RACS PHARMACHEM (INDIA) PVT LTD



KIADB INDUSTRIAL AREA, GOWRIBIDANUR, CHIKKABALLAPUR, KARNATAKA-561208.

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## **1. INTRODUCTION**

#### **1.1. ABOUT THE INDUSTRY.**

RACS PHARMACHEM (INDIA) PVT LTD is proposing a new unit for the manufacture of seven(07) synthetic organic chemicals and three(03) bulk drugs along with their intermediate compounds at its plot no IP 13 PART-2, KIADB, Gowribidanur Industrial area,1<sup>st</sup>Phase,Kudumalakunte(village),Gowribidanur(Taluk),Chikkaballapur(Dist), Karnataka state. The extent of the industrial plot is 3300.24 square meters.

The industry has got registered with Registrar of companies Karnataka under the companies act, 1956 as a private limited company in the year 2013. The unit was got allotted the industrial plot no IP 13 PART-2, KIADB, Gowribidanur Industrial Area,1stPhase,Kudamulakunte(village),Gowribidanur(Taluk),Chikkaballapur(Dist), measuring 3300.24 square meters in the KIADB. Through the "Agreement for lease-cum-sale on 15-06-2013 through document BKI 1050/13/u. The gross capital investment on land, building, plant and machinery is about 3.80 crore. The unit allocated 60.00 lakhs for environmental protection measures and the recurring cost on pollution control measures will be about 13.00 lakhs per annum. The present proposal is to obtain the "Environmental clearance" from the 'ministry of Environment and forests' for the manufacture of seven(07) synthetic organic chemicals and three(03) bulk drugs along with their intermediate compounds on campaign basis i.e. any three (03) products will be manufactured at any time based on the market demand.

#### **1.2. PURPOSE OF THE REPORT.**

RACS PHARMACHEM (INDIA) PVT LTD is proposing to install a new unit for the manufacture of seven(07) synthetic organic chemicals and three(03) bulk drugs along with their intermediate compounds at their plot no IP 13 PART-2, KIADB, Gowribidanur Industrial Area, 1<sup>st</sup> phase, Kudamulakunte (village),Gowribidanur (Taluk),Chikkabalapur (Dist) Karnataka State. As per the Environmental impact assessment (EIA) notification SO 1533, dated 14th Sep 2006 of GOI, this proposal is categorized as 5(f) of category "A" and is needed to obtain the ENVIRONMENTAL CLEARANCE from MOE&F of Government of India. In accordance to the same, the FORM 1 along with pre- feasibility report and draft Tor, is being submitted for yours kindful approval.

### **1.3. JUSTIFICATION OF THE PROJECT.**

Bulk drug industry in India was grown and is growing with an amazing rate. Having a strong net work of marketing and sales to promote the exports, good proficiency in cost effective manufacturing technologies, presence of globally operating pharma MNCs, inventing valuable process developments through R&D, Expiry of international patents on some Drug molecules, Indian bulk drug industry has recorded an excellent growth in the recent past. Still there has been an increase in the demand for life-saving drugs in international market. In such a favorable situation, the proponents of this proposal have concluded to manufacture the proposed chemicals which are being mainly consumed by the indigenous bulk drug manufacturers as intermediate chemicals in their drugs manufacturing and pharmaceutical formulations.

The contribution of the unit to the exchequer of our country will help to improve the socio-economic conditions of the people. The unit will provide employment for local people for about 70 members.

#### **1.4. LOCATION OF THE PROJECT.**

RACS PHARMACHEM (INDIA) PVT LTD , was registered in the year 2013 as a private ltd company, having its registered office at 505, block no-32, S-MIG-B, V<sup>th</sup> phase, Yelahanka new town, Banglore-560 064 Karnataka and its manufacturing unit is located at plot no IP 13 PART-2, KIADB, Gowribidanur Industrial Area,1<sup>st</sup> phase, Kudumulakunte(village),Gowribidanur(Taluk), Chikkballapur(Dist), Karnataka State.Presently the registered office was changed to its works address of KIADB industrial area ,Gowribidanur.karnataka-561208.

#### 1.5. LAND FEATURES OF THE PROJECT LAND.

The project site is within the notified Industrial Estate of Karnataka state at Kudumulakunte (village), Gowribidanur (Taluka), Chikkabalapur (Dist). The nearest habitation by name Kudumulakunte (village) is at about 1.5 km radial distance to this industrial area. There are no any ecologically sensitive areas, national parks within 15 km Radial distance to the site. The possessed and developed industrial plot, measuring about 3300.24 square meters is found to sufficient and suitable for the proposed activities. Good road net work, water availability, electrical supply, other technical supporting units, general drainage facilities are provided to this industrial area there by to the unit. The location is about a height of 694 meters to MSL. The location is not a flood prone area. After compare and contrast the land use will be ensured as the environmentally compatible usage with its surroundings.

#### **1.6. PROJECT COST.**

The proposed gross capital investment in land, buildings, plant, machinery etc is about 380 lakhs. Out of this the unit was allocated 60 lakhs towards pollution control measures, green belt development and social welfare activities. The recurring cost of environmental protection measures is about 13 lakhs per annum. The capital investment break-up of the project is as follows;

S,no	Investment on	Investment in
		lakhs
1	LAND & BUILDING	100.00
2	PLANT & MACHINERY	100.00
3	ELECTRICALS&PROCESS FECILITIES	70.00
4	POLLUTION CONTROL EQUIPMENTS	60.00
	& MEASURES	
5	PLANT ERECTION & COMMISSION	30.00
6	CONTINGENCIES	20.00
	TOTAL	380.00

### 1.7. PROPOSED PRODUCTS AND THEIR CAPACITIES FOR WHICH ENVIRONMENTAL CLEARANCE IS SOLICITED.

S.NO	Names of the products proposed for the manufacture	Capacity in TPA
1	2- CHLOROPHENOTHIAZINE	12
2	3- CHLORO IMINODIBENZYL	06
3	2-METHYL BENZOPHENONE	24
4	ETHYL AMYL KETONE	12
5	TERTIARY BUTYL BENZENE 24	
6	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2- FLUORO PHENYL)1H-1,4 –BENZODIAZEPINE. 2.4	
7	IMINODIBENZYL.	06
8	OMEPRAZOLE. 24	
9	LANSOPRAZOLE. 12	
10	ESOMEPRAZOLE. 12	
	TOTAL	134.40

Any three (03) products out of ten proposed products will be manufactured at a time on campaign basis.

# **1.8. RESOURCES OF TECHNOLOGY (RAW MATERIALS, PROCESSING TECHNOLOGY, PLANT AND MACHINERY).**

The Technical know-how about raw material procurement, manufacturing process technologies, quality tests, plant and machinery, required for the manufacture of the proposed products is present with the management and will be sufficiently available indigenously. Plant and machinery will be fabricated by local fabricating industries. The raw material requirement will be sourced from the indigenous manufacturers.

#### **1.9. TECHNO-ECONOMIC FEASIBILITY OF THE PROJECT.**

The project management has identified that there are about 30 units making bulk drugs for national and export markets in and around Karnataka. Most of these units are being used the products which have been proposed by this project to make in this region. Presences of the following factors rationally assure the techno-economic feasibility of the project.

Abundant availability of necessary technical experts, skilled operators and workers for operation of the project.

Availability of required electrical power from Karnataka state electricity department.

The expected capacity utilization of the plant will be as follows; 50% in the first year of operation; 70% in the second year of operation and 80% in and after the third year of operation. The breakeven of the project is calculated to 50% of capacity utilization.

The plot is provided with all industrial infrastructure facilities like approach roads, district and state high ways, Water availability by KIADB( Karnataka industrial area development board) of Karnataka state.

Presence of requisite number of consumer industries for the produced products nearby to the proposed unit.

Availability of key raw materials and plant machinery indigenously.

Utilization of trained and experienced man power, internal common infrastructural and industrial utility facilities multi purposely.

#### **1.10. SOCIO-ECONOMIC BENEFIT BY THE PROJECT.**

The organization along with neighbor industries will contribute to the development of public amenities of this area. The management will provide some employment to the educated local people for about 70 members. The contribution of the unit to the exchequer of our country will help to improve the socio-economic conditions of the people.

#### 1.11. ABOUT THE PROJECT PROPONENT.

The industry will be leaded by its Managing director sri ch.Jagannadha Raju, post Graduate in chemical science, and having an industrial experience of 20 years in various executive levels and he is well versed in the manufacturing technologies of drugs & pharmaceuticals, technical maintenance of industry, having good awareness about pollution and environmental aspects. To execute and monitor the project operations, persons with educational and technical qualifications will be appointed. Employee's participation will be encouraged for the growth of the organization and society. Transparent management policies will be practiced in the organization for good and smooth running of the unit.

## **2. PROJECT DESCRIPTION**

#### 2.1. LAND USE AND BUILT-UP REQUIREMENT.

To perform various operations of the proposed project viz storage of raw materials and finished goods, to execute the activities concerned to the manufacture of proposed products ,to accommodate the utility machinery and processing equipment of the plant and to provide the domesticity to the employees, civil constructions are needed to the project. The calculated built-up requirement for these purposes is about 1125.00 Square meters. The total area of the plot is measuring to 3300.24 square meters. 1124.75 square meters (34% of total plot area) was allotted for green belt development. The required built-up areas and their utilization were given below.

S.No	NAME/PURPOSE OF CONSTRUCTION	BUILT-UP AREA IN SQUARE METERS
1	PRODUCTION BLOCK (G+1)	450.00
2	FINISHED GOODS & RAW MATERIAL STORES	250.00
3	QC,QA & R&D	85.00
4	ADMN.OFFICE	100.00
5	SECURITY/VISITOR/CANTEEN ROOMS	30.00
6	UTILITY BLOCK	150.00
7	EFFLUENT TREATMENT PLANT	60.00
8	GREEN BELT AREA	1124.75
9	AREA FOR INTERNAL ROADS	532.50
10	OPEN AREA	517.99
	TOTAL	3300.24

#### 2.2. PLANT & MACHINERY REQUIREMENT.

The proposed project requires different kinds of machinery, equipments, auxiliaries and other facilitating systems to produce the proposed products. These are of different kinds in terms of their sizes/material of construction/purposed for etc. All the machinery required by this project is indigenously fabricated. The following is the list of the machinery which will be installed within the project.

S.NO	Name/description of machinery/equipment	Capacity/volume	Quantity to be installed
1	Stain less steel reactor with all of its auxillaries	5000 liters	03 numbers
2	Stain less steel reactor with all of its auxillaries	3000 liters	02 numbers
3	Stain less steel reactor with all of its auxillaries	600 liters	01 number
4	Stain less steel reactor(hydrogenator) with all of its auxillaries	1000 liters	01 number
5	Glass lined Reactor with all of its auxillaries	3000 liters	01 number
6	Stain less steel centrifugals	36 inches(size)	02 numbers
7	SS leaf filter	150 liters	01 number
8	Stain less steel nutche filter	250 liters	01 number
9	Mild steel measuring tanks	1500 liters	02 numbers
10	SS tray driers	48 trays	02 numbers
11	SS Multi mill		01 number
12	SS Blender		01 number
13	SS Swifter		01 number
14	Mild steel storage tanks	15000 liters	02 numbers
15	Freon based chilling plant	30 TR	01 number
16	150 KVA DG Set	150 KVA	01 number
17	Cooling Tower	300 TR	01 number
18	Cooling Tower	150 TR	01 number
19	Coal fired Boiler with pollution control equipment	1 TPH	01 number
20	Diesel fired Boiler with pollution control equipment	1 TPH	01 number
21	Thermic fluid Heater with pollution control equipment	2 lakhs Kicals/hour	01 number
22	Analytical(quality) testing equipments		
23	Forced evaporation system	3000 liters	01 number
24	Effluent storage and treatment tanks	5000 liters	04 numbers
25	Material weighing balances	600 kg	02 numbers
26	Material packing equipment		

#### 2.3. POWER AND FUEL REQUIREMENTS.

The electrical power requirement for this project is estimated to 250 KW. This entire amount will be got sanctioned from the State electricity board of Karnataka state.150 KVA DG set will be installed as a stand by source for power while power failures occur. In addition to this 02 TPD (tones per day) coal is needed for the purpose of steam generating boiler, and it will be sourced from the local vendors. The consumption of diesel by the DG set per hour will be 16 liters but its usage is very minimal extent.

#### 2.4. WATER REQUIREMENT:

The water requirement to cater the various needs of the project in operational phase is estimated to a maximum of 08.40 KLD and it will be sourced from the outside vendors. The water consumption (08.40 KLD) is maximum while producing the group of products or product mix (03 products out of 10 products) with the product omeprazole, otherwise i.e ; exclusive of product Omeprazole it will be about 06.00 KLD. The consumption breakup of water is given below:

CONSUMING DEPARTMENT	CONSUMING FOR	CONSUMPTION IN KLD
	IN THE MANUFACTURE OF PROPOSED PRODUCTS	1.50
BBODICTION	PROCESS WASH	0.50
PRODUCTION	FOR THE SCRUBBING OF	
	GASEOUS EMISSIONS OF	0.60
	PROCESS	
	STEAM GENERATING BOILERS	3.00
PLANT UTILITIES	COOLING TOWERS	1.00
	WATER VACCUM PUMPS	0.30
DOMESTIC	DRINKING,BODY WASH &TOILETS	0.60
GARDENING & ASH QUENCH	WATERING OF PLANTS, FLY ASH WETTING.	0.90
	TOTAL	8.40

# 2.5. QUANTITY REQUIREMENT OF KEY RAW MATERIALS FOR THE MANUFACTURE OF PROPOSED PRODUCTS.

The raw materials and their quantity requirement for the manufacture of the proposed products in accordance with their projected tonnage per annum will be given below. All the raw materials, solvents etc will be sourced from indigenous manufacturers there is no any need of imports.

S.NO	Names of the products proposed for manufacture	Projected capacity in tones per annum	Names of the Key raw materials required	Quantity required in kg per annum
			1-chloro 3-nitro benzene	8736
1	2-	12.00	Bromo benzene	8530
	12.00	Sulphur	1715	
			Iodine	13600
			2-Nitro toluene	8900
2	3- CHLORO	06.00	Sodium Methoxide	1750
2	IMINODIBENZYL	00.00	Phosphoric acid	3050
			Acetyl chloride	2400
	O METUVI		2-Methyl Benzoyl	19200
3	Z-MEINIL BENZADUENANE	24.00	chloride	
	BENZOFHENONE		Benzene	9600
4	FTHVI AMVI KFTONF	12.00	Methyl Ethyl Ketone	14100
4 6	EIIII AMIL REIONE	12.00	Nickel catalyst	600
5	TERTIARY BUTYL	24.00	Tertiary Butyl chloride	16800
BENZENI	BENZENE	24.00	Benzene	14200
2-AMINOMETHYL-7- CHLORO-2,3-DIHYDRO-5-		Methyl Benzo phenone	2300	
	CHLORO-2,3-DIHYDRO-5-	02 40	Chloro Acetol	1470
(2-FLUORO PHENYL)1H- 1,4 –BENZODIAZEPINE		02.40	Nitro methane	520
7			2-Nitro toluene	8900
1	IMINODIBENZIL	06.00	Sodium methoxide	1750
			3,5-Lutidine	10.046
		24.00	Dimethyl sulphate	11.440
8	OMEPRAZOLE		2-Mercapto 5-Methoxi	13.440
			benzimidazole	
			Triethyl Amine	0.216
			2,3-Lutidine	4080
9	LANSOPRAZOLE	12.00	Trifluoro ethanol	3700
9		12.00	Thionyl chloride	4225
			2-Mercaptobenzimidazole	5220
	ESOMEPRAZOLE	12.00	Omeprazole sulphide	11040
10			Diethyl tartarate	1400
			Cumene	5050
			hydrogenperoxide	

#### 2.6. SOURCES OF KEY RAW MATERIAL.

The key raw materials required for the manufacture of the proposed products are available indigenously. The following are the manufacturers/dealers of the key chemicals required by the unit.

S.NO	Names of the key raw materials	Name of the supplier
1	1-chloro 3-Nitrobenzene	S.Amit & CO; Rumith international
2	Bromo benzene	Bhavika chemical corporation; Neogen chemicals
3	Potassium carbonate	Canton laboratories pvt ltd; Ketul chem pvt ltd
4	2-Nitro toluene	Vertex Dye chem corporation; JP Dye chem. Pvt ltd
5	Sodium methoxide	Global chemicals inc.; Nutron pharmaceuticals pvt ltd
6	Phosporic Acid	Ankita chemical corp; crescent chemicals
7	Acetyl chloride	Arihant enterprises; Sima products
8	2-Methyl benzoyl chloride	Ketan chemical corp; Shetal chemicals
9	Benzene	Crescent chemicals; Ketul chem. Pvt ltd
10	Methyl ethyl ketone	Atul chemicals; Pacific agencies
11	Nickel	Jayesh industries ltd; Jigs chemcals
12	Teritary Butyl chloride	Ultima chemicals; Desicca chemicals
13	Methyl benzophenone	Vapoor chemicals; Trade link
14	Chloro acetol	Spar chem.; Sanjay chemicals
15	Nitro methane	Choice organics pvt ltd; Multichem specialities pvt ltd
16	Nitro toluene	Vertex Dye chem. Corp; Jp dye chem. Pvt ltd
17	3,5-Lutidine	Sigma In corp
18	Dimethyl sulphate	Setal chemicals; Bharat jyothi impex
19	Tri ethyl amine	RR innovative pvt ltd; Manisha traders
20	Magnesium chloride	Vertex Dye chem corporation
21	methanol	Spar chem. Industries;
22	Toluene	Klj group of industries;
23	Isopropyl alcohol	Solvo chem.;
24	Aluminium chloride	Kerala minerals & metals corp;
25	Pet ether	Bharat jyothi impex;

#### 2.7. CONSUMERS OF THE PROPOSED PRODUCTS.

There are sufficient numbers of industrial consumers to the proposed products in the local region. The proposed products are being consumed by the following industries for their internal consumption to make the final form of the drugs of different categories and pharmaceutical formulations.

S.no	NAME OF THE ORGANISATION	CONSUMER FOR
1	Jubilant organosys Ltd	2- CHLOROPHENOTHIAZINE;TERTIARY BUTYL BENZENE;IMINODIBENZYL.
2	Karnataka Malladi Biotics ltd	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2- FLUORO PHENYL)1H-1,4 –BENZODIAZEPINE;2- METHYL BENZOPHENONE;ETHYL AMYL KETONE.
3	Shasun chemicals& Drugs ltd	LANSOPRAZOLE;OMEPRAZOLE;ESOMEPRAZOLE;3- CHLORO IMINODIBENZYL.
4	Alembic pharmaceuticals ltd	ESOMEPRAZOLE;2-CHLOROPHENOTHIAZINE;2- METHYL BENZOPHENONE
5	Neuland laboratories	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2- FLUORO PHENYL)1H-1,4 –BENZODIAZEPINE;2- METHYL BENZOPHENONE;ETHYL AMYL KETONE.
6	Mylan laboratories ltd	ESOMEPRAZOLE;2-CHLOROPHENOTHIAZINE;2- METHYL BENZOPHENONE
7	Global bluk drugs& fine chem ltd	2- CHLOROPHENOTHIAZINE;TERTIARY BUTYL BENZENE;IMINODIBENZYL
8	R.L.Fine chem.	3-CHLORO IMINODIBENZYL; 2- CHLOROPHENOTHIAZINE; TERTIARY BUTYL BENZENE;IMINODIBENZYL; 2-AMINOMETHYL-7- CHLORO-2,3-DIHYDRO-5-(2-FLUORO PHENYL)1H- 1,4 –BENZODIAZEPINE;2-METHYL BENZOPHENONE;ETHYL AMYL KETONE.
9	FDC ltd	2- CHLOROPHENOTHIAZINE;TERTIARY BUTYL BENZENE;IMINODIBENZYL
10	Dr Reddy's laboratories ltd	LANSOPRAZOLE;OMEPRAZOLE;ESOMEPRAZOLE;3- CHLORO IMINODIBENZYL.
11	Natco pharma ltd	ESOMEPRAZOLE;2-CHLOROPHENOTHIAZINE;2- METHYL BENZOPHENONE
12	Dishman pharmaceuticals	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2- FLUORO PHENYL)1H-1,4 –BENZODIAZEPINE;2- METHYL BENZOPHENONE;ETHYL AMYL KETONE.
13	Micro labs	2- CHLOROPHENOTHIAZINE; TERTIARY BUTYL

r	1	<b>T</b>
		BENZENE;IMINODIBENZYL
14	Aurobindo pharma ltd	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2-
	_	FLUORO PHENYL)1H-1,4 -BENZODIAZEPINE;2-
		METHYL BENZOPHENONE; ETHYL AMYL KETONE.
15	Hetero drugs ltd	ESOMEPRAZOLE;2-CHLOROPHENOTHIAZINE;2-
	_	METHYL BENZOPHENONE
16	Nicolas piramal India ltd	LANSOPRAZOLE; OMEPRAZOLE; ESOMEPRAZOLE; 3-
	-	CHLORO IMINODIBENZYL
17	Elder pharmaceuticals	ESOMEPRAZOLE;2-CHLOROPHENOTHIAZINE;2-
	-	METHYL BENZOPHENONE
18	Glenmark pharma	2- CHLOROPHENOTHIAZINE;TERTIARY BUTYL
	-	BENZENE;IMINODIBENZYL
19	Shilpa Antibiotics ltd	LANSOPRAZOLE; OMEPRAZOLE; ESOMEPRAZOLE; 3-
	-	CHLORO IMINODIBENZYL
20	Biocon India ltd	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2-
		FLUORO PHENYL)1H-1,4 -BENZODIAZEPINE;2-
		METHYL BENZOPHENONE; ETHYL AMYL KETONE.

#### 2.8. GREEN BELT DEVELOPMENT.

Green belt will be developed and maintained in about the land of extent of 1124.75 square meters (34% of total plot area). Requisite funds will be allotted for this purpose. It will be planted with the sustainable perennial plants to control and capture the fugitive emissions, noise attenuation, and ambient air temperature control in and around the unit.

#### 2.9. IMPLEMENTATION SCHEDULE OF THE PROJECT.

The project implementation schedule will starts immediate after awarding the Environmental Clearance from MoE&F GOI, and Consent for establishment (CFE) from state PCB and planned to complete the project erection and commission within eighteen to nineteen months.

## **3. PRODUCTS DESCRIPTION**

This chapter narrates about the manufacturing process of the products proposed for manufacture, Reactions of synthesis, Material balances in the synthesis and process flow charts. The following is the list of the products proposed for manufacture along with their respective installed capacities. These products will be made on campaign basis i.e. any three products will be made at a time out of the ten products depending on the market demand.

S.NO	Names of proposed products	Projected capacity TPA
1	2- CHLOROPHENOTHIAZINE	12.00
2	3- CHLORO IMINODIBENZYL	06.00
3	2-METHYL BENZOPHENONE	24.00
4	ETHYL AMYL KETONE	12.00
5	TERTIARY BUTYL BENZENE	24.00
6	2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2-	02.40
0	FLUORO PHENYL)1H-1,4 –BENZODIAZEPINE	02.40
7	IMINODIBENZYL.	06.00
8	OMEPRAZOLE	24.00
9	LANSOPRAZOLE	12.00
10	ESOMEPRAZOLE	12.00
	TOTAL	134.40

# 3.1.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF 2-CHLOROPHENOTHIAZINE.

3-chloro nitro toluene was hydrogenated with hydrogen in presence of Nickel catalyst to get the first stage product. This first stage product was made to react with Bromobenzene in presence of copper catalyst to get the second stage intermediate product which upon further treatment with sulphur and iodine will give the final product 2-chlorophenothiazine.

## 3.1.1. REACTIONS OF SYNTHESIS OF 2-CHLORO PHENOTHIAZINE



## **3.1.1.2. MATERIAL BALANCE IN 2-CHLORO PHENOTHIAZINE**

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	3-chloro nitro benzene	182.00	Product/s	2-Chlorophenothiazine	250.00
2	Hydrogen gas	07.00	By-products	Potassium bromide	132.709
3	Nickel catalyst	10.00		Sodium iodide	321.199
4	Water	360.00			
5	Bromo benzene	177.80	Recoveries	Nickel catalyst	10.00
6	Elemental copper	10.00		Copper catalyst	10.00
7	Potassium carbonate	78.00		Toluene	496.00
8	Toluene	500.00		Acetone	495.00
9	Elemental sulphur	35.685	Process Emissions	Carbon dioxide	71.645
10	Sodium carbonate	118.209		Water	430.07
11	Elemental Iodine	283.255	Solvent losses	Toluene	04.00
12	Acetone	500.00		Acetone	05.00
			Un reacted /Semi converted raw materials		36.326
	TOTAL	2261.949		TOTAL	2261.949

#### **3.2.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF**

#### **3-CHLORO IMINODIBENZYL.**

#### 1<sup>st</sup> Stage;

Ortho nitro toluene was allowed to intermolecular condensation in presence of sodium methoxide and ethyl formate to get the first stage product.

#### 2<sup>nd</sup> stage;

First stage product was Hydrogenated with hydrogen gas in presence of nickel catalyst to get second stage product.

#### 3<sup>rd</sup> stage;

Second stage product was made to react with phosphoric acid to get third stage product of Iminodibenzyl.

#### 4<sup>th</sup> stage;

Third stage product was made to react with Acetyl chloride to get fourth stage intermediate product.

#### 5<sup>th</sup> stage;

Fourth stage intermediate product was nitrated with Sulphuric acid and Nitric acid to get nitrated Iminodibenzyl.

#### 6<sup>th</sup> stage;

Fifth stage product was reduced to sixth stage product in presence of Acetic acid, Iron catalyst and water.

#### 7<sup>th</sup> stage;

Sixth stage product was chlorinated with Cupric chloride in presence of water to get the chloroiminodibenzyl.

#### 8<sup>th</sup> stage;

Seventh stage product was treated with sodium hydroxide to get final product of 3chloro iminodibenzyl.

# 3.2.1.REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

# I<sup>st</sup> STAGE



# **3.2.1.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

1<sup>st</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
s.no	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	2-Nitro toluene	297.00	<b>Product</b> /s	1 <sup>st</sup> stage intermediate	289.00
2	Sodium methoxide	58.50	Recoveries	Sodium methoxide	58.50
3	Ethyl Formate	80.00		Pet Ether	588.00
4	Pet Ether	600.00		Ethyl Formate	78.00
5	Nitrogen gas	100.00	<b>Process Emissions</b>	Hydrogen Gas	2.124
				Nitrogen gas	100.00
			Solvent loss	Pet Ether	12.00
				Ethyl Formate	02.00
			Un reacted/Semi converted Raw materials		05.876
	Total	1135.500		Total	1135.500

# 3.2.2.REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

II<sup>nd</sup> STAGE



# **3.2.2.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

2<sup>nd</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	1 <sup>st</sup> stage intermediate	289.00	Product/s	2 <sup>nd</sup> stage intermediate	220.74
2	Nickel catalyst	10.00	Recoveries	Nickel catalyst	10.00
3	Methanol	600.00		Methanol	580.00
4	Hydrogen gas	12.750	Process Emissions/Genera tions	Water	75.00
			Solvent loss	Methanol	20.00
			Un reacted/Semi converted Raw materials		6.010
	Total	911.750		Total	911.750

## 3.2.3.REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

III<sup>rd</sup> STAGE



## **3.2.3.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

3<sup>rd</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	2 <sup>nd</sup> stage intermediate	220.74	<b>Product</b> /s	IMINODIBENZYL	200.00
2	Phosphoric acid	102.00	By Product	Ammonium phosphate	118.00
3	Water	880.00		Water	880.00
			Un reacted/Semi converted Raw materials		04.740
	Total	1202.740		Total	1202.740

## 3.2.4. REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

IV<sup>th</sup> STAGE



# **3.2.4.2. MATERIAL BALANCE IN 3-CHLOROIMINODIBENZYL**

4<sup>th</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	3 <sup>rd</sup> stage intermediate	200.00	<b>Product</b> /s	4 <sup>th</sup> stage intermediate	235.718
2	Acetyl chloride	80.00	By Product	Hydrogen chloride	36.30
3	Toluene	400.00	Solvent recovery	Toluene	396.00
			Solvent Loss	Toluene	04.00
			Un reacted/Semi converted Raw materials		07.982
	Total	680.00		Total	680.00

# 3.2.5.REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

V<sup>th</sup> STAGE



## **3.2.5.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

5<sup>th</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	4 <sup>rth</sup> stage intermediate	235.718	<b>Product</b> /s	5 <sup>th</sup> stage intermediate	269.269
2	Sulphuric acid	98.00	By Product	Diluted sulphuric acid (33.88%)	298.00
3	Nitric acid	63.00	Process generations	Water	17.00
4	Water	200.00	Un reacted/Semi converted Raw materials		12.449
	Total	596.718		Total	596.718

## 3.2.6. REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

# VI<sup>th</sup> STAGE



## **3.2.6.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

6<sup>th</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	5 <sup>rth</sup> stage intermediate	269.269	<b>Product</b> /s	6 <sup>th</sup> stage intermediate	231.014
2	Iron	106.50	By Product	Ferric oxide	146.40
3	Acetic acid	229.00	Process generations	Acetic acid	229.00
4	Water	17.00	Un reacted/Semi converted Raw materials		15.355
	Total	621.769		Total	621.769

# 3.2.7. REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

VII<sup>th</sup> STAGE


## **3.2.7.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

## 7<sup>th</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	6 <sup>rth</sup> stage intermediate	231.014	Product/s	7 <sup>th</sup> stage intermediate	241.420
2	Cupric chloride	123.00	By Product	Cuprous chloride	88.00
3	Water	16.50		Liquor Ammonia	3.023
			Un reacted/Semi converted Raw materials		38.071
	Total	370.514		Total	370.514

## 3.2.8. REACTION OF SYNTHESIS OF 3-CHLORO IMINODIBENZYL.

VIII<sup>th</sup> STAGE



## **3.2.8.2. MATERIAL BALANCE IN 3-CHLORO IMINODIBENZYL**

8<sup>th</sup> stage

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	7 <sup>rth</sup> stage intermediate	241.420	<b>Product</b> /s	3-Chloro Iminodibenyl	200.00
2	Sodium Hydroxide	35.50	By Product	Sodium Acetate	71.50
3	Water	100.00		Water	100.00
			Un reacted/Semi converted Raw materials		05.420
	Total	376.920		Total	376.920

## 3.3.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF 2-METHYL BENZOPHENONE.

2-Methyl benzoyl chloride was treated with benzene in presence of Aluminium chloride to get 2-Methyl benzophenone.

The catalyst Aluminium chloride was treated with water to get Aluminium hydroxide

3.3.1. REACTIONS OF SYNTHESIS OF 2-METHYL BENZOPHENONE.



## **3.3.1.2. MATERIAL BALANCE IN 2-METHYL BENZOPHENONE**

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	2-Methyl Benzoyl chloride	200.00	<b>Product</b> /s	2-Methyl Benzophenone	250.00
2	Benzene	100+500	By Product	Hydrogen chloride	118.00
3	Aluminium chloride	87.00		Aluminium Hydroxide	50.83 (In 65.00kg water)
4	Water	100.00	Solvent Recovery	Benzene	496.50
			Solvent loss	Benzene	04.00
			Un reacted/Semi converted Raw materials		02.67
	Total	987.00		Total	987.00

## 3.4.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF ETHYL AMYL-KETONE.

Methyl ethyl ketone was made into intermolecular condensation in presence of sodium methoxide to get the first stage intermediate which upon hydrogenation in presence of nickel catalyst will give Ethyl Amyl ketone

## 3.4.1.REACTIONS OF SYNTHESIS OF ETHYL AMYL KETONE



## 3.4.1.2. MATERIAL BALANCE IN ETHYL AMYL KETONE

INPUT DETAILS			OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	Methyl Ethyl Ketone	235.00	Product/s	Ethyl Amyl Ketone	200.00
2	Sodium methoxide	88.00	By Product	Methanol	51.438
3	Toluene	500.00		Sodium Hydroxide	64.298(In 400 kg of water)
4	Nickel catalyst	10.00	Catalyst Recovery	Nickel	10.00
5	Hydrogen gas	03.214	Solvent Recovery	Toluene	496.00
6	Water	400.00	Solvent Loss	Toluene	04.00
			Un reacted/Semi converted Raw materials		10.478
	Total	1236.214		Total	1236.214

## 3.5.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF TERTIARY BUTYL BENZENE.

Tertiary butyl chloride was made to react with benzene in presence of Aluminium chloride to give Tertiary butyl benzene.

Aluminium chloride was made to react with water to get Aluminium hydroxide.

# 3.5.1.REACTIONS OF SYNTHESIS OF TERTIARY BUTYL BENZENE



### **3.5.1.2. MATERIAL BALANCE IN TERTIARY BUTYL BENZENE**

INPUT DETAILS			OUT PUT DETAILS			
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG	
1	Tertiary Butyl chloride	175.00	Product/s	Tertiary Butyl Benzene	250.00	
2	Benzene	148+500	By Product	Hydrogen chloride	68+104	
3	Aluminium chloride	127.00		Aluminium Hydroxide	74.00(In 48.00kg water)	
4	Water	100.00	Solvent Recovery	Benzene	498.00	
			Solvent loss	Benzene	04.50	
			Un reacted/Semi converted Raw materials		03.50	
	Total	1050		Total	1050	

## 3.6.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF BENZODIAZIPINE.

Benzophenone was made to react with chloro acetal in toluene media to get the first stage intermediate which upon further treatment with Hydroxyl amine hydrochloride will give second stage product. This stage was made to react with Nitro methane, subsequent hydrogenation in presence of nickel catalyst will give Benzo diazipine.

# 3.6.1. SYNTHEIC REACTIONS OF 2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2-FLUROPHENYL)-1H-1,4 BENZODIAZEPINE

# Ist & IInd STAGES



# 3.6.1. SYNTHEIC REACTIONS OF 2-AMINOMETHYL-7-CHLORO-2,3-DIHYDRO-5-(2-FLUROPHENYL)-1H-1,4 BENZODIAZEPINE

IIIrd STAGE (FINAL PRODUCT)



### **3.6.1.2. MATERIAL BALANCE IN BENZODIAZIPINE**

	INPUT DETAILS		OUT PUT DETAILS		
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	Benzophenone	24.00	Product/s	Benzo Diazipine	25.00
2	Chloro Acetol	15.30	By Product	Ethanol	08.50
3	Toluene	75.00	Catalyst Recovery	Nickel	02.00
4	Hydroxyl Amine.HCl	06.42	Solvent Recovery	Toluene	73.875
5	PET Ether	100.00		Pet Ether	98.00
6	Nitro Methane	05.35	Solvent Loss	Toluene	01.125
7	Hydrogen Gas	00.700		Pet Ether	02.00
8	Nickel catalyst	02.00	<b>Process Emissions</b>	Hydrogen Chloride	06.20
9	Water	75.00		Water	81.00
			Un reacted/Semi converted Raw materials		06.07
	Total	303.770		Total	303.770

# 3.7.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF IMINODIBENZYL.

#### 1<sup>st</sup> Stage;

Ortho nitro toluene was allowed to intermolecular condensation in presence of sodium methoxide and ethyl formate to get the first stage product.

#### 2<sup>nd</sup> stage;

First stage product was Hydrogenated with hydrogen gas in presence of nickel catalyst to get second stage product.

#### 3<sup>rd</sup> stage;

Second stage product was made to react with phosphoric acid to get third stage product of Iminodibenzyl.

## 3.7.1.REACTION OF SYNTHESIS OF IMINODIBENZYL.

# I<sup>st</sup> STAGE



## 3.7.2. REACTION OF SYNTHESIS OF IMINODIBENZYL.

II<sup>nd</sup> STAGE



## 3.7.3. REACTION OF SYNTHESIS OF IMINODIBENZYL.

# III<sup>rd</sup> STAGE



	INPUT DETAILS		OUT PUT DETAILS			
S.NO	NAME OF THE CHEMICALS/SOLVENTS/ CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG	
1	2-Nitro Toluene	297.00	Product/s	Iminodibenzyl	200.00	
2	Sodium methoxide	58.50	By products	Ammonium phosphate	118.00	
3	Ethyl formate	80.00	Recoveries	Nickel catalyst	10.00	
4	Pet ether	600.00		Sodium methoxide	58.50	
5	Nickel catalyst	10.00		Ethyl formate	78.00	
6	Methanol	600.00	Solvent Recovery	Pet ether	588.00	
7	Hydrogen gas	12.75		Methanol	580.00	
8	Phosporic acid	102.00	Process Emissions/Waste	Water	75.00	
				Hydrogen gas	2.124	
			Solvent loss	Methanol	20.00	
				Pet ether	12.00	
				Ethyl formate	02.00	
			Unreacted/Semi converted materials		16.626	
	Total	1760.25		Total	1760.25	

#### **3.7.1.2. MATERIAL BALANCE IN IMINODIBENZYL.**

#### **3.8.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS**

#### OF OMEPRAZOLE.

#### Stage 1

3,5-Lutidine , hydrogen peroxide and nitric acid are made to react in presence of acetic acid and sulphuric acid so as to yield 4-Nitro-3,5-Dimethyl Pyridine-N-oxide.

#### Stage 2

4-Nitro-3, 5- Di methyl Pyridine-N-oxide, Methanol, Sodium hydroxide and Dimethyl sulphate are made to react in presence of toluene so as to yield 4-Methoxy-3, 5-Dimethyl pyridine-N-oxide.DMS salt.

#### Stage 3

4-Methoxy-3, 5-Dimethyl pyridine-N-oxide.DMS salt, sodium hydroxide, Methanol and ammonium persulphate are made to react in the medium of methylene dichloride so as to give 2-Hydroxy Methyl-4-Methoxy3, 5-Dimethyl Pyridine.

#### Stage 4

2-Hydroxy Methyl-4-Methoxy3, 5-Dimethyl Pyridine and thionyl chloride are made to react, in the presence of toluene and methylene chloride to give 2-chloromethyl-4-methoxy 3, 5-dimethyl pyridine.Hcl.

#### Stage 5

2-chloromethyl-4-methoxy 3, 5-dimethyl pyridine.Hcl and 2-mercapto-5methoxy Benzimidazole are made to react in presence of sodium hydroxide and methylene chloride to give 5-Methoxy-2[(4-Methoxy-3,5-Dimethyl Pyridinyl)Methyl Thio]1H-Benzimidazole.

#### Stage 6

5-Methoxy-2[(4-Methoxy-3,5-Dimethyl Pyridinyl)Methyl Thio]1H-Benzimidazole is made to react with hydrogen peroxide in presence of Catalysts in the medium of acetic acid and acetone so as to yield Omeprazole.

## 3.8.1. REACTIONS OF SYNTHESIS OF OMEPRAZOLE. (STAGE WISE REACTIONS)





I<sup>st</sup> STAGE

## **3.8.1.2. MATERIAL BALANCE IN STAGE 1 OF OMEPRAZOLE**

In put details			Output details		
S.No	Names of the chemicals/Solvents/ Catalysts.	Qty in kg	Classification of out puts.	Name of the chemical.	Qty in kg
1	3,5-Lutidine	105.00	Product/s	4-Nitro-3, 5-dimethyl Pyridine-N-oxide.	156.6164
2	Hydrogen peroxide (50%)	66.727	Recovery/s	Acetic acid	255.150
3	Nitric acid (60%)	103.015	Evaporation/fugitive losses	Acetic acid	07.350
4	Sulphuric acid	175.60	Spent acid	Sulphuric acid + Water	175.60 + 843.1293
5	Water	735.00	Organic residue/process impurities	A complex with un- reacted lutidine and nitric acid.	09.9963
6	Acetic acid	262.50			
	TOTAL	1447.842		TOTAL	1447.842

## **3.8.2. REACTION OF SYNTHESIS OF OMEPRAZOLE.**

## **STAGE - 2.**



## **3.8.2.2. MATERIAL BALANCE IN STAGE 2 OF OMEPRAZOLE.**

	Input details		Output details			
SNo.	Names of the chemicals/Solvents/Catalyst s	Qty in kg	Classification of out puts.	Name of the chemical.	Qty in kg	
1	4-Nitro-3, 5-dimethyl Pyridine-N-oxide.	156.6164	<b>Product/s</b>	4-methoxy- 3,5-Dimethyl Pyridine-N- oxide.DMS salt.	234.0788	
2	Methanol	313.00	<b>Recovery</b> /s	Methanol	277.5684	
3	Sodium hydroxide	40.00		Toluene	608.472	
4	Dimethyl sulphate	119.50	Evaporation/fugitiv e losses	Methanol (loss)	08.5845	
5	Toluene	626.00		Toluene(loss)	17.5280	
6	water	1000.00	Effluent/hazardous waste	Sodium nitrite in water	57.8904(sod, nit)+1105(Water)	
Ö		1090.00	Organic residue/process impurities	Organic and inorganic residue.	35.9943	
	TOTAL	2345.1164		TOTAL	2345.1164	

## **3.8.3.REACTION OF SYNTHESIS OF OMEPRAZOLE.**

III<sup>rd</sup> STAGE



III<sup>rd</sup> STAGE

## **3.8.3.2. MATERIAL BALANCE IN STAGE 3 OF OMEPRAZOLE.**

	Input details		Outr	out details	
SNo.	Names of the chemicals/Solvents/Catalysts	Qty in kg	Classification of out puts	Name of the chemical	Qty in kg
1	4-Methoxy-3,5-Dimethyl Pyridine-n-oxide.DMS salt	234.0788	<b>Product</b> /s	2- hydroxyMeth yl-4-Methoxy 3,5-Dimethyl Pyridine	133.1046
2	Ammonium persulphate	195.00	Recovery/s	Methanol	904.00
3	Methanol	900.00		Methylene Dichloride	680.750
4	Sodium hydroxide	69.00	Evaporation/fugitiv e losses	Methanol	28.00
5	Methylene Dichloride	700.00		Methylene Dichloride	19.250
			Effluent/hazardous waste	Sodium sulphate	113.1787
				Ammonium per sulphate	195.00
6	Water	1750.00		water	1764.3466
			Organic residue/process impurities	Un-reacted raw materials & transient states.	10.4489
	TOTAL	3848.0788		TOTAL	3848.0788

## 3.8.4. REACTION OF SYNTHESIS OF OMEPRAZOLE.

IV<sup>th</sup> STAGE



(STAGE 3)

IV<sup>th</sup> STAGE

## **3.8.4.2. MATERIAL BALANCE IN STAGE 4 OF OMEPRAZOLE.**

	Input details		Ou	tput details	
SNo.	Names of the	Qty in kg.	Classification of out	Name of the	Qty in kg
	chemicals/Solvents/Catalysts.		puts.	chemical.	
1	2-Hydroxy Methyl-4-Methoxy 3,5- Dimethyl Pyridine	133.1046	Product/s	2-chloroMethyl-4- Methoxy 3, 5- Dimethyl Pyridine.Hcl.	171.627
2	Thionyl chloride	96.50	Recovery/s	Methylene Dichloride	291.00
3	Methylene Dichloride	300.00		Toluene	390.00
			Evaporation/fugitive losses	Methylene Dichloride	09.00
				Toluene	10.00
4	Toluene	400.00	Effluent/hazardous waste	Sulphur Dioxide	49.4780
			Organic residue/process impurities	Un –reacted raw materials & transitory compounds.	08.4996
	TOTAL	929.6046		TOTAL	929.6046

# 3.8.5. REACTION OF SYNTHESIS OF OMEPRAZOLE. V<sup>th</sup> STAGE



V<sup>th</sup> STAGE

## **3.8.5.2. MATERIAL BALANCE IN STAGE 5 OF OMEPRAZOLE**

	Input details		Output details			
SNo.	Names of the chemicals/Solvents/Catalysts	Qty in kg	Classification of out puts.	Name of the chemical.	Qty in kg	
1	2-ChloroMethyl-4-Methoxy 3, 5-Dimethyl Pyridine. Hydrochloride.	171.627	<b>Product</b> /s	5-Methoxy-2-[(4-Methoxy 3, 5-Dimethyl Pyridinyl) Methyl Thio]-1H- Benzimidazole.	244.1737	
2	2-Mercapto-5-Methoxy Benzimidazole.	140.50	Recovery/s	Methylene Dichloride	497.50	
3	Sodium hydroxide	65.00	Evaporation/fugitive losses	Methylene Dichloride(loss)	15.50	
4	Methylene Dichloride	513.00	Effluent/hazardous waste	Sodium chloride in water(86.8338+546.7180)	633.5518 (86.8338 +546.7180)	
5	Water	520.00	Organic residue/process impurities	Un-reacted raw materials & Transitory compounds	19.4015	
	TOTAL	1410.127		TOTAL	1410.127	

## **3.8.6. REACTION OF SYNTHESIS OF OMEPRAZOLE.**



## **3.8.6.2. MATERIAL BALANCE IN STAGE 6 OF OMEPRAZOLE**

Input details			Output details		
SNo.	Names of the chemicals/Solvents/Catalysts.	Qty in kg	Classification of out puts.	Name of the chemical.	Qty in kg
1	5-Methoxy-2-[(4-Methoxy-3, 5- Dimethyl Pyridinyl) Methyl Thio]- 1H-Benzimidazole.	244.1737	<b>Product</b> /s	Omeprazole	250.912
2	Hydrogen peroxide (50%)	52.50	Recovery/s	Methanol	589.50
3	Catalyst 1.	2.50		Acetone	582.00
4	Catalyst 2.	2.50	Evaporation/fugitive losses	Methanol	10.50
5	Methanol	600.00		Acetone	18.00
6	Acetone	600.00	Effluent/hazardous waste	Spent catalysts (2.5+2.5Kg) and Sodium acetate(41.00Kg) in Water(1948.341Kg) solution	1994.341
7	Sodium hydroxide	20.00	Spent carbon		12.00
8	Acetic acid	30.00	Organic	Un-reacted raw	
9	Activated carbon	12.00	residue/process	materials &	6.4207
10	Water	1900.00	impurities	impurities	
	TOTAL	3463.6737		TOTAL	3463.6737

# 3.9.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF LANSOPRAZOLE.

#### Stage 1;

2,3-Lutidine , hydrogen peroxide and nitric acid are made to react in presence of acetic acid and sulphuric acid so as to yield 4-Nitro-2,3- Dimethyl Pyridine-N-oxide.

#### Stage 2;

Stage 1 product was made to react with Trifluoro ethanol, acetic anhydride

And Hydrogen chloride in presence of Potassium carbonate and Sodium

Hydroxide to give second stage product.

#### Stage 3;

Second stage product was made to react with Thionyl chloride to give third stage product.

#### Stage 4;

Third stage intermediate product was allowed to react with 2-Mercapto benzimidazole in presence of sodium hydroxide to give fourth stage product.

#### Stage 5;

Fourth stage product was made to react with Hydrogen peroxide to give Lansoprazole.

## 3.9.1.REACTIONS OF SYNTHESIS OF LANSOPRAZOLE.

1<sup>st</sup> Stage


<b>3.9.1.2 MATERIA</b>	<b>BALANCE IN</b>	STAGE 1	<b>OF LANSOPRAZOLE</b>
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	INPUT DETAILS			<b>OUT PUT DETAILS</b>	
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	2,3-Lutidine	34.00	<b>Product</b> /s	1 <sup>st</sup> stage intermediate	51.80
2	Hydrogen peroxide	11.00	Solvent Recovery	Acetic acid	147.00
3	Nitric acid	20.00	Solvent Loss	Acetic acid	03.00
4	Sulphuric acid	31.00	Process Emissions/Genera tes	Water	11.099
5	Acetic acid	150.00		Sulphuric acid	31.00
6	Water	25.00		Water	25.00
			Un reacted/Semi converted Raw materials		2.101
	Total	271.00		Total	271.00

# 3.9.2. REACTIONS OF SYNTHESIS OF LANSOPRAZOLE



4-(2,2,2-Trifluoro ethoxy)-2-Hydroxymethyl -3-methyl Pyridine Hydro chloride

### STAGE 2.

RACS PHARMACHEM (INDIA) PVT LTD.

3.9.2.2 MATERIAJ	<b>BALANCE I</b>	N STAGE 2 OF	LANSOPRAZOLE
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	INPUT DETAILS			<b>OUT PUT DETAILS</b>	
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	1 <sup>st</sup> stage intermediate	51.80	<b>Product</b> /s	2 <sup>nd</sup> stage intermediate	76.22
2	Tri fluoro ethanol	30.83	Solvent Recovery	Methyl Isobutyl ketone	117.50
3	Potassium carbonate	42.55		Toluene	98.50
4	Acetic anhydride	31.45	Solvent loss	Methyl Isobutyl ketone	02.50
5	Sodium hydroxide	12.50		Toluene	01.50
6	Hydrogen chloride	11.25	By products	Potassium bicarbonate	29.60
7	Methyl Isobutyl ketone	120.00		Potassium nitrite	25.16
8	Toluene	100.00		Sodium acetate	24.272
9	Water	150.00		Acetic acid	17.760
				Water	150.00
			Un reacted/Semi converted Raw materials		07.368
	Total	550.380		Total	550.380

# 3.9.3. REACTIONS OF SYNTHESIS OF LANSOPRAZOLE





### **STAGE III**

### 3.9.3.2 MATERIAL BALANCE IN STAGE 3 OF LANSOPRAZOLE .

	<b>INPUT DETAILS</b>			<b>OUT PUT DETAILS</b>	
S.NO	NAME OF THE CHEMICALS/SOLV ENTS/CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	2 <sup>nd</sup> stage intermediate	76.22	Product/s	3 <sup>rd</sup> stage intermediate	80.06
2	Thionyl chloride	35.224	Solvent Recovery	Toluene	198.00
3	Toluene	200.00	Solvent loss	Toluene	02.00
			<b>Process Emissions</b>	Sulphur dioxide	18.564
				Hydrogen chloride	10.587
			Un reacted/Semi converted Raw materials		02.223
	Total	311.444		Total	311.444

### 3.9.4. REACTIONS OF SYNTHESIS OF LANSOPRAZOLE

### 4<sup>th</sup> Stage



# **3.9.4.2 MATERIAL BALANCE IN STAGE 4 OF LANSOPRAZOLE .**

	INPUT DETAILS		0	UT PUT DETAILS	
S.NO	NAME OF THE CHEMICALS/SOLVENTS/ CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	3 <sup>rd</sup> stage intermediate	80.06	Product/s	4 <sup>th</sup> stage intermediate	98.00
2	2-Mercaptobenzimidazole	43.50	Process Emissions/Generati ons	Sodium chloride	32.50
3	Sodium hydroxide	23.20		Water	10.00
4	Water	250.00		Water	250.00
			Un reacted/Semi converted Raw materials		06.26
	Total	396.76		Total	396.76

# 3.9.5. REACTIONS OF SYNTHESIS OF LANSOPRAZOLE

5<sup>th</sup> Stage



### **3.9.5.2 MATERIAL BALANCE IN STAGE 5 OF LANSOPRAZOLE .**

	INPUT DETAILS		0	UT PUT DETAILS	
S.NO	NAME OF THE CHEMICALS/SOLVENTS/ CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	4 <sup>th</sup> stage intermediate	98.00	Product/s	Lansoprazole	100.00
2	Hydrogen peroxide	09.50	Process Emissions/Generati ons	Water	04.878
3	Isopropyl alcohol	100.00		Water	200.00
4	Water	200.00	Solvent recovery	Isopropyl alcohol	98.00
			Solvent loss	Isopropyl alcohol	02.00
			Un reacted/Semi converted Raw materials		02.622
	Total	407.50		Total	407.50

# 3.10.0. CONCISE DESCRIPTION OF MANUFACTURING PROCESS OF ESOMEPRAZOLE.

Omeprazole sulphide was made to react with (-) Diethyl Tartrate ,potassium hydroxide,Cumene hydrogen peroxide and magnesium chloride in Toluene and Acetic acid media.The product was purified with activated carbon and Hyflo in Methanol medium.

### 3.10.1.REACTION OF SYNTHESIS OF ESOMEPRAZOLE



	INPUT DETAILS			OUT PUT DETAILS	
S.NO	NAME OF THE CHEMICALS/SOLVENTS/ CATALYSTS	QTY IN Kg	CLASSIFICATION OF THE OUT PUTS	NAME OF THE CHEMICAL	QTY IN KG
1	Omeprazole sulphide	226.00	Product/s	Esomeprazole	50.00
2	Diethyl tartarate	28.30	By products	Omeprazole sulphide	189.60
3	Potassium hydroxide	23.00		Potassium diethyl tartrate	38.74
4	Cumene hydrogen peroxide	104.40		Cumene hydrogen peroxide	93.41
5	Magnesium chloride	06.50		Potassium chloride	10.19
6	Water	3.80	Solvent Recovery	Acetic acid	196.00
7	Acetic acid	200		Toluene	247.00
8	Carbon	05.00		Methanol	246.00
9	Hyflow	03.00	Process Emissions/Waste	Spent Carbon	05.00
10	Toluene	250.00		Spent Hyflow	03.00
11	Methanol	250.00		Water	07.39
			Unreacted/Semic onverted materials		13.67
	Total	1100.00		Total	1100.00

### **3.10.1.2 MATERIAL BALANCE IN ESOMPRAZOLE .**

# Pre feasibility report



#### 3.11.0. GENARALISED PROCESS FLOW CHART OF MANUFACTURING PROCESSESS OF PRODUCTS.

### **4.0 ENVIRONMENTAL MANAGEMENT PLAN**

### 4.1. Environmental management plan:

An environmental management plan, with a well described environmental monitoring program, covering the aspects of preventing the generation of pollution, mitigation of the pollution and recuperation methods to reinstate the environment in and around the unit will be constructed. Qualified and trained staff will be allocated to implement the EMP so that to ensure the Environmental compliance with the statutory norms of pollution control boards. Sufficient funds will be granted to implement the environmental protective measures.

### 4.2. Air environment:

To protect the air environment from pollution due to various industrial operations of this project, the following abatement and mitigating measures of pollution control will be adopted to follow.

- The coal fired boilers were equipped with requisite bag filters to arrest the particulate matter and control the ground level concentration of the particulate matter.
- A stack of height 30 meters with the requisite flue gas exit velocity will be maintained for proper dispersal of the pollutant gases Sox, Nox and particulate matter.
- > The Nox emissions will be controlled by controlling the combustion measures.
- Fugitive dust will be controlled by adopting the dust suppression measures.
- > Fly ash will be kept wet by sprinkling of water.
- DG set (150 KVA) was equipped with a stack of height 2.5 meter above the roof of the shed.
- All process gaseous emissions from the processing equipment will be channelized and let it in to the scrubber where they are neutralized (or) dissolved into the water.
- > All processing machinery will be maintained leak proof.
- > Green belt with perennial plants will be developed.

### 4.3. Ground & Ground water environment:

- Ground and ground water pollution/contamination will be prevented by implementing the following measures in the industry;
- > The waste waters from various operations of the unit are collected, segregated and treated as per their characteristics in the effluent treatment plant as per the designed procedure ,so as to attain the specified standards of quality and then used to gardening/ash quenching/wherever suitable.
- The domestic effluent will be sent to the septic tank followed by soak pit.
- > The solid waste generated from different sources from the unit will be collected, segregated and sent to the authorized TSDF facility.
- > Hazardous wastes generated will be sent to TSDF as per the approved procedure/standards.
- > Fly ash will be sent to local brick manufacturers.
- Rain water harvesting system will be constructed to replenish the ground water.

### 4.4. Effluent treatment & hazardous waste management.

The liquid effluent which is generated by the various operations of the plant will be segregatively collected and treated as per their characteristics .The outcomes from the effluent treatment plant will be reused wherever suitable and the hazardous wastes will be sent to the authorized TSDF.

### 4.5. Noise environment.

The noise levels within the plant would be kept within the stipulated limits by implementing the noise control measures. The dg set will be equipped with acoustic enclosure. Noise attenuation in and around the plant will be achieved by developing the green belt around the periphery of the plot. Effective mechanical maintenance of the plant machinery will be maintained.

#### **5.0 FINANCIAL FEASIBILITY.**

### M/S,R A C S PHARMACHEM (INDIA) PRIVATE LIMITED, IP 13- Part-2, Road No-8, First Phase Industrial area, Kudumalakunte Village, Gowribidabur Taluk Chikkaballapur Distri, Karnataka - 561 208

		PROJECTE	D BALANCESHEE	T		2017 10	2018-19	2019-20
	PARTICILLARS		2014-15	2015-16	2016-17	2017-18	2010-15	50 62 22 572
SL No	Share Capital		75,12,000 78,00,000	3,13,83,102	13,99,76,919 -	28,78,10,540	44,02,64,280	59,03,52,372
2	Share Application Money Add: Profit & Loss, General Reserve		1,60,71,102	10,85,93,817	14,78,33,620	15,24,53,741 44,02,64,280	15,60,68,292 59,63,32,572	75,58,90,931
з	Term Loan		2,70,00,000	2,10,00,000	1,50,00,000	90,00,000	30,00,000	-
4	Secured Loan		-		-	•	-	-
5	Sundry Creditors & Current Liabilities	1	1,05,000	75,000	1,02,000	1,02,000	1,02,000	1,02,000
100		TOTAL	5,84,88,102	16,10,51,919	30,29,12,540	44,93,66,280	59,94,34,572	75,59,92,931

			2015-16	2016-17	2017-18	2018-19	2019-20
SL No	PARTICULARS	2014-15	2013-10	2 25 00 464	2 93 90 690	2,57,61,647	2,26,30,534
.1	Fixed Assets .	78,68,560	3,84,83,532	5,55,55,404	2,50,50,000	-	
	Land Cost			-		-	-
	Add: Cost of Construction	63,00,000	-	2 25 00 464	2 93 90 690	2.57.61.647	2,26,30,53
(G)		1,41,68,560	3,84,83,532	3,35,99,404	2,33,50,050	-	• -
	Plant and Machinery	2,69,38,703	-	-			
				12 00 774	26 29 043	31,31,113	27,03,22
	Less: Depreciation	26,23,731	48,84,068	42,08,774	30,23,043	2 26 30 534	1,99,27,30
	Less. Deprecionent	3,84,83,532	3,35,99,464	2,93,90,690	2,57,01,047	24 00 000	29,00,0
7	Salany advances	4,00,000	- 9,00,000	14,00,000	19,00,000	24,00,000	-
2	Destal Advances	-	-	-		2 05 25 000	2 45.25.0
3	Leans & Advances	50,00,000	85,25,000	1,25,25,000	1,65,25,000	2,03,23,000	-,,,-
4	Closing Stock	-		-	-	20 28 12 000	22 40.97.2
5	Closing Stock	1,35,00,000	10,04,25,000	19,49,22,000	19,88,22,000	20,28,12,000	18 45 43 3
6	Sundry Debtors	10,44,570	1,75,62,455	6,46,54,850	20,63,57,633	35,10,67,030	40,45,45,5
7	Cash and Ballk Dalances	60,000	40,000	20,000	-		
8	Miscellaneous Expenditure to the			Lamma	Associa	CS	75 59 97 9
	Extent of Not Written On	5,84,88,102	16,10,51,919	1 30,29,12,540	44,93,66,280	59,94,34,572	13,33,32,3
			T	Chartered .			
				Yusr M.No	: 19955		

			CASH FLOW STA	TEMENT				
	PARTICULARS		2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
		-						
	Net Profit After Tax		1,60,71,102	10,85,93,817	14,78,33,620	15,24,53,741	15,60,68,292	15,95,58,359
	Depreciation		26,23,731	48,84,068	42,08,774	36,29,043	31,31,113	27,03,229
	TOTAL	(A)	1,86,94,833	11,34,77,885	15,20,42,394	15,60,82,784	15,91,99,405	16,22,61,588
1. The second	SOURCES OF FUNDS	2527	2 00 00 000					
10. E	Loan Received		78.00.000		÷			-
	Share Application Money			-				
	Increase in Creditors		(4,95,000)					
	Renavment of Un secured Loan		-					
	Decrease in Current Assets							
	TOTAL	(B)	3,73,05,000	-	-	-		-
	APPLICATION OF FUNDS		50.00.000	35,25,000	40.00.000	40.00.000	40.00.000	40.00.000
	Repayment of secured Loan		-	-	-	2		
	Repayment of Un secured Loan			-	- 1			-
	Decrease in Creditors		-	30,000	(27,000)	-	-	-
	Salary Advances Advances		4,00,000	5,00,000	5,00,000	5,00,000	. 5,00,000	5,00,000
	Lease/Rental Advances		-	-	-	· · · ·	-	-
	Construction of Building		63,00,000					
	Payment towards Purchase of Plant & Machinery		2,69,38,703		-		-	-
	Loan Repayment		30,00,000	60,00,000	60,00,000	60,00,000	60,00,000	30,00,000
	Increase in Current Assets		1,34,80,000	6,69,05,000	9,44,77,000	56,80,000	- 39,90,000	2,12,85,250
	TOTAL	(C)	5,51,18,703	9,69,60,000	10,49,50,000	1,43,80,000	1,44,90,000	2,87,85,250
	OPENING BALANCE		1,63,440	10,44,570	1,75,62,455	6,46,54,850	20,63,57,633	35,10,67,038
1	ADD: NET SURPLUS	(A) +(B) - ( C)	8,81,130	1,65,17,885	4,70,92,394	14,17,02,784	14,47,09,405	13,34,76,338
	CLOSING BALANCE		10,44,570	1,75,62,455	6,46,54,850	20,63,57,633	35,10,67,038	48,45,43,376
					For	swamy P	ssociate	9
					Cha	rtered Ac	octintants	
	8°*1				Keen	1 -ser	E.	
				/	prov		T	
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÷						Proprie	teor .	

		Details of	Salary and Wages				
	Particulars Chemist [in Number] Skilled Worker [in Number] Semi Skilled Worker [in Number] Accountant [IN Numer] Security	2014-15   in Number Amount in   4 24000 4   4 14400 10   10 270000 1   1 60000 2	2015-16 .oer Amount 8 1075200 8 645120 20 1209600 2 268800 5 436800	780 7280   2016-17 Amount   in Number 120424   8 7225344   420 1354752   20 301056   5 489216	2017-18   in Number Amount   8 1348731   8 809239   20 1517322   2 337183   5 547922	2018-19 in Number Amount in 8 1510579 8 906347 20 1699401 2 377645 5 613672.6	2019-20 n Number Amount 8 1691848 8 1015109 20 190329 2 422962 5 687313.3
		792000	3635520	4071782	4560396 For Ch	Sioned Swamy Association artered Association M.No: 19955 Proprietor	5720561 nits
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		Dep	preciation Sched	ulè				
	PARTICULARS	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
Fixed Assets:			2,49,18,300	2,11,80,555	1,80,03,472	1,53,02,951	1,30,07,508	-
Land Cost		21,02,000	21,02,000	21,02,000	21,02,000	21,02,000	21,02,000	21,02,000
Less: Depreciation		-	-		-	-	-	-
Total		21,02,000	21,02,000	21,02,000	21,02,000	21,02,000	21,02,000	21,02,000
Building		57,66,560	57,66,560	1,14,63,232	1,03,16,909	92,85,218	83,56,696	75,21,026
Add: Addition During	the Year		63,00,000	-		-	-	-
Less: Depreciation		-	6,03,328	11,46,323	10,31,691	9,28,522	8,35,670	7,52,103
lotal		57,66,560	1,14,63,232	1,03,16,909	92,85,218	83,56,696	75,21,026	67,68,923
Plantan Machinery		-	26938703	24918300	21180555	18003472	15302951	13007508
Less: Depreciation		-	2020403	3737745	3177083	2700521	2295443	1951126
	Total		24918300	21180555	19002472	15202051	12007508	11056382
			24310300	21180555	18003472	15302951	1300/500	
Depreciation:			·			10,31,031 9,26,522 8,35,670 11,212   92,85,218 83,56,696 75,21,026 67,68,923   21180555 18003472 15302951 1300750   3177083 2700521 2295,443 1951127   18003472 15302951 13007508 1105638;   1031691 928522 835670 75210;   3177083 2700521 2295,443 1951127		
Land @ NIL		0	· 0					
Building @10%		0	603328	1146323	1031691	928522	835670	752103
Plant and Machinery (	<u>۵</u> 15%	0	2020403	3737745	3177083	2700521	2295443	1951126
						1. 1. A.		
		0	2623731	4884068	4209774	3629043	3131113	2703229
					Cha	Add made	ntants	
					guor	T	-	
					$\vee$	21 No. 1 do -		
						Proprietor	5	2.10
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#### M/S,R A C S PHARMACHEM (INDIA) PRIVATE LIMITED, IP 13- Part-2, Road No-8, First Phase Industrial area, Kudumalakunte Village, Gowribidabur Taluk Chikkaballapur Distri, Karnataka - 561 208

Projected Profitability Statement:												
PARTICULARS	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20						
Net Profit After Tax	1,60,71,102	10,85,93,817	14,78,33,620	15,24,53,741	15,60,68,292	15,95,58,359						
Depreciation	26,23,731	48,84,068	42,08,774	36,29,043	31,31,113	27,03,229						
Interest on Term Loan	38,19,000	31,59,000	23,78,000	15,93,000	8,13,000	1,14,000						
	2,25,13,833	11,66,36,885	15,44,20,394	15,76,75,784	16,00,12,405	16,23,75,588						
••												
Instalment of Term Loan	30,00,000	60,00,000	60,00,000	60,00,000	60,00,000	30,00,000						
Interest on Term Loan	38,19,000	31,59,000	23,78,000	15,93,000	8,13,000	1,14,000						
1	68,19,000	91,59;000·	83,78,000	75,93,000	68,13,000	31,14,000						
DSCR	. 3.30	12.73	18,43	20.77	23.49	52.14						

Walley As SOCI

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Jus -1.No: 19958 Proprietor

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