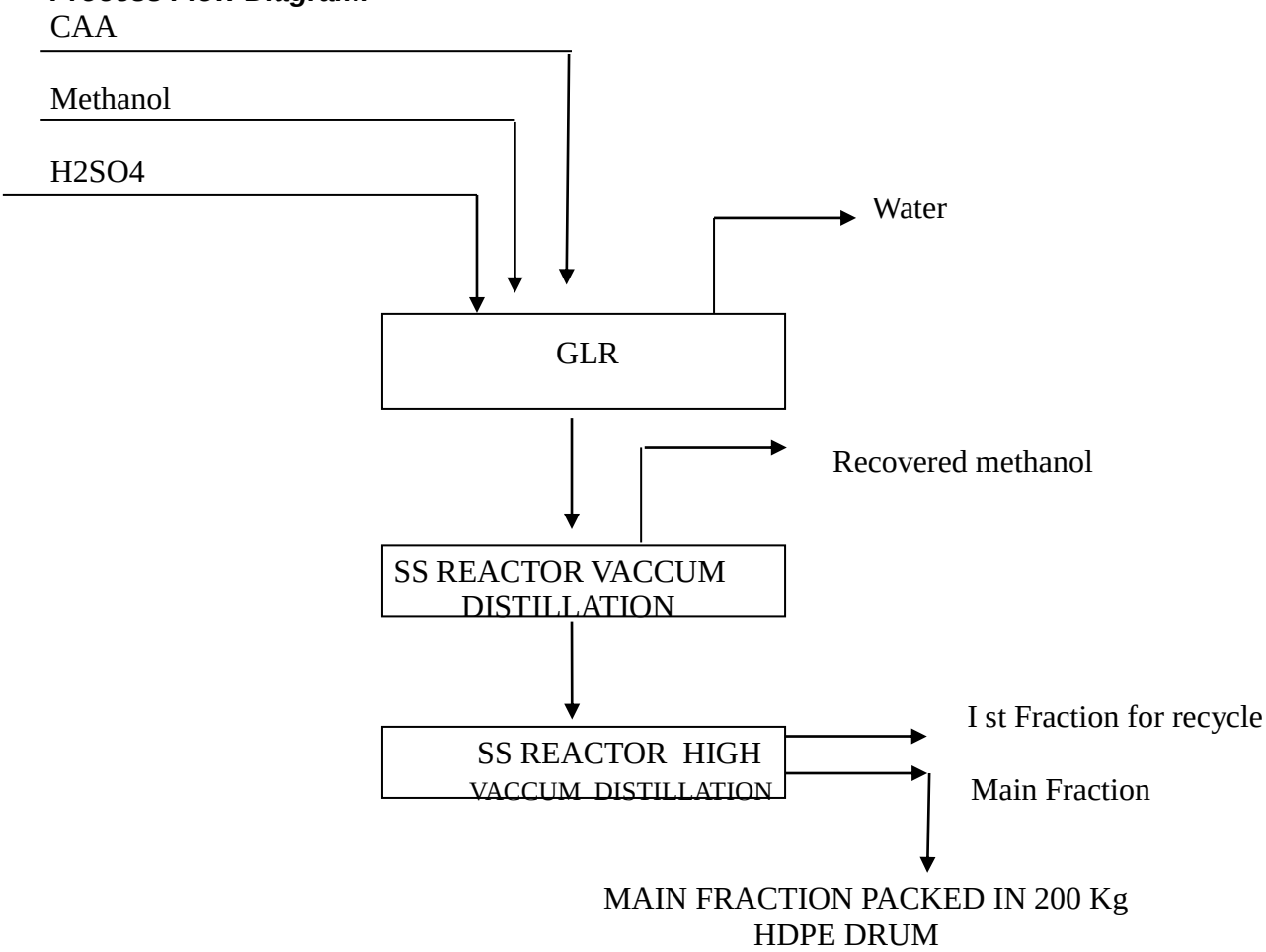
Reaction:

$$CH_3OH + CNCH_2COOH \longrightarrow CNCH_2COOCH_3 + H_2O$$

Material balance:

Input	Kg. per batch	Output	Kg. per batch
Cyanoacetic acid	500.0	Product	580.0
Methanol	600.0	Recovered mehtanol	380.0
Sulphuricacid	5.0	Fumigation loss	31.0
		Water	114.0
Total	**1105.0**		**1105.0**

Process Flow Diagram:



3.5.8 Cyanoacetamide

Manufacturing process:

In a Glass lined/ss reactor prepare 25%ammonia solution cool the mass at 0-5 Deg. Add slowly methyl cyano acetate at 10-15 Deg. Filter the product and wash the cake with chilled methanol .Dry the product in a tray drier and packed in 25 kgs fibre drums. Collect all the mother liquor for methanol recovery.

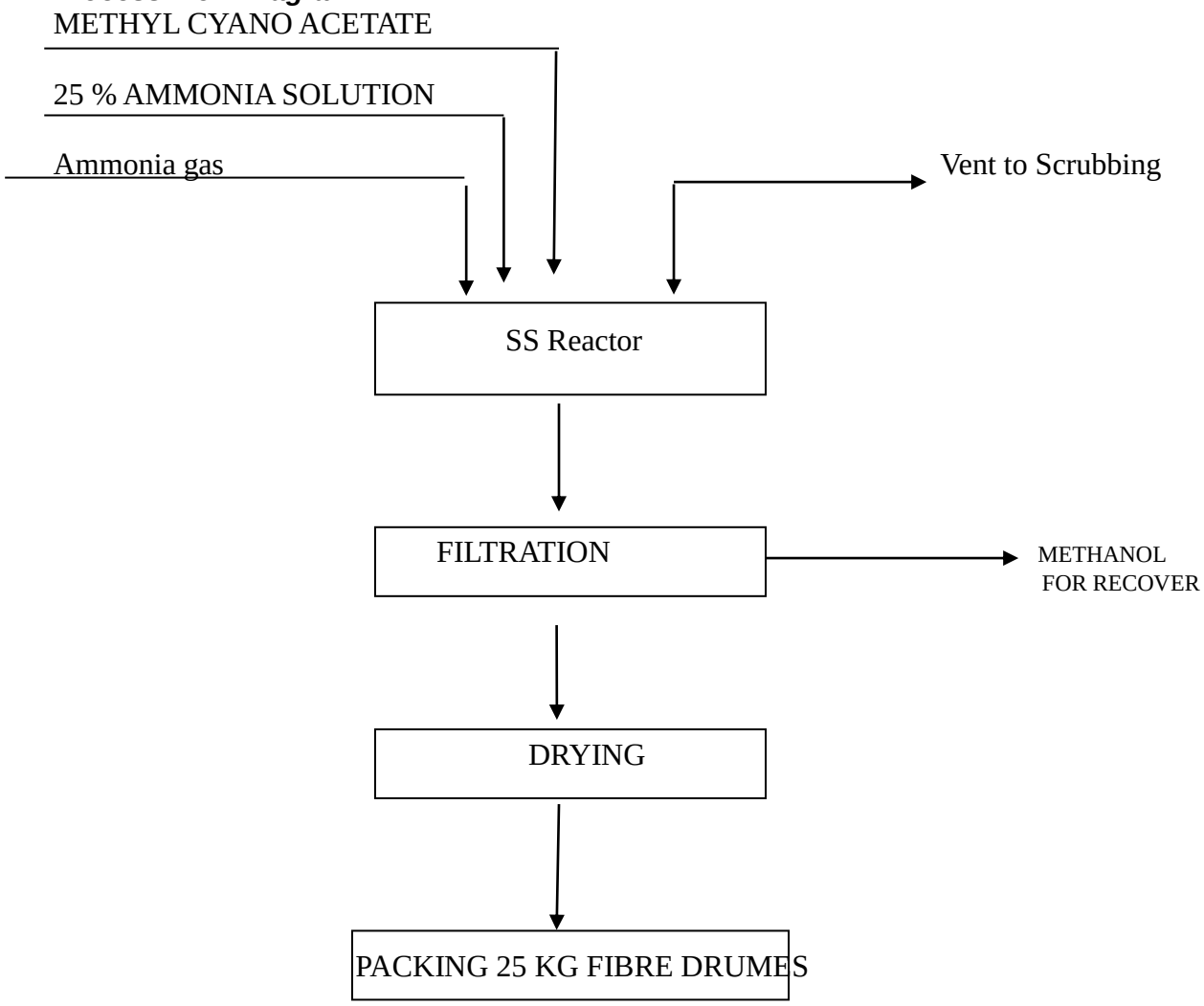
Reaction:

$CNCH_2COOCH_3 + NH_4OH$ $CNCH_2CONH_2 + CH_3OH + H_2O$

Material balance:

Input	Kg. per batch	Output	Kg. per batch
Methylcyanoacetate	400.0	Product	339.0
Ammonia gas	35.0	Recovered methanol	346.0
Water	250.0		
Total	**685.0**		**685.0**

Process Flow Diagram:



3.5.9 Metformin hydrochloride

Manufacturing process:

In a glass lined reactor charge Dimethyl acetamide, DCDA, DMA HCl.

Slowly heat the reaction to 60°C-70 °C .Check the clear solution.

Maintain for 30 min .Again heat the reactor slowly to 140 °C -142 °C.

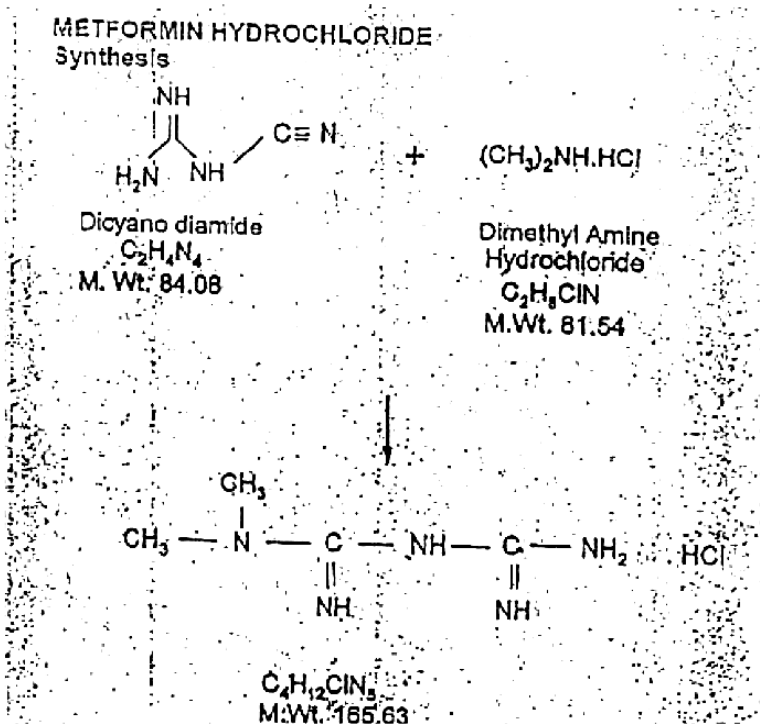
and maintain the temperature for 6 Hrs.

Cool to 60 – 70 charcoline.The mass and filter through the sparkler into SS Reactor

and wash the cake with Dimethyl acetamide.

Cool to RT and filter the cake and dry the material in FBD and Packed in Fiber drums.

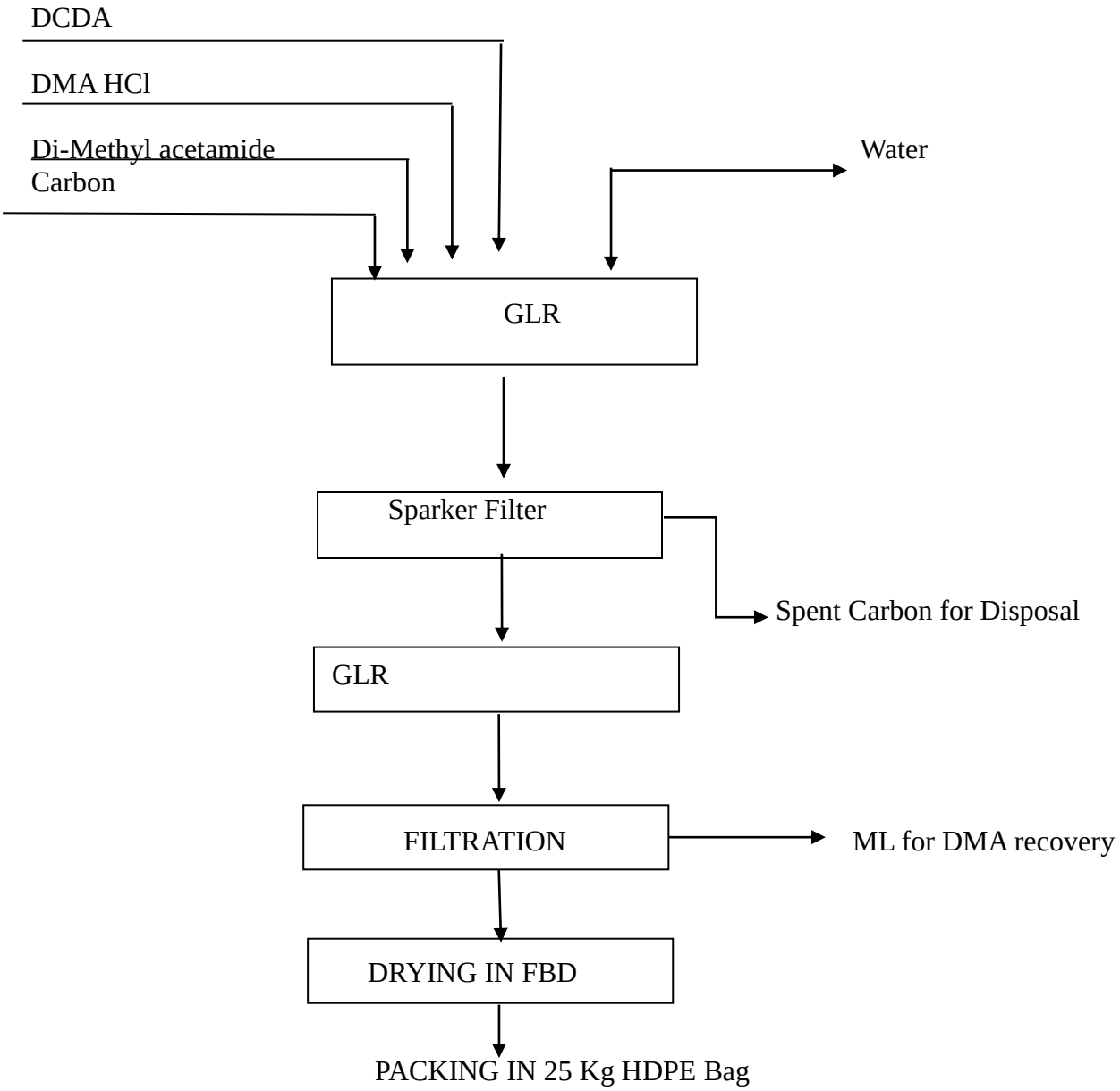
Reaction:



Material balance:

Input	Kg. per batch	Output	Kg. per batch
Dcda	1150.0	Product	2100
Dmahcl	1340.0	Recovered dimethyl acetamide	3215
Dimethyl acetamide	3280.0	Fumigation loss	65
Carbon	5.0	Spent carbon	5.0
		Solvent residue	390.0
Total	**5775.0**		**5775.0**

Process Flow Diagram:



3.6 Raw Material required along with estimated quantity, likely source, marketing area offinal product/s, mode of transport of raw material and Finished product.

We will procure the raw material from domestic market by roads. Finished Product will be transported using roadways.

Table 1.2 List of Raw Material

Sr. No.	Product Name	Raw Materials required	Quantity, MT/M	Physical form (Solid/Liquid)	Storage Condition	Capacity of storage condition
1	Cyano Acetic Acid	Sodium Cyanide (NaCN)	50	Solid	Metal Drums	15 MT
		Sodium Mono Chloro Acetic Acid (SMCA)	150	Sold	HDPE Bags	30 MT
		Sulphuric Acid (H_2SO_4)	80	Liquid	MSTank	15 KL
		Carbon	0.4	Solid	Bags	03 MT
		Sodium Hydrosulphite	0.4	Solid	Bags	01 MT
		Ethylene Di Amine Tetra Acetic Acid	0.2	Solid	HDPE Drums	50 KGs
		Methyl Iso Butyl Ketone	20	Liquid	Tank	12 KL
		Acetone	3	Liquid	HDPE Drums	01 MT
		N-Hexane	2	Liquid	HDPE Drums	01 MT
2	Cyclohexanyle Acetonitrile (Alkyle Nitrile)	Cyano Acetic Acid	30.00	Solid	HDPE Bags	20 MT
		Cyclohexanone	34.00	Liquid	HDPE Bags	12 MT
		Ammonium Acetate	1.00	Solid	HDPE Bags	02 MT
		8-Hydroxy Quinolene	0.006	Solid	HDPE Bags	0.5 MT
		Soda Ash	1.00	Solid	HDPE Bags	02 MT
3	Caffiene	Soda Salt	6.0	Solid	HDPE Drms	04 MT
		Di-Mithyl Sulphate	3.0	Liquid	HDPE Barrels	1.6 MT
		Hydrochloric Acid	0.1	Liquid	FRPTank	15 KL

Sr. No.	Product Name	Raw Materials required	Quantity, MT/M	Physical form (Solid/Liquid)	Storage Condition	Capacity of storage condition
		Caustic Flake	0.1	Solid	HDPE Bags	01 MT
		Activeted Carbon	0.5	Solid	HDPE Bags	03 MT
4	Theophylline	Soda Salt	6	Solid	HDPE Drums	04 MT
		Hydrochloric Acid	2	Liquid	FRP Tank	15 KL
		Activeted Carbon	2	Solid	HDPE Bags	03 MT
5	Theobromine	ABMU	10.00	Solid	HDPE Bags	05 MT
		Mono Methyl Amine Gas	10.00	Gas	Cylinder	500*2=01 MT
		Formic Acid	2.40	Liquid	HDPE Carboys	03 MT
		Caustic Flakes	3.00	Solid	HDPE Bags	04 MT
		Hydrochloric Acid	0.12	Liquid	Tank	15 KL
		Carbon	0.60	Solid	HDPE Bags	03 MT
		Ethylene Di Amine Tetra Acetic Acid	0.01	Solid	HDPE Drums	50 KGs
		Sulphuric Acid	3.60	Liquid	MS Tank	15 KL
6	Ethyl Cyano Acetate	Cyano Acetic Acid	5.00	Solid	HDPE Bags	2.50 MT
		Ethanol	6.00	Liquid	MS Drums	3.00 MT
		Sulphuric Acid	0.050	Liquid	MS Tank	15 KL
7	Methyl Cyano Acetate	Cyano Acetic Acid	5.00	Solid	HDPE Bags	2.50 MT
		Methanol	6.00	Liquid	MS Drums	3.00 MT
		Sulphuric Acid	0.050	Liquid	MS Tank	15 KL
8	Cyano Acetamide	Methyl Cyano Acetate	2.40	Liquid	HDPE Drums	2.40 MT
		Ammonia Gas	0.210	Gas	Cylinder	0.210 MT

Sr. No.	Product Name	Raw Materials required	Quantity, MT/M	Physical form (Solid/Liquid)	Storage Condition	Capacity of storage condition
9	Metformin Hydrochloride	DCDA	5.75	Liquid	HDPE Drums	4.00 MT
		DMA HCL	6.70	Liquid	HDPE Drums	4.00 MT
		Di-methyl Acetamide	16.40	Solid	HDPE Bags	10.00 MT
		Carbon	0.025	Solid	HDPE Bags	0.40 MT

3.7 Resource optimization/recycling and reuse envisaged in the project, if any, should be briefly outlined.

After set up of unit, every effort will put to recycle/reuse the solvents. Wastewater will be treated in proposed ETP and will be sent to CETP for further treatment.

3.8 Availability of water its source, energy/power requirement and source

3.8.1 Water Source

The source of water for the proposed project will meet through MIDC water supply. Total water requirement for the proposed project will be 51.9 KLD. The total wastewater generation from Industrial will be 34.30 KLD, while 1.12 KLD domestic effluentwill be generated.

Table 1.3 Water Requirement & Wastewater Generation

Sr. No.	Purpose	Water Consumption, KLD	Wastewater Generation, KLD
1	Domestic (Including Flushing)	1.4	1.12
2	Gardening	5.0	0.0
3	Industrial		
a.	*RO & DM*	21.00	6.30
	Industrial Processing	14.70	23.22
b.	*Industrial cooling*	6.0	0.24
c.	*Boiler*	13.5	0.54
d.	*Chiller*	1.0	0.0
e.	*Washing (Equipment +Floor Washing)*	4.00	4.00
Total (Industrial)		***45.5***	***34.30***
Total (1+2+3)		**51.9**	**35.42**

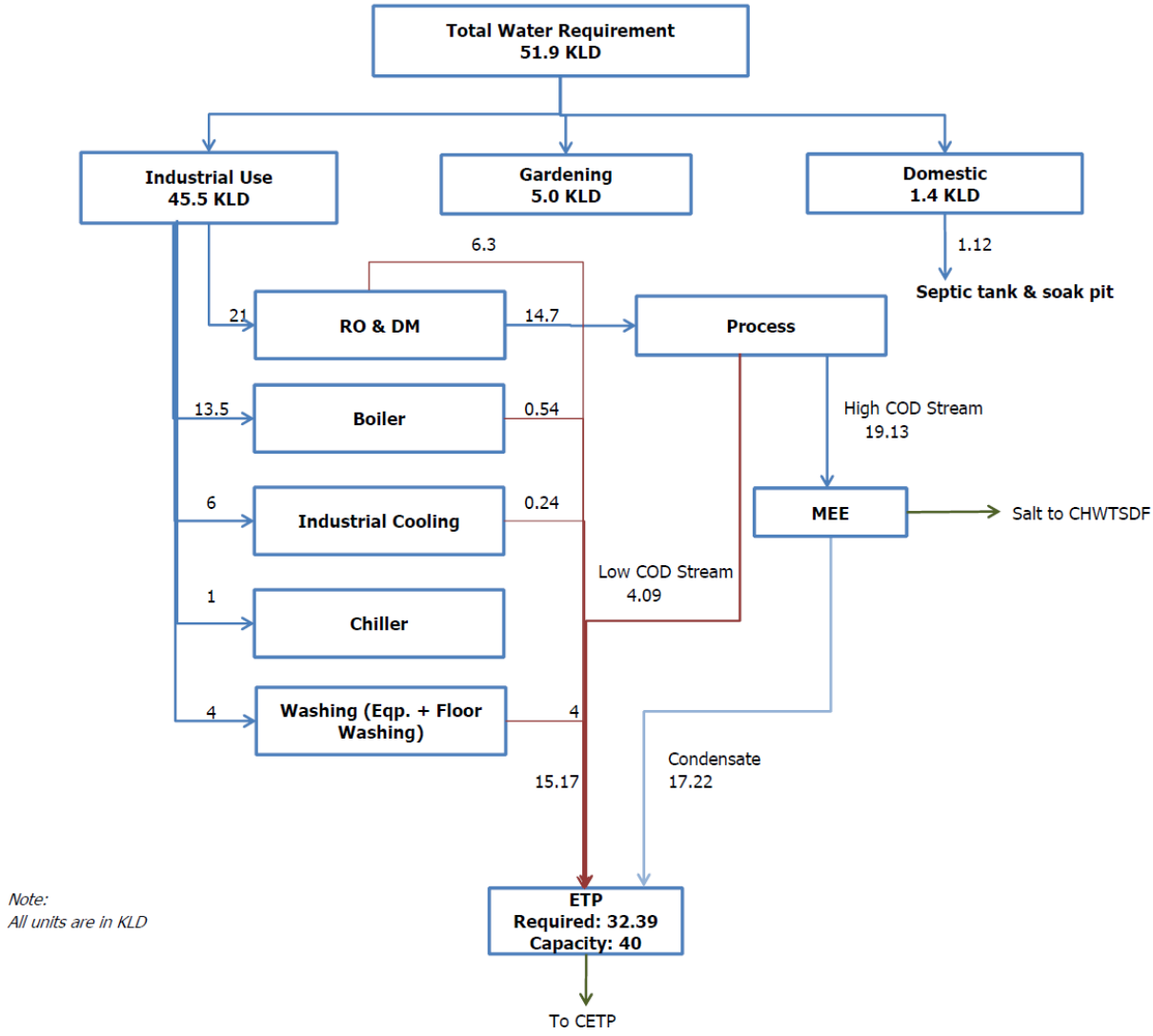


Figure 1.5 **Water Balance Diagram**

3.8.2 Electricity Requirement

Electricity shall be obtained from MSEDCL. Agro waste will be used as a fuel for Boiler and Diesel will be used as a fuel for D.G set. The total power & fuel requirement for the proposed projectis given in below table:

Table 1.4 Electricity requirement

S. No.	Source	Proposed
1.	MSEDCL	250 KVA
2.	D.G Set (Stand By)	250 KVA

3.8.3 Fuel requirement

Table 1.5 Fuel Requirement

Sr. No	Particulars	Capacity	Name of Fuel	Fuel Quantity
1	Boiler	1.5 TPH	Briquette	3.0 MT/day
2	D.G. Set	250 KVA	Diesel	50 Litres/hr

3.8.4 Stack details

Table 1.6 Details of Flue gas Stacks

Sr. No	Stack attached to	Capacity	Fuel consumption	Stack Ht. (m)	Stack Dia. (m)	Stack gas temp (˚C)	APCM
1.	Boiler	1.5 TPH	Briquette-3 MT/day	30.00	0.5	110	Multi cyclone separator followed by Bag filter
2.	DG set	250 KVA	Diesel – 50 Litres/hr	13.00	0.15	120	Adequate stack height

Table 1.7 Details of Process gas Stacks

Sr. No	Stack attached to	Capacity	Stack Ht. (m)	Stack Dia. (mm)	Stack gas temp (˚C)
1.	Scrubber (Process Reactor)	3000 CFM x 3 Nos.	14	150 mm	Ambient

3.9 Quantity of wastes to be generated (liquid and solid) and scheme for their management/Disposal

3.9.1 Waste Water generation & Management plan

The total wastewater generation from industrial process will be 34.30 KLD, which will be segregated into high COD and low COD streams. High COD stream will be treated in MEE and condensate will be sent to ETP for further treatment, while low COD stream will be directly treated in ETP and sent to CETP for further treatment. 1.12 KLD domestic effluents will be disposed through septic tank & soak pit.

3.9.2 Solid & Hazardous waste generation & Management plan

Details of hazardous wastes and non-hazardous wastes are given in below tables:

Table 1.8 Details of Hazardous Waste

Sr. No.	Type of waste	Category	Waste generating process	Physical Characteristics	Quantity	Management
1.	ETP Sludge	34.3	ETP	Solid/Semi-solid	10 Kg/day	Collection, Storage, Transportation, Disposal at TSDF site.
2.	MEE Salts	34.3	MEE	Solid/Semi-solid	600 Kg/day	Collection, Storage, Transportation, Disposal at TSDF site.
3.	Discarded containers/ barrels/liners	33.3	Production processes	-	25 Nos./ Month	Return back to raw material supplier
4.	Used/spent oil	5.1	Machinery & D.G set	Liquid	5 Litres/Month	Sold to authorized reprocessor
5.	Process residue/Bottom fraction	28.1	Process	Solid/Semi-solid	383 Kg/day	Sold to authorized vendor

Table 1.9 Details of Non-hazardous waste

Sr. No.	Type of waste	Quantity	Mode of Disposal
1.	Activated carbon	46.4 kg/day	Sold to Brick manufacturer
2.	Ash	600 Kg/day	Sold to Brick manufacturer
3.	Paper waste	10 Kg/day	Sold to authorized vendor

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

4. SITE ANALYSIS

4.1 Connectivity

- Site is very well connected by road and railway network.

Table 1.10 Environment Settings

Sr. No.	Particulars	Details	Distance, Km	Direction
1	Nearest Village	Chincholikati	1.87	South
2	Nearest Town/City	Solapur	13	SE
3	Nearest Railway Station	Pakani Railway Station	6.50	SSW
4	Nearest Hospital	Primary Hospital	1.9	South
5	Nearest Highway	NH-9	3.4	SSW
		SH-151	6.2	East
6	Nearest Airport	Solapur Airport	20.5	SE
7	Nearest Water Body	Sina River	6.73	SSW
8	Wild Life Sanctuary	The Great Indian Bustard Sanctuary, Nannaj	3.5	NE

4.2 Land Form, Land Use and Land Ownership

Land Form: Proposed project site is within the industrial area (MIDC Chincholi).

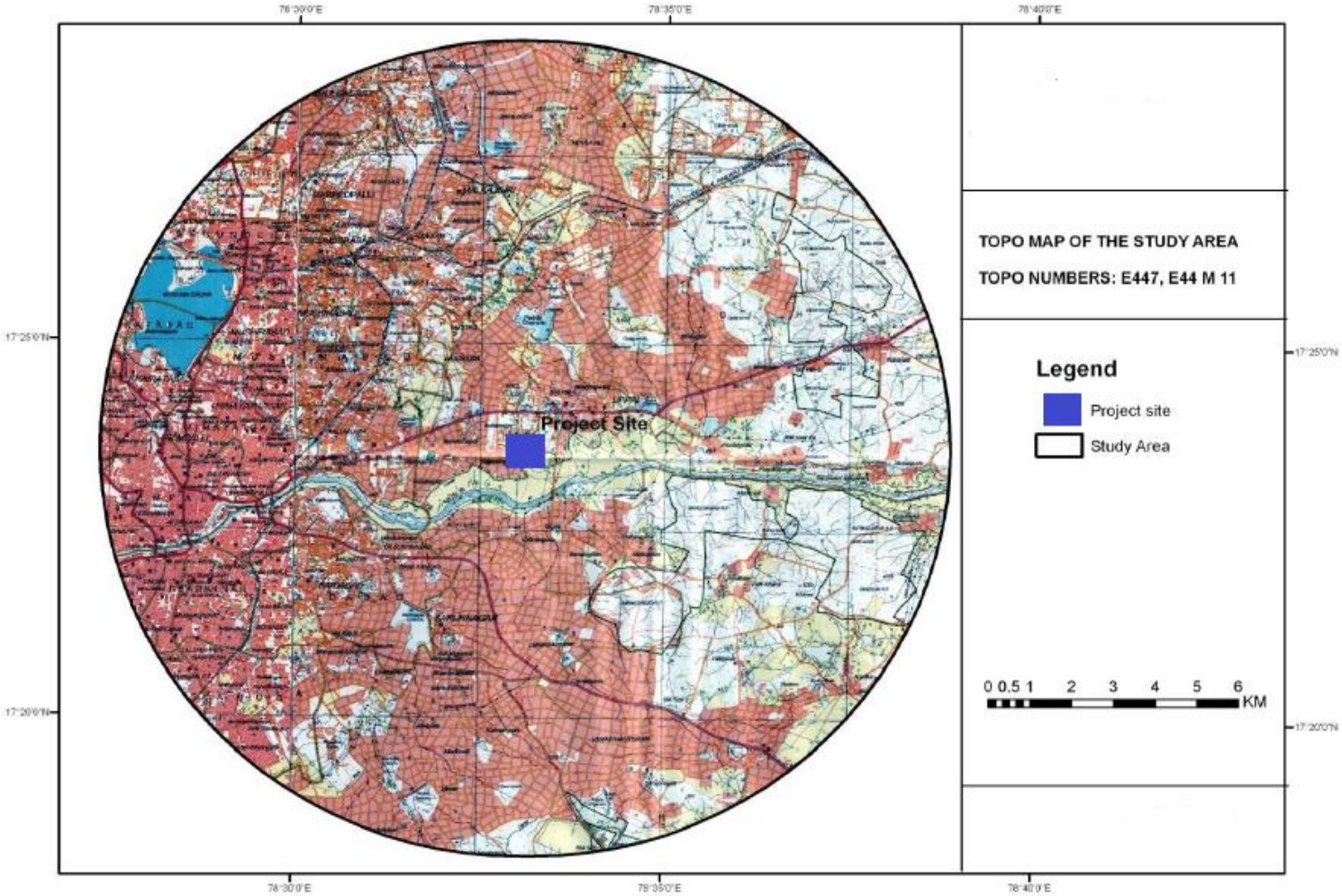
Land use: Industrial purposefor proposed project of Manufacturing of Bulk Drugs, Intermediates & Allied Products.

Land Ownership: Private land on lease basis.

4.3 Topography (along with map).

Project site is located almost in the central part of state of Maharashtra at an altitude of approximately 1975 ft (500 meters) above the sea level. It is bounded by the Solapur hills.

The topography map of the area is given below:



4.4 Existing land use pattern (agriculture, non-agriculture, forest, water bodies (including area under CRZ)), shortest distances from the periphery of the project to periphery of the forests, national park, wild life sanctuary, eco sensitive areas, water bodies (distance from HFL of the river), CRZ. In case of the notified industrial area, a copy of the Gazette notification should be given.

The project falls inside the notified industrial area (MIDC-Chincholi).

The Great Indian Bustard sanctuary, Nannaj islocated 3.5 Km from project site.

CRZ is not applicable to the project.

4.5 Existing Infrastructure

This is new project. Hence, there is no any infrastructure present at site.

4.6 Soil Classification

The soil in the proposed site is mostly brownish black to black colored and clay textured. Detailed soil testing of the industrial premises as well as 10 Km area surrounding the project site would be done in order to assess the existing soil quality. The results of same will be incorporated in final EIA report.

4.7 Climatic data from secondary sources

The climate of the study area and surrounding region is generally dry except in the southwest monsoon season. The year may broadly be divided into four seasons.

Winter season : December to February

Pre-monsoon season : March to May

Monsoon season : June to September

Post monsoon season : October and November

Temperature:

In the months of April and May, it is the period of continuous increase in temperature. May isthe hottest month of the year. The climate of the district is characterized by hot summer andgeneral dryness throughout the year except during the south-west monsoon period, i.e. June to September. The mean minimum and maximum temperatures observed are 14.8°C and 40°C respectively.

Rainfall:

The district gets rainfall from south west monsoon winds. The average annual rainfall overthe district is about 584 mm.

4.8 Social infrastructure available

This proposed project is located at notified MIDC of Chincholi, in Solapur district, Maharashtra. The Site is 13 km from Solapur city and 6.5 km from Pakani railway Station. The land and infrastructure ismade available by MIDC and the raw materials are easily available through easy transport via road connectivity. The site is well connected by the National Highway-9 & State Highway-151.

5. PLANNING BRIEF

5.1 Planning Concept (type of industries, facilities, transportation etc) Town and Country Planning/Development authority classification.

Type of Industry: Proposed Bulk Drugs, Intermediates & Allied products manufacturing company.

5.2 Population Projection

The proposed project would require 15 workers and 16 staff during the operation of the project.

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

Table 1.11 Area Break-up

Sr. No.	Details of Land	Proposed Area (In Sq. m)
1.	Adm. Building & QC lab	168.80
2.	Production block	200.00
3.	Raw material & Finished Goods storage	240.00
4.	Cooling tower	56.00
5.	Ejector system	84.00
6.	Boiler house	155.00
7.	Utility block	155.00
8.	Storage tank Farm	155.00
9.	ETP area	155.00
10.	Green belt	1980.00
11.	Security cabin + Canteen + Change room	124.00
12.	Watchman room	9.00
13.	Parking area	501.00
14.	Open space & Road	2017.2
Total		**6000.00**

5.4 Assessment of Infrastructure Demand (Physical & Social)

On the basis of the preliminary site visit, the infrastructure demand in the villages was assessed on the basis of need and priority. Employment would be as per prevailing norms of state government for skilled andunskilled people for the proposed project activity.

5.5 Amenities/Facilities

Proper site services such as First Aid, Canteen, Drinking Water, Maintenance Workshop, etc. will be provided to the workers.It is proposed to construct one room for labor.

6. PROPOSED INFRASTRUCTURE

6.1 Industrial Area (Processing Area)

Processing Area (Plant facilities, R&D, ETP Area and Utility Services)

Developed Area: 665 Sq.m.

6.2 Residential Area (Non Processing Area)

Non Processing Area (Green belt, Raw material storage area, Admin and open area).

Area: 4406 Sq.m.

6.3 Green Belt

Total 6000 square meters land area at proposed site; out of this 1980 Sq.m. will be used for development of green belt.

6.4 Social Infrastructure

Depending on the growth of the company the required social infrastructure will be provided.

6.5 Connectivity (Traffic and Transportation Road/ Rail/Metro/ Water ways etc)

Road and railways are very close to the working site. There is no proposal to make any new kind of connectivity.

6.6 Drinking water Management (Source & Supply of water)

Water for drinking and operations will be 51.9 KLD, which will be met from MIDC water supply.

6.7 Sewerage System

Domestic waste water will be treated into septic tank followed by soak pit.

6.8 Industrial Waste Management

Please refer section 3.9.2.

6.9 Solid Waste Management

It is proposed that the total wastes will be used for levellingof the worked out area.

6.10 Power Requirement & Supply/Source

Electricity shall be obtained from MSEDCL. The total power requirement for the proposed project is 250 KVA.

7. REHABILITATION AND RESETTLEMENT (R & R) PLAN

7.1 Policy to be adopted (Central/ state) in respect of the project affected persons including home oustees, land oustees and landless labourers

Not Applicable because the proposed project site within the MIDC-Chincholi.

8. PROJECT SCHEDULE & COST ESTIMATES

8.1 Likely date of start of construction and likely date of completion (Time schedule forthe project to be given).

We shall start construction after getting environmental clearance.

8.2 Estimated Project cost along with analysis in terms of economic viability of theproject.

Total Project Cost for proposed project activity is Rs. 4.75 Crores.

9. ANALYSIS OF PROPOSAL (FINAL RECOMMENDATIONS)

9.1 Financial and social benefits with special emphasis on the benefit to be local peopleincluding tribal population, if any, in the area.

The project will be prove time by time for beneficial to the people as the company progress and expands its activity. By CSR activity company management will committed to improve infrastructural facilities for the local people like Educational facilities, Medical facilities, Transportation facilities etc. as well the local people especially tribal population will be taken as employers which will improve the socioeconomic environment of the area.