PREFEASIBILITY REPORT

FOR

"MODIFICATION & EXPANSION OF BULK DRUG AND INTERMEDIATES UNIT"

AT

PLOT NO. 94 & 95 (P), KIADB INDUSTRIAL AREA,
SITUATED IN SY NO. 214 OF GADWANTHI VILLAGE,
HUMNABAD HOBLI & TALUK, BIDAR DISTRICT, KARNATAKA

PROMOTER:

M/s. LAKSHMIDURGA DRUGS & INTERMEDIATES (P) LTD

BIDAR

For Lakshmi Durga Drugs & Intermediates Pvt. Ltd.
D. Sai Babu
Authorised Signatory

1. EXECUTIVE SUMMARY

M/s. Lakshmidurga Drugs & Intermediates (P) Ltd is situated in Industrial area**,** Humnabad in **Bidar** district of **Karnataka State**. Lakshmidurga Drugs & Intermediates Pvt Ltd is currently engaged in manufacturing bulk drugs & intermediates for the Pharmaceutical industries, fortified with a vision to be a reliance partner with global pharmaceutical companies and dedicated to continuous improvement of product quality and quantity. The company is promoted by technically qualified and professionally experienced technocrats who crave for innovation and value addition. The Company M/s. Lakshmidurga Drugs & Intermediates Private Limited was incorporated by Mr. R. Vijaya Krishna & Mr. D. Saibabu with an objective of setting up a manufacturing unit for production of Bulk Drugs & Intermediates. The Company has acquired land of 4 acres of industrial land situated in Humnabad Industrial Area established by Karnataka Industrial Development Board in Bidar District. There are a good number of pharma units in the said industrial estate. All the infrastructural facilities are available there. The said area is feasible for manufacture of bulk drugs & intermediates in terms of availability of raw material, skilled and unskilled labor and industrial approvals etc. The place is about 150 km from Hyderabad with good road facility and nearer to Bombay highway (1 km) and about 55 km from Gulbarga on Bangalore State Highway.

Our Vision:

To be one of the leading pharmaceutical manufacturers and suppliers in India.

Our Mission:

They aim to be the country's most valued manufacturer and supplier of pharmaceuticals, healthcare products and health information in order to improve quality of life and deliver outstanding value to our customers and stakeholders.

Quality Policy:

Lakshmidurga Drugs & Intermediates Pvt Ltd provide tremendous service in terms of supplying quality products to all our customers as per customer specifications following cGMP guidelines. This is achieved by continual improvement in terms of Product quality, technology, procedures & personnel skills.

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2. INTRODUCTION OF THE PROJECT/BACKGROUND INFORMATION

i. Identification of project and project proponent. In case of mining project, a copy of mining lease/letter of intent should be given

The proposed project is modification and expansion by stopping existing product and proposed new product mix of bulk drugs and intermediates at existing manufacturing unit at Plot No. 94 & 95 (P), KIADB Industrial Area, situated in Sy No. 214 of Gadwanthi Village, Humnabad Hobli & Taluk, Bidar District, Karnataka.

ii. Brief description of nature of the project

The project area comes under notified Industrial Area. Hence the project falls under item no-5(f) of schedule to EIA notification, dated 14th September 2006 and can be classified as **Category B.**

iii. Need for the project and its importance to the country or region

India with its large talented manpower, cost effective chemical synthesis, legal & financial framework is poised to become sourcing destination of bulk drugs to the global market.
Lakshmidurga Drugs & Intermediates Pvt Ltd is positioned to become one of leading Pharmaceuticals and Specialty Chemicals Manufacturing Company in India.

The pharmaceutical industry in India ranks third in the world in terms of volume and contributes 10% to the global pharmaceutical production. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry is pegged at Rs 810 bn, which includes domestic sales. The industry is the fourteenth-largest in the world in terms of value and accounted for 1.5% of the global pharmaceutical market. The industry has a lower share in the global market because Indian products are available at a price that is 5-50% lower than that in the developed countries. According to the Department of Pharmaceuticals, the sector employs

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about 340,000 persons and an estimated 400,000 doctors and 300,000 chemists are serving its 1 bn-plus market.

iv. Demand and supply gap

The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is estimated to be worth $ 4.5 billion, growing at about 8 to 9 percent annually. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple pain killers to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. Indian Pharmaceutical Industry boasts of quality producers, and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

The domestic pharmaceutical industry is quite fragmented with the top five companies constituting only 22% of the market share. Unlike the global pharmaceutical industry, where the top 10 companies account for 40% of the global pharmaceutical sales, in India, the top 20 companies account for 57% of the domestic market share. The Indian pharmaceutical industry comprises around 250 large units and about 80,000 small scale units that operate across the pharmaceutical value chain ranging from new drug discovery to marketing and distribution.

India's pharmaceutical industry is now the third largest in the world in terms of volume and stands 14th in terms of value. According to data published by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between September 2008 and September 2009 was US$ 21.04 billion. Of this the domestic market was worth US$ 12.26 billion.

The Indian pharmaceuticals market is expected to reach US$ 55 billion in 2020 from US$ 12.6 billion in 2009. The market has the further potential to reach US$ 70 billion by 2020 in an aggressive growth scenario.

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

Further estimates the healthcare market in India to reach US$ 31.59 billion by 2020. The market size is expected to grow at higher percentages in future years with more and more international companies depending on India to meet their bulk-drug supply needs.

During the market survey, it was found, that the following drugs are active and high potential demand in local. Hence, the management has opted to manufacture the same by adopting latest technology available in India. The company has decided to manufacture the following drugs like Ketoconazol Intermediate, Itraconazole and its intermediates etc., by increasing capacity for manufacturing of existing Drugs. For convenience the products are identified as groups and will be produced a specified group in particular when the demand arise. This report gives detailed manufacturing process present and proposed drugs. This report also discusses the treatment proposal for controlling the water pollution, air pollution and handling of solid waste.

v. Imports v/s. Indigenous production

Active Pharmaceutical ingredients (APIs) play a pivotal role in any strategy designed to rise the standard of living of the people. The consumption level of the medicines is a barometer for measuring the growth of the country's health and present Indian population has recognized the importance of Healthcare and Health-care products. The API industry has shown good results in the last decade accepting the challenges on import substitution, meeting and fulfilling the input needs of the pharmaceutical industry through indigenous production.

India is well known for technically qualified manpower and good English speaking population. During the last few decades a large number of professionals entered the field of APIs with a high degree of motivation based on the promises and prospect evident in the demand projection of various APIs. These technocrats have done well not only in producing

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quality APIs but also in bringing down the prices of wide range of APIs, which are being imported in large quantities.

As a result of constant and considerable progress, the present production covers a wide range of APIs including antibiotics, vitamins, hormones, sulpha drugs, besides practically the entire range of pharmaceuticals, required by the medical profession. The technology adopted for the production of different bulk drugs and drug intermediates covers intricate and sophisticated fermentation technology, synthetic operations and extraction and purification of the active principles contained in the plant and animal kingdom.

M/s Lakshmidurga Drugs & Intermediates Pvt Ltd has reasonably sound base to overcome the technological barrier to meet the challenges of the industry. The demand for the bulk drugs is on increase, the industry is poised for substantial growth in the coming years.

vi. Export Possibility

The company has no plans to export its products to outside the countries. All the products and intermediates produced are requirement of domestic market.

vii. Domestic/ Export Markets

Over 60 per cent of India's bulk drug production is exported. India's pharmaceutical exports are to the tune of Rs 87 billion, of which formulations contribute nearly 55 per cent and the rest 45 per cent comes from bulk drugs.

In financial year 2005, exports grew by 21 per cent. The Indian pharmaceutical market has been forecasted to grow to as much as US$ 25 billion by 2010 as per Organization of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom's market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009.

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Domestic pharmaceutical exports, growing at 30 per cent per annum, touched a new height of US$4.8 billion in the financial year 2006-07. The Year's exports will push the drug sectors contribution to India's Forex earnings to 7.75 per cent from the current 5 per cent.

viii. Employment generation (direct and indirect) due to the project

The total strength of the Lakshmidurga Drugs & Intermediates Pvt Ltd plant facilities is 50 people it included both on roll and off roll, with a staggered weekly off.

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3. PROJECT DESCRIPTION

i. Type of project including interlinked and interdependent project if any

To cater the needs of the market & it is proposed to stop existing product and proposed new product mix of bulk drugs and intermediates at existing manufacturing unit at Plot No. 94 & 95 (P), KIADB Industrial Area, situated in Sy No. 214 of Gadwanthi Village, Humnabad Hobli & Taluk, Bidar District, Karnataka.

All the required concrete structures for the manufacture of the proposed change product with its capacity are already available with additional few machineries/equipments to be erected.

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

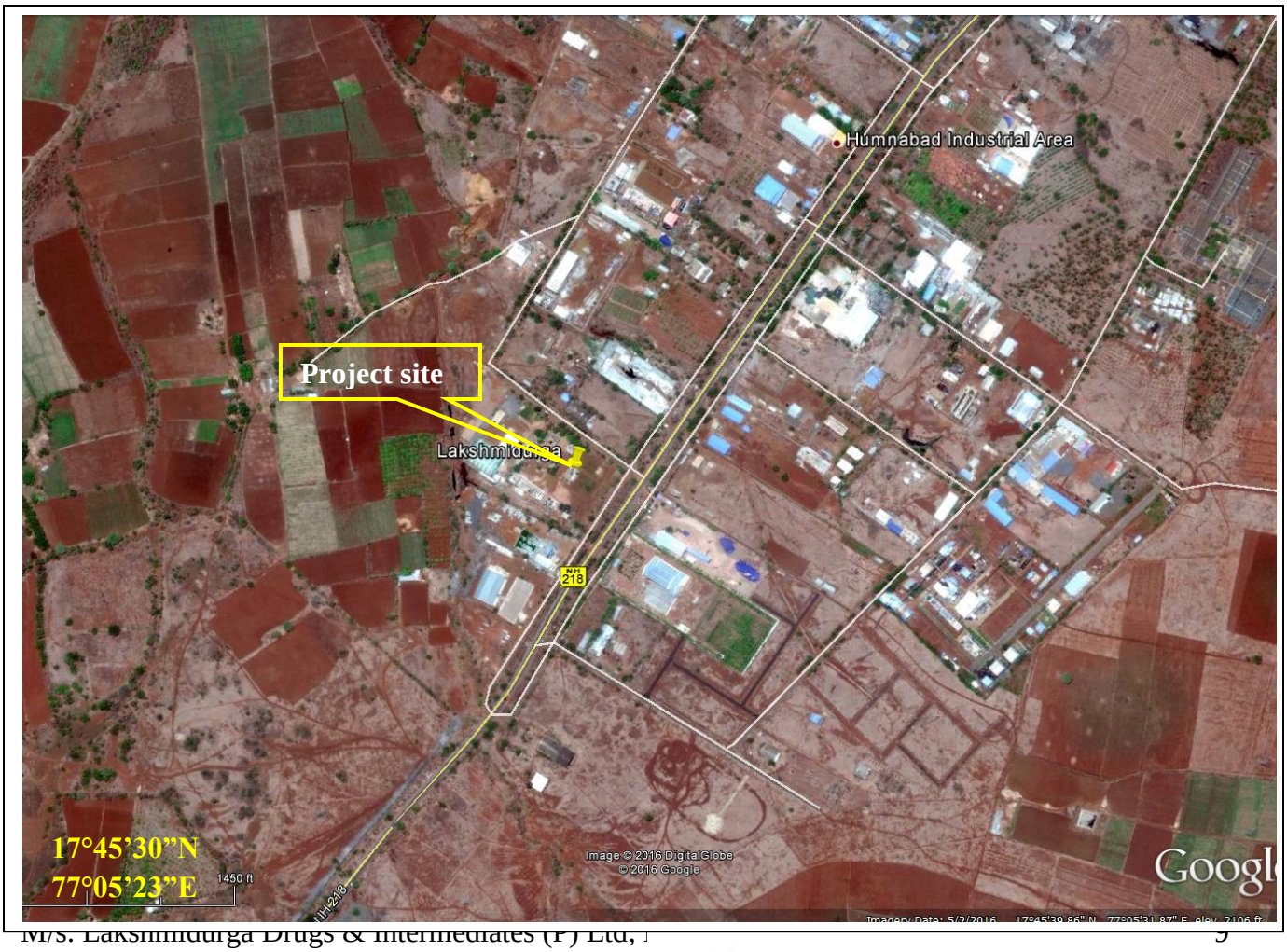

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FIGURE: GOOGLE VIEW OF THE PROJECT SITE

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

There is no any alternate site as the proposed site is acquired.

Table 3.1 DETAILS OF ENVIRONMENTAL SETTINGS

Sl.No.	Particulars	Details
1	Plant site latitude	17°45'30"N
2	Plant site longitude	77°05'23"E
3	Temperature Max. Min.	42º C 20º C
4	Present land use	Industrial area
5	Nearest Highway	NH- 218 – 0.2 km.
6	Nearest railway Station	Humnabad railway station – 5.3 Km
7	Nearest Airport	Rajiv Gandhi International Airport Hyderabad – 115 Km
8	Nearest village	Gadwanthi -2.0 Km
9	Nearest major city	Humnabad – 4.4 Km
10	Nearest water body	Dhumansur lake – 6 Km (NE)
11	Nearest forest	Pandaragera reserve forest – 8 Km (SW)

iv. Size or magnitude of operation

M/s. Lakshmidurga Drugs & Intermediates Pvt Ltd, is presently planning to stop existing product and proposed new product mix of bulk drugs and intermediates at existing manufacturing unit at Plot No. 94 & 95 (P), KIADB Industrial Area, situated in Sy No. 214 of Gadwanthi Village, Humnabad Hobli & Taluk, Bidar District, Karnataka.

The details of the manufacturing chemical drug products are given in below table.

TABLE 3.4.1: LIST OF EXISTING AND PROPOSED PRODUCTS

List of Existing product

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S. No.	Name of the product	Quantity in MTPM
1	Ibuprofen	1.8

Note: Existing product has been stopped

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List of proposed products

S. No.	Name of the product	Quantity in MTPM
1	**Ketoconazole and its intermediates**	**1**
a	Cis-Tosylate	4
b	Cis-Bromobenzoate	20
2	**Itraconazole and its intermediates**	**0.5**
a	Triazole alcohol	2
b	Cys-mesylate	2
3	**2-Chloroacetamide**	1
4	**Fluconazole and its intermediates**	**2**
a	1-(2,4-Difluorophenyl)-1-(1H-1,2,4- triazole-1yl)-ethanone (DFTA)	5
b	2-(2,4-Difluorophenyl)-1-(1H-1,2,4-triazole-1yl) 2,3Epoxy propane-Methane sulphonate (EPOXY MESYLATE)	3
5	**Azacyclonol**	**2**
6	**Sumatriptan succinate and its intermediates**	**0.1**
a	4-Hydrazino-N-methylbenzenemethane sulfonamide (HMBS)	1
b	4-Chlorobutyraldehydesodiumbisulfite (CBA)	1
7	**Amlodipine besylate**	**2**
8	**Octyl methoxy cinnamate**	**20**
9	**Veratric acid**	**2**
10	**Clopidogrel intermediates**	
a	2-Chlorophenyl glycine methyl ester tartarate	5
b	(+)-N-(2-(2-Thionyl) ethyl)-2-chlorophenyl glycine methyl ester hydrochloride	1.5
11	**Recovered Cis-Bromobenzoate**	**5**

Note: Maximum two to three products will be produced at a time.

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

Description of products

1. KETOCONAZOLE AND ITS INTERMEDIATES:

KT-I:

CBB is reacted with IMD in the presence of DMF as solvent. The reaction mass is quenched in sodium bicarbonate solution and the product is extracted with toluene. The aqueous layer is

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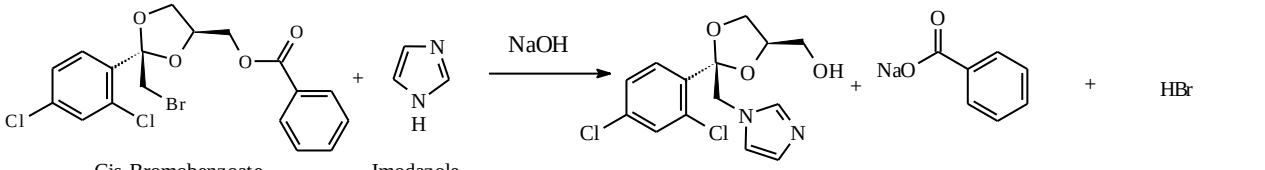
kept for IMD recovery. The organic layer containing the product is reacted with sodium hydroxide solution. After completion of the reaction, the pH of the mass is adjusted with hydrochloric acid. The mass is diluted with water and centrifuged. The wet cake is dissolved in ethyl acetate and treated with carbon. The mass is filtered and the ethyl acetate is distilled off. The residue is cooled and centrifuged. The mass is dried to produce KT-I.



Cis-Bromobenzoate
$C_{18}H_{15}O_4BrCl_2$ (446.12)

Imodazole
$C_3H_4N_2$ (68.07)

[(2S,4R)-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methanol

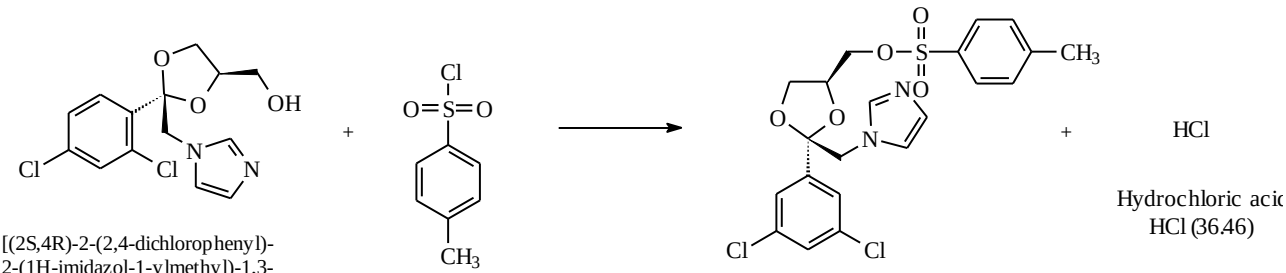
$C_{14}H_{14}N_2O_3Cl_2$ (329.18)

Sodium benzoate
$C_7H_5O_2Na$ (144.10)

Hydrogen Bromide
HBr (80.91)

KT-II

KT-I is reacted with PTSC in the presence of sodium carbonate and methylene chloride as solvent. The reaction mass is diluted and the organic layer separated. Methylene chloride is distilled off completely from the organic layer and the residue is diluted with methanol and water. The mass is centrifuges and washed with methanol and water mixture. The mass is dried to produce Cis-Tosylate (KT-II).



[(2S,4R)-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methanol

$C_{14}H_{14}N_2O_3Cl_2$ (329.18)

Para-Toluenyl sulphonyl chloride
$C_7H_7O_2ClS$ (190.64)

Cis-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl)methyl nethane sulfonate

$C_{21}H_{20}N_2O_5SCl_2$ (483.36)

Hydrochloric acid
HCl (36.46)

KT-III

Cis-Tosylate (KT-II) is reacted with Para hydroxyl phenyl N-acetyl piperazine and sodium methoxide in the presence of dimethyl sulfoxide as solvent. After completion of the reaction, sodium hydroxide solution is charged into the reactor and maintained. The mass is

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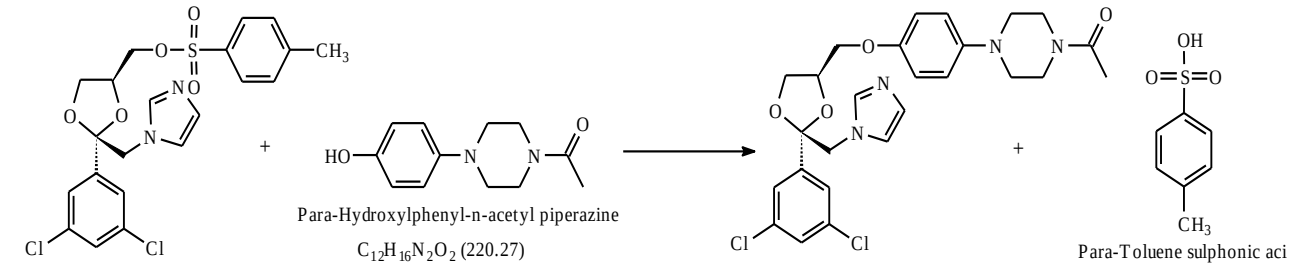
centrifuged. The wet cake is treated with water and further by acetone. The wet cake is taken for next stage.

KT-IV

The wet cake is dissolved in ethyl acetate and methanol, and treated with carbon. The mass is filtered and the solution distilled off. The residue is cooled and centrifuged. The material is dried to produce Ketoconazole.



Cis-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl)methyl nethane sulfonate

$C_{21}H_{20}N_2O_5SCl_2$ (483.36)

Para-Hydroxylphenyl-n-acetyl piperazine

$C_{12}H_{16}N_2O_2$ (220.27)

Ketoconazole

$C_{26}H_{28}N_4O_4Cl_2$ (531.43)

Para-Toluene sulphonic aci

$C_7H_8O_3S$ (172.19)

Raw material:

Raw Material	Quantity	CC
CBB	780.0	1.53
IMD	333.0	0.65
DMF	37.2	0.07
Sodium Bicarbonate	148.2	0.29
P-toluene sulfonyl chloride	465.0	0.91
Methylenechloride	193.5	0.38
Sodium carbonate	307.5	0.60
Carbon	26.0	0.05
Vacuum salt	6.0	0.01
Sodium hydroxide	170.0	0.33
Hydrochloric acid	169.5	0.33
Acetone	40.0	0.08
Toluene	68.5	0.13
Sodium methoxide powder	70.0	0.14
Dimethyl sulfoxide	68.0	0.13
Para hydroxyl phenyl n- acetyl piperazine	285.0	0.56
Ethyl acetate	200.4	0.39

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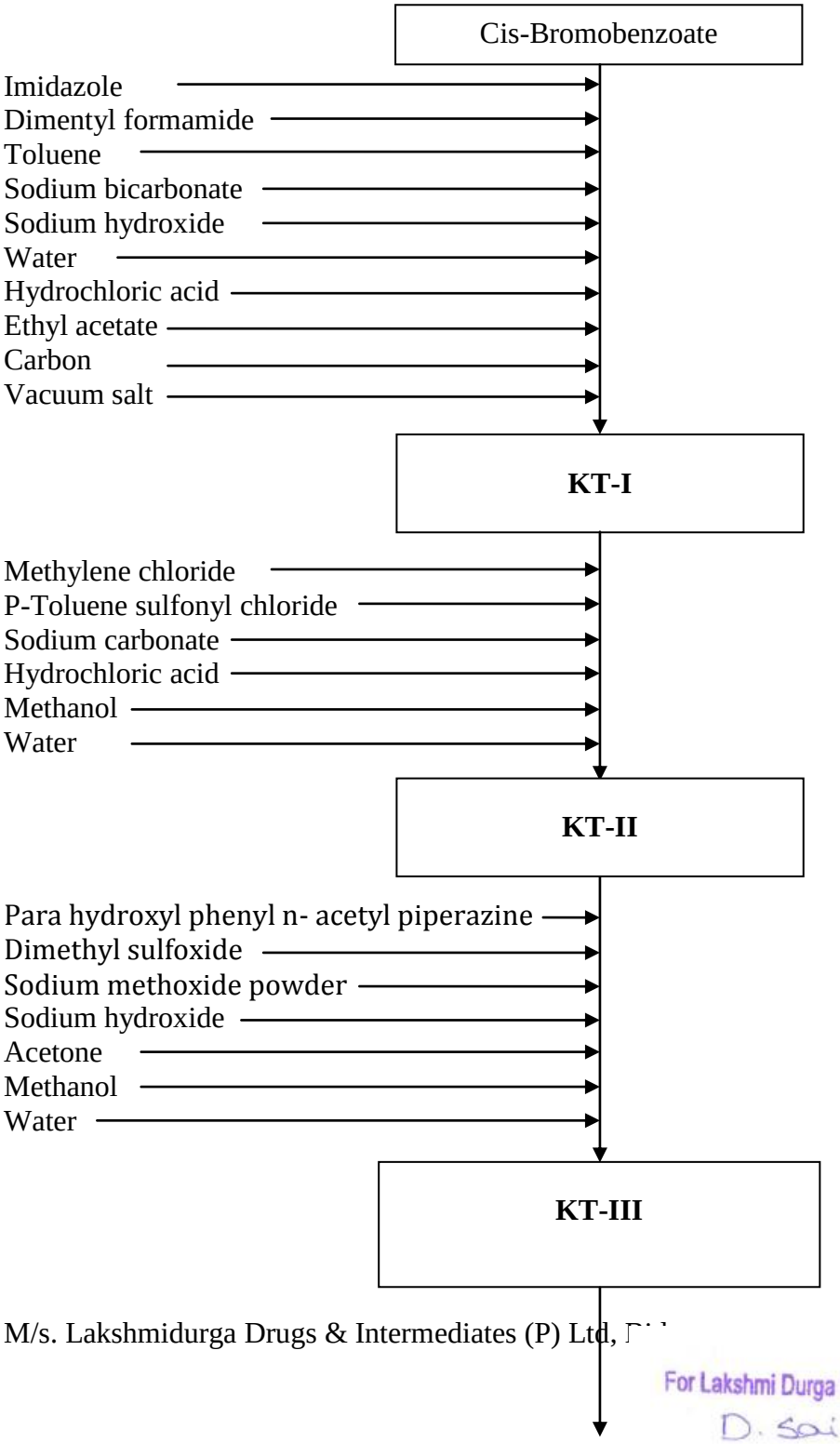
Methanol	70.0	0.14
Ketoconazole	510.0	1.00

Flow Chart:



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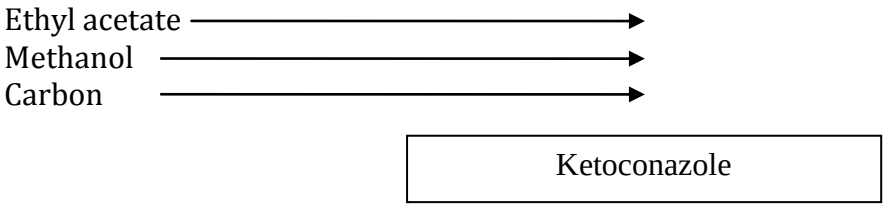

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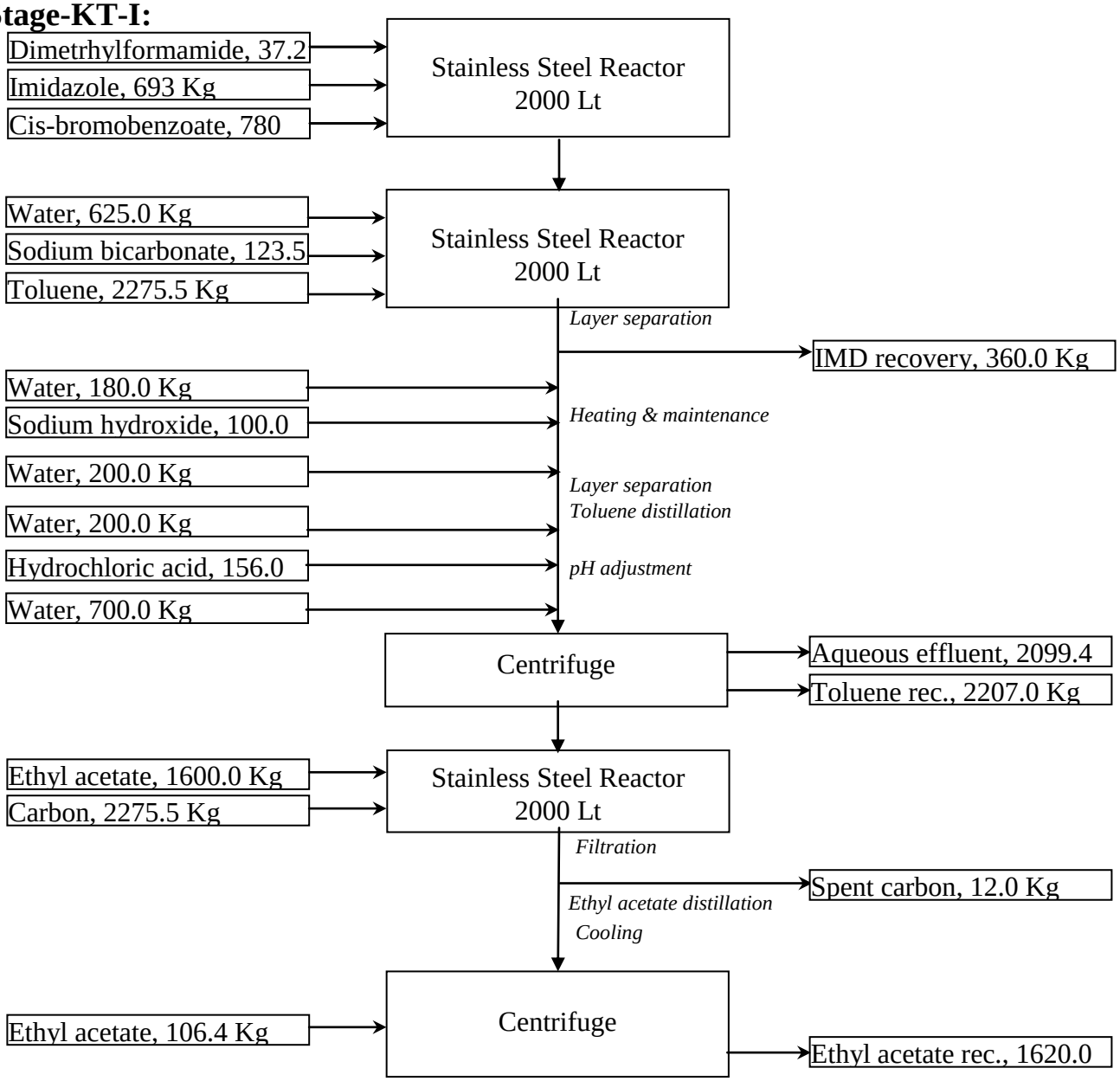
Stage-KT-I:



Batch Cycle Time:

Description	Time in hours
Reaction time	72
Centrifugation	8
Total	**80**
Reaction time	6
Centrifugation	8
Total	**14**
Drying time	8

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Solvent distillation	40
Total process time	**142**

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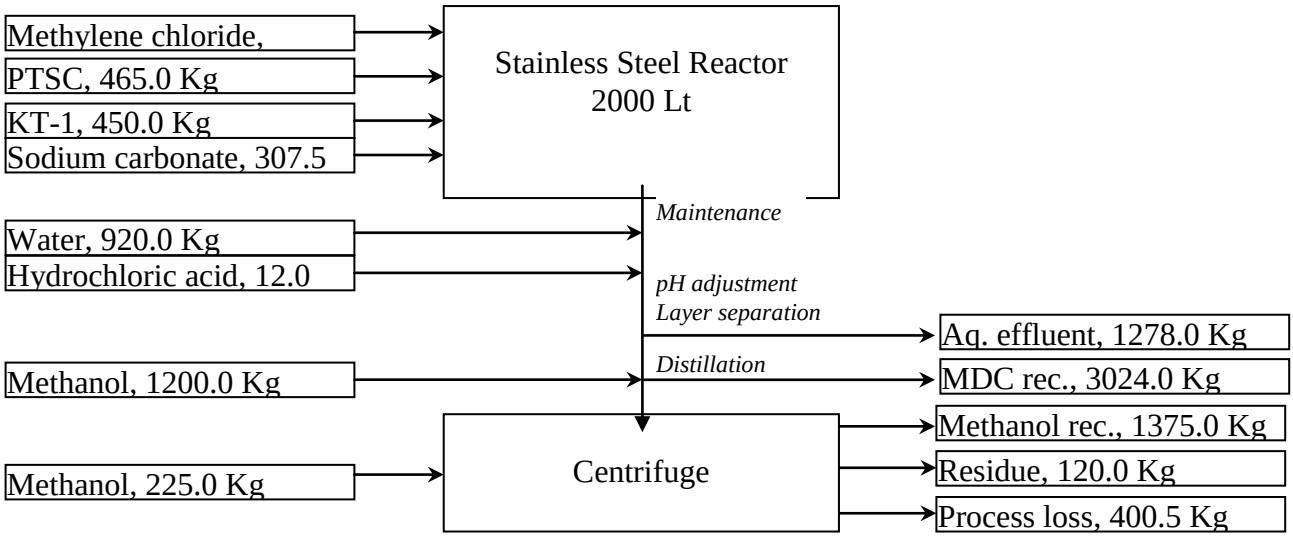
Stage-KT-II:



Batch Cycle Time:

Description	Time in hours
Reaction time	16
Distillation	18
Centrifugation	8
Total	**42**
Drying time	8
Solvent distillation	15
Total process time	**65**

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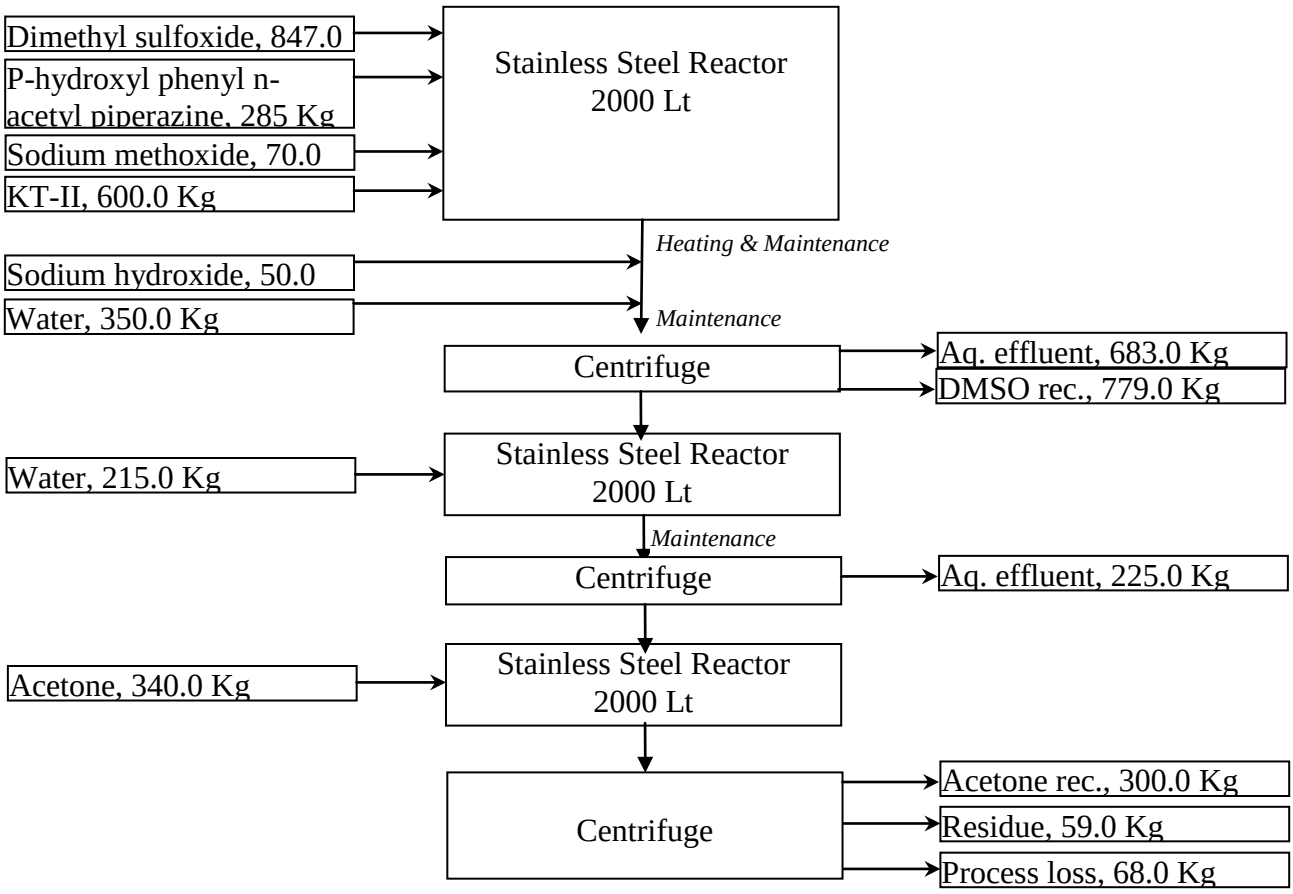
Stage-KT-III:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	26
Centrifugation	8
Total	**34**
Reaction time	4
Centrifugation	8
Total	**12**
Reaction time	8
Centrifugation	6
Total	**14**
Solvent distillation	15
Total process time	**75**

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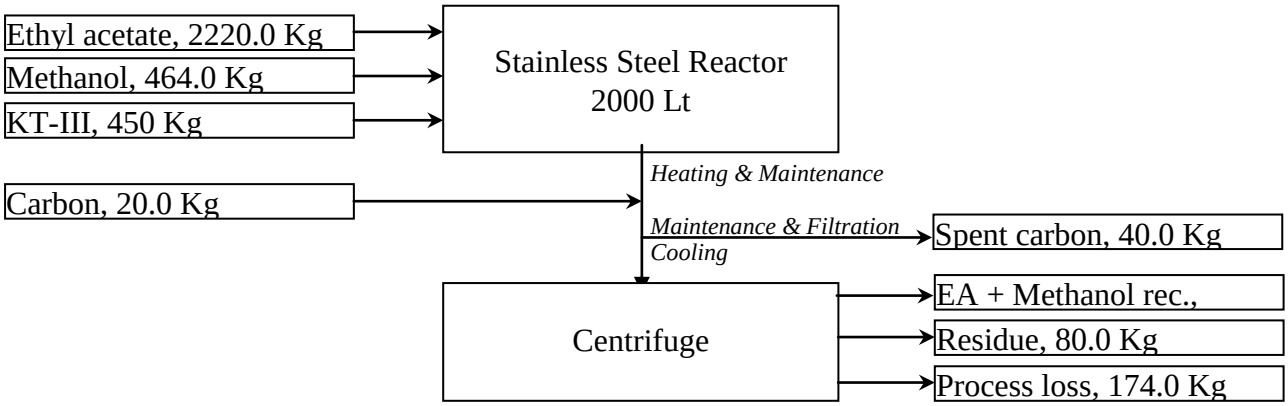
Stage-KT-IV:



Batch Cycle Time:

Description	Time in hours
Reaction time	8
Centrifugation	8
Total	**16**
Drying time	8
Solvent distillation	15
Total process time	**39**

Material Balance:

Ketoconazole			
Stage-I			
Input		**Output**	
CBB	780.0		450.0
IMD	693.0		
DMF	37.2	IMD (Rec)	360.0
Toluene	2275.5	Toluene (Rec)	2207.0
Sodium Bicarbonate	148.2	Ethyle acetate (Rec)	1620.0
Sodium hydroxide	120.0		
Water	1205.0	Aq. Effluent	2099.4
HCL	156.0	Spent carbon	12.0
Ethyl acetate	1706.4	Residue	130.0
Carbon	6.0	Process loss	254.9
Vacuum salt	6.0		

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Total	**7133.3**	**Total**	**7133.3**

Stage-II			
Input		**Output**	
KT-I	450.0	KT-II	600.0
Methylenechloride	3217.5		
P-toluene sulfonyl chloride	465.0	Methylenechloride (Rec)	3024.0
Sodium carbonate	307.5	Methanol (Rec)	1375.0
Hydrochloric acid	12.0	Aq. Effluent	1278.0
Methanol	1425.0		
water	920.0	Residue	120.0
		Process loss	400.5
Total	**6797.0**	**Total**	**6797.5**

Stage-III			
Input		**Output**	
Cis-tosylate (kt-ii)	600.0	KT-III	650.0
Para hydroxyl phenyl n-acetyl piperazine	285.0		
Dimethyl sulfoxide	847.0	Dimethyl sulphoxide (Rec)	779.0
Sodium methoxide powder	70.0	Acetone (Rec)	300.0
Sodium hydroxide	50.0	Aq. Effluent	908.0
Acetone	340.0	Residue	59.0
Methanol	7.0	Process loss	68.0
Water	565.0		
Total	**2764.0**	**Total**	**2764.0**

Stage-IV			
Input		**Output**	
KT-III	650.0	Ketoconazole	510.0
Ethyl acetate	2220.0	Ethyl acetate + Methanol (Rec)	2550.0
Methanol	464.0		
Carbon	20.0	Spent carbon	40.0
		Residue	80.0
		Process loss	174.0
Total	**3354.0**	**Total**	**3354.0**

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Water Usage	Quantity
Stage-I	1205.0
Stage-II	920.0
Stage-III	565.0
Stage-IV	0
Total	**2690.0**

Aqueous Effluent	Qty	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-I	2099.4	6.5	851.0	1800.0	2000.0	265.0	0.0	FE
Stage-II	1278.0	7.0	1150.0	1100.0	1200.0	300.0	0.0	FE
Stage-III	908.0	8.5	765.0	1200.0	1600.0	0.0	0.0	FE
Stage-IV	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-
Total	4285.4	7.1	921.9	1464.1	1676.7	219.3	0.0	

Solid Waste	Residue	Spent CB	Spent SS	Spent HF
Stage-I	130	12	0	0
Stage-II	120	0	0	0
Stage-III	59	0	0	0
Stage-IV	80	40	0	0
Total	**389**	**52**	**0**	**0**

CIS-BROMO BENZOATE:

Stage-I:

Charge toluene, 2,4-dichloroacetophenone and glycerin onto a stainless steel reactor. Charge PTSA and water into the reactor, and heat the mass to reflux. Maintain the mass at reflux for 24 hours. After completion of the reaction, cool the mass below 35°C and transfer the mass to a glass lined reactor. Charge n-butanol in the reactor containing the mass and cool below 15°C. Slowly add bromine into the reactor and maintain the mass below 15°C. After completion of the reaction, adjust the pH of the mass to 8 with liquor ammonia. Charge water into the reactor, stir and settle. Separate the organic layer and wash with water. Meanwhile, charge water and sodium hydroxide into a stainless steel reactor. Transfer the organic layer from GL reactor into the SS reactor. Cool the mass and charge TEBAC. Add benzoyl chloride slowly into

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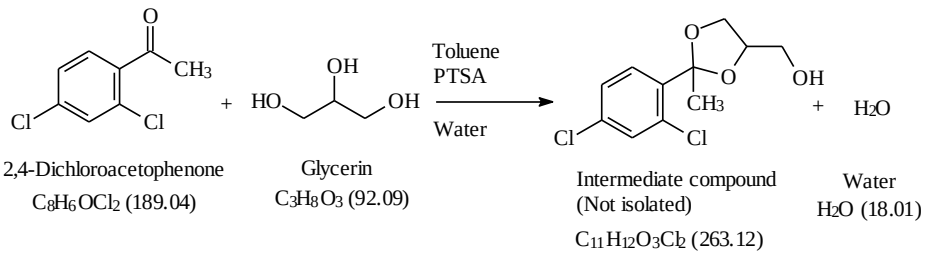
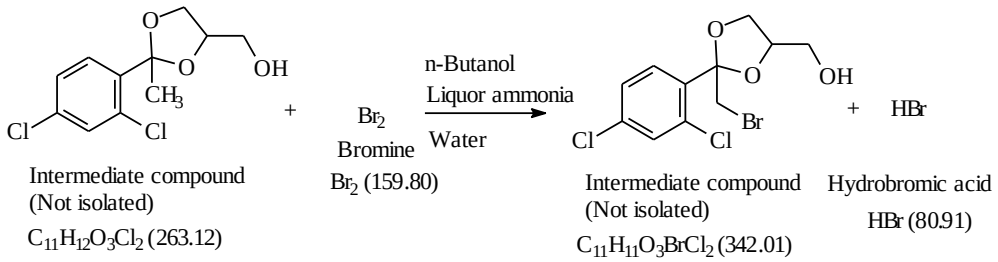
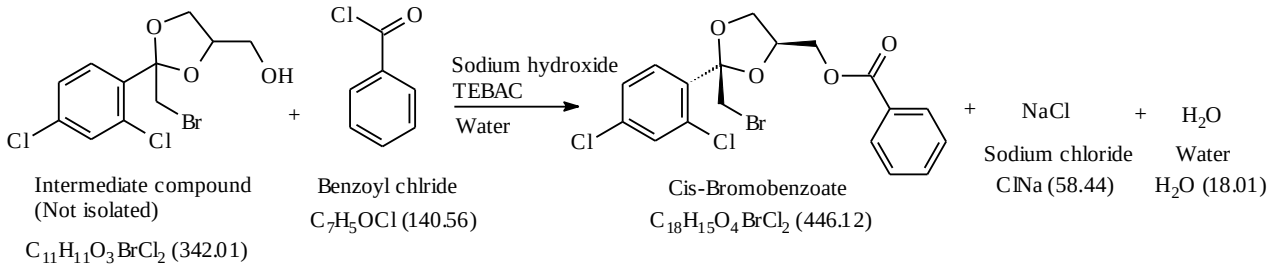
the reactor below 20°C and maintain. After completion of the reaction, settle the mass. Separate the organic layer and wash with sodium bicarbonate solution followed by water. Distill off toluene completely and dilute the residue with methanol. Cool the mass and centrifuge. Dry the material at 60 – 65°C to produce Cis-bromo benzoate.







Raw Material:

Raw Materials	Quantity	CC
2,4-Dichloroacetophenone	500.0	0.67
Benzoyl Chloride	464.0	0.62
Bromine	468.0	0.62
CS Flakes	181.0	0.24
Glycerin	271.0	0.36
Liq. Ammonia	374.5	0.50
Methanol	2172.5	2.90
N- Butanol	150.0	0.20
PTSA	13.5	0.02
Sodium Bicarbonate	30.0	0.04
TEBAC	9.5	0.01
Toluene	1720.0	2.29

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Output - CBB	750.0	1.00

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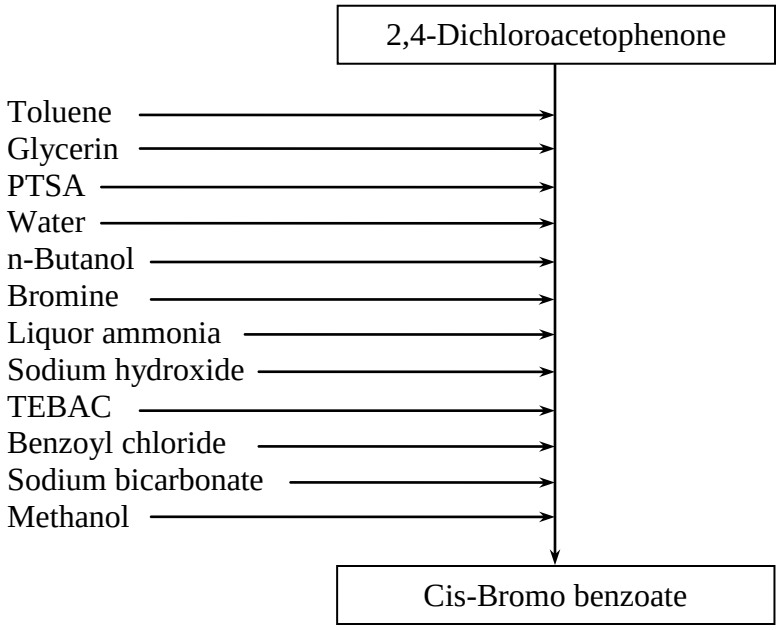
FLOW CHART OF CIS-BROMO BENZOATE:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	60
Workups	12
Centrifugation	4
Total	**76**
Drying time	5
Solvent distillation	10
Total process time	**91**

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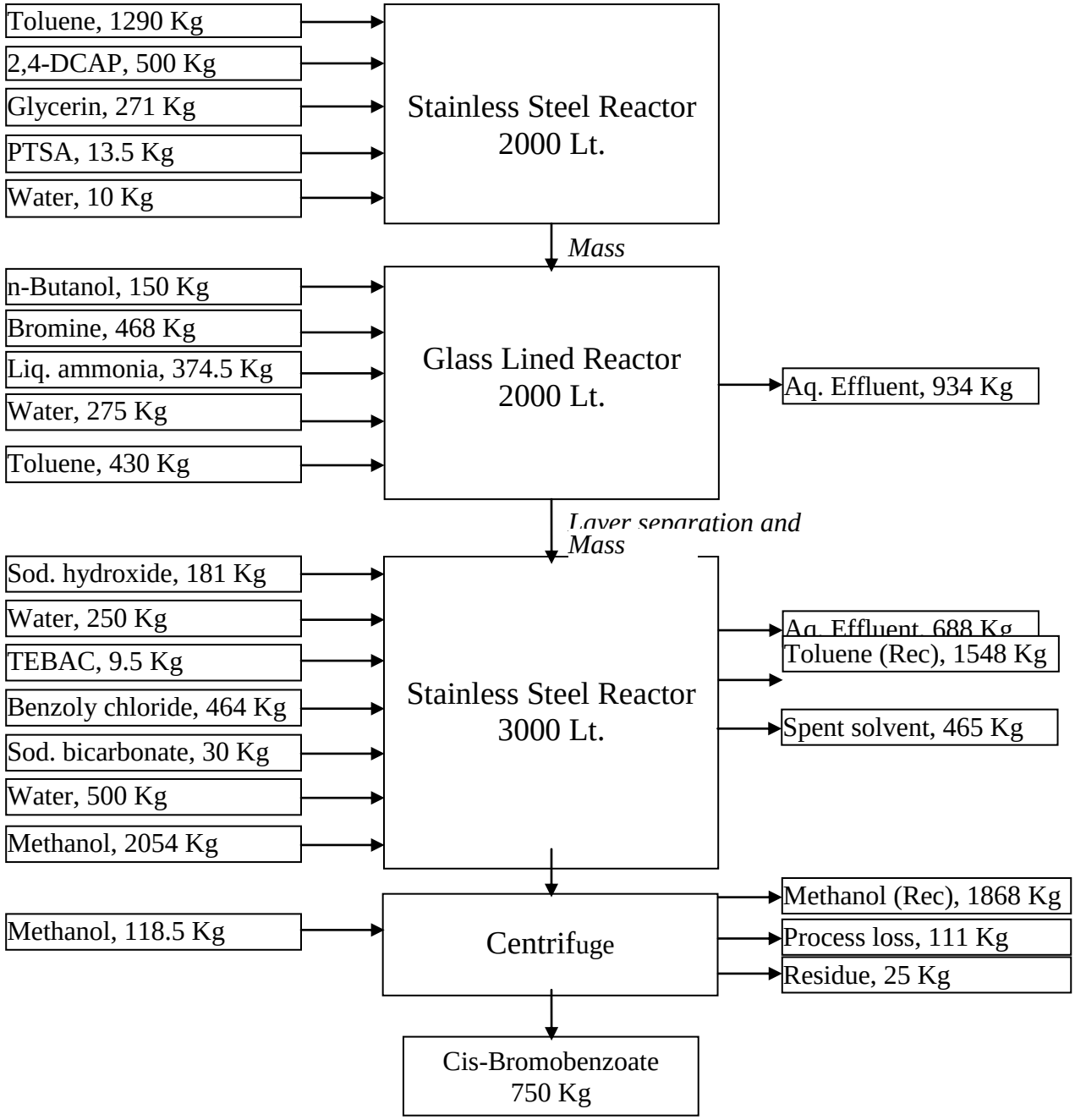
Stage-1:



Material Balance:

Stage-I			
Input	**Quantity**	**Output**	**Quantity**
2,4-DCAP	500	Cis-Bromo benzoate	750

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Benzoyl Chloride	464		
Bromine	468	Methanol (Rec)	1868
CS Flakes	181	Toluene (Rec)	1548
Glycerin	271	Aq. HBR (HBR Rec)	1000
Liq. Ammonia	374.5	Spent solvent	465
Methanol	2172.5		
N- Butanol	150	Aqueous effluent	1622
PTSA	13.5		
Sodium Bicarbonate	30		
TEBAC	9.5		
Toluene	1720	Residue	25
Water	1035	Process loss	111
Total	**7389**	**Total**	**7389**

Water Usage	**Quantity**
Stage-I	1035.0
Total	**1035.0**

Aqueous Effluent	**Kg**	**pH**	**TDS**	**BOD**	**COD**	**Chloride**	**Sulphate**	**Disposal**
Int-A-I	1622.0	7.5	2800	1500	4000	300	0	
Total	1622.0	7.5	2800	1500	4000	300	0	**FE**

Solid waste	**Residue**	**Spent CB**	**Spent SS**	**Spent HF**
Stage-I	25	0	0	0
Total	**25**	0	0	0

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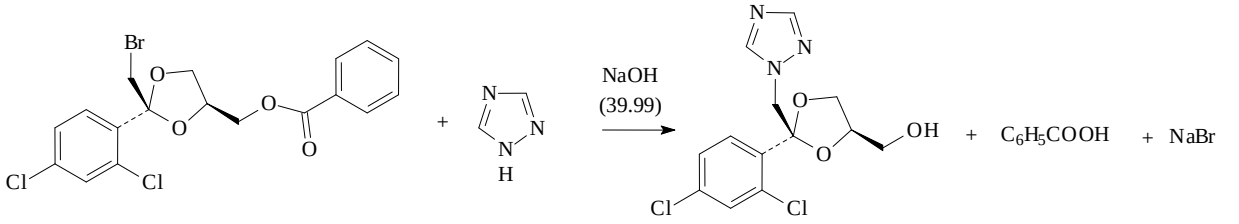
2. ITRACONAZOLE AND ITS INTERMEDIATES:

DESCRIPTION OF PRODUCTION PROCESS – ITR-INT-A

Stage-I:

charge dimethyl formamide, cis-2[bromomethyl-2-(2,4 dichlorophenyl)1,3 dioxalane-4-yl)methyl benzoate and 1H-1,2,4 triazole into a reactor. Charge sodium hydroxide solution into the reactor. Heat to reflux and maintain for 8 hours. After completion of reaction, cool the mass below 35°C and charge potassium carbonate. Stir the mass for 30 minutes and filter. Charge the filtrate and distill off DMF completely. Charge water and toluene into the reactor and stir for 30 minutes. Discard the bottom aqueous layer to ETP. Cool the organic layer to 10-15°C. Centrifuge the material and wasn with toluene. Dry the material at 60-65°C to produce Cis-[2-(2,4-dichlorophenyl)-2-(1H,1,2,4-triazol-1yl methyl)1,3 dioxolan-4yl]methanol.



cis-2-[bromomethyl-2-(2,4-dichloro phenyl)-1,3-dioxalene-4-yl) methyl benzoate

$C_{18}H_{15}O_4BrCl_2$ (446.12)

1H-1,2,4-triazole

$C_2H_3N_3$ (69.06)

cis-2-[(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxalene-4-yl) methanol

$C_{13}H_{13}N_3O_3Cl_2$ (330.17)

$C_7H_6O_2$ (122.12) (102.89)

Stage-II:

Charge methylene dichloride, Step-I compound and triethyl amine into a reactor. Slowly add methane sulfonyl chloride into the reactor at 10-15°C. After completion of the reaction, charge water and stir for 30 minutes. Separate the layers. Charge organic layer in to the reactor and charge carbon. Stir for 30 minutes and filter the mass into another reactor. Add hydrochloric acid into the reactor at 25-30°C. Cool the mass to 10-15°C. Centrifuge and wash with methylene dichloride. Dry the material at 45-50°C to produce Cis-[2-(2, 4 - dichlorophenyl) - 2 - (1H,1, 2, 4 - triazol - 1yl- methyl) 1,3-dioxolan-4yl]-methyl methane sulfonate (ITR-INT-A).

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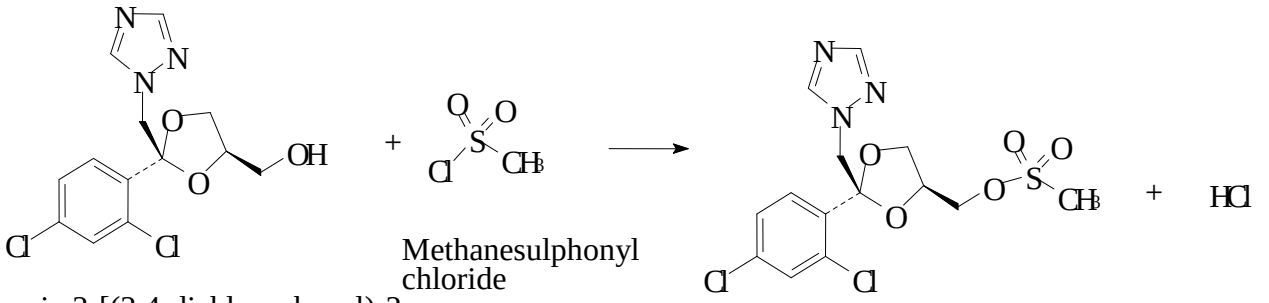


cis-2-[(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxalene-4-yl) methanol

$C_{13}H_{13}N_3O_3Cl_2$ (330.17)

Methanesulphonyl chloride

CH_4O_2SCl (114.54)

cis-[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl] methyl methanesulphonate

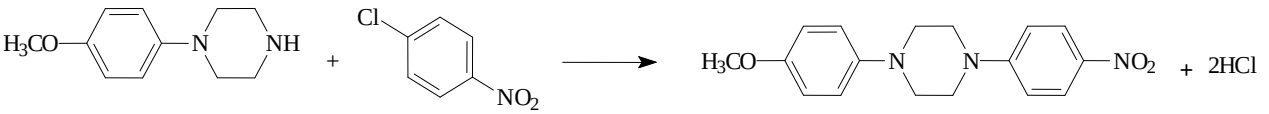
$C_{14}H_{15}N_3O_5SCl_2$ (408.25)

HCl (36.46)

DESCRIPTION OF PRODUCTION PROCESS – ITR-INT-B

Stage-I:

Charge dimethyl formamide, potassium carbonate and 1-(4-Methyxy) piperadine into a reactor. Heat the mass to 60-65°C. Add paranitro chlorobenzene for 3-4 hours at same temperature. After completion of the reaction distill off the dimethyl formamide completely. Cool the mass and charge methanol ad carbon into the reactor. Maintain the mass for 30 minutes at 50-55°C and filter into another reactor. Cool the filtrate to 10-15°C and centrifuge. Wash the material in water. Slurry wash the cake with acetone to produce 1-(4-Methoxyphenyl)-1-(4-nitrophenyl) piperazine.



1-(4-Methoxyphenyl) piperazine

$C_{11}H_{17}N_2OCl$ (228.76)

Paranitro chlorobenzene

$C_6H_4NO_2Cl$ (157.53)

1-(4-Methoxyphenyl)-1-(4-nitrophenyl) piperazine (72.92)

$C_{17}H_{19}N_3O_3$ (313.35)

Stage-II:

Charge DMF, palladium carbon and 1-(4-Methoxyphenyl)-1-(4-nitrophenyl) piperazine into the reactor. Heat the mass to 50-55°C. Pass hydrogen gas for 18 hours. After completion of the reaction, cool the mass below 35°C and filter the mass. Cool the filtrate to 0-5°C and maintain. Centrifuge the mass to produce 1-(4-Methoxyphenyl)-1-(4-aminophenyl) piperazine

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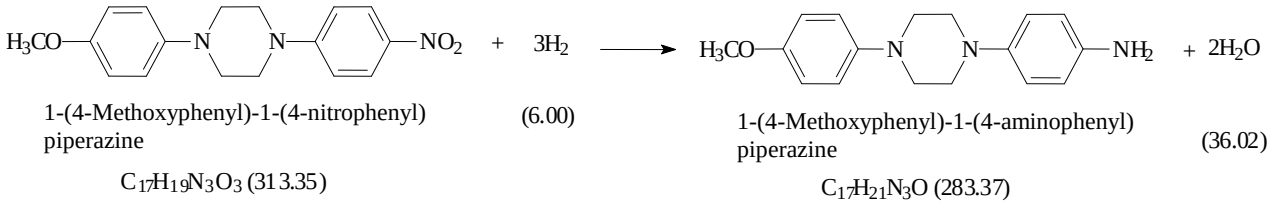


1-(4-Methoxyphenyl)-1-(4-nitrophenyl) piperazine

$C_{17}H_{19}N_3O_3$ (313.35)

(6.00)

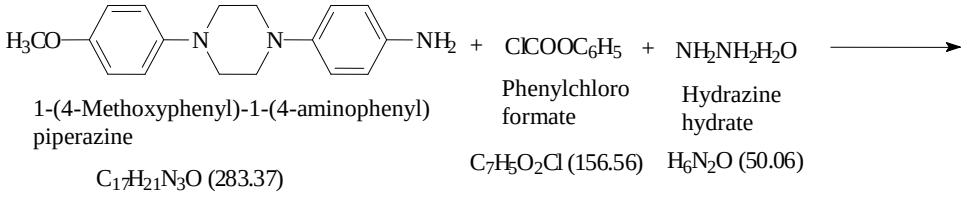
1-(4-Methoxyphenyl)-1-(4-aminophenyl) piperazine

$C_{17}H_{21}N_3O$ (283.37)

(36.02)

Stage-III + IV:

Charge Methylene chloride and 1-(4-Methoxyphenyl)-1-(4-aminophenyl) piperazine compound into a reactor. Heat the mass to 35-45°C. Add phenyl chloroformate for 5-6 hours at same temperature. After completion of the reaction, charge water into the reactor. Separate the layers. Discard aqueous layer and charge organic layer. Distill off Methylene chloride completely and charge n-butanol into the reactor. Heat the mass to 55-60°C. Add hydrazine hydrate into the reactor. maintain for 4 hours at same temperature and cool the mass. Centrifuge the mass and wash with n-butanol to produce 2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl hydrazine carboxamide.



1-(4-Methoxyphenyl)-1-(4-aminophenyl) piperazine

$C_{17}H_{21}N_3O$ (283.37)

Phenylchloro formate

$C_7H_5O_2Cl$ (156.56)

Hydrazine hydrate

H_6N_2O (50.06)

2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl] hydrazine carboxamide

$C_{18}H_{23}N_5O_2$ (341.41)

(94.11) (36.46) (18.01)

Stage-V:

Charge DMF and carboxamide compound into the reactor and heat to 70-75°C. Add formanidine acetate into the reactor slowly. After completion of the reaction, cool the mass and centrifuge, to produce 2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl phenyl]-3H-1,2,4-triazole-3-one

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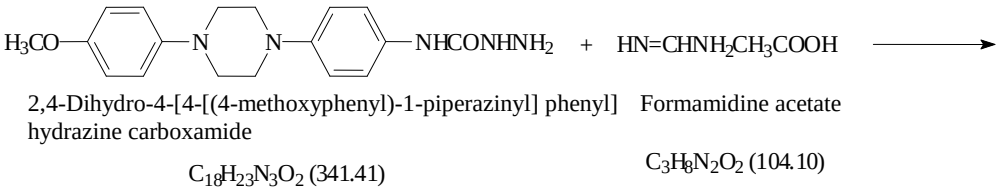
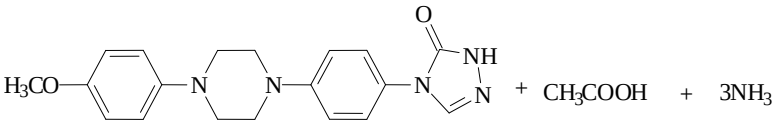


2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl] hydrazine carboxamide

$C_{18}H_{23}N_3O_2$ (341.41)

Formamidine acetate

$C_3H_8N_2O_2$ (104.10)



2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl]-3H-1,2,4-triazole-3-one

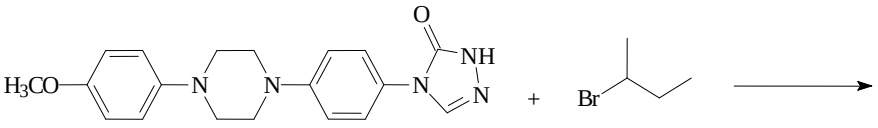
$C_{19}H_{21}N_5O_2$ (351.40)

CH_3COOH $C_2H_4O_2$ (60.05)

$3NH_3$ (34.60)

Stage-VI:

Charge 2-bromobutane, potassium carbonate and triazole compound into a reactor. Heat to reflux and maintain for 8 hours. After completion of reaction filter the mass and distill off 2-bromebutane completely. Charge DMF into the reactor and acedify the mass with hydrochloric acid. Centrifuge the material and wash with DMF to produce 2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one

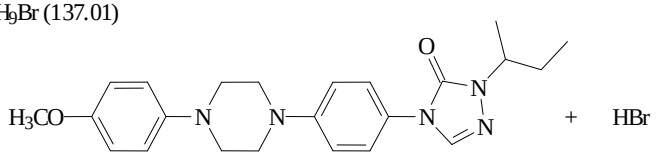


2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl]-3H-1,2,4-triazole-3-one

$C_{19}H_{21}N_3O_2$ (351.40)

2-Bromobutane

C_4H_9Br (137.01)



2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one

$C_{23}H_{29}N_5O_2$ (407.51)

HBr (80.91)

Stage-VII:

Charge hydrobromic acid and stage-VI compound into a reactor and heat the mass to reflux. After completion of the reaction, distill off HBr completely and charge water into the reactor. Neutralize the mass with soda ash. Centrifuge the mass and wash with water to produce 2,4-

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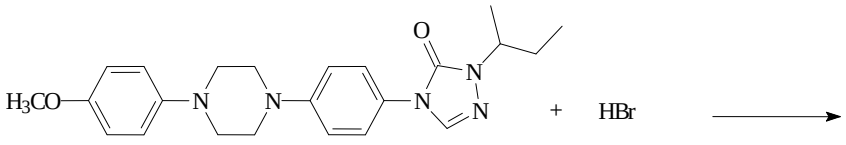
Dihydro-4-[4-[(4-hydroxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one (ITR-INT-B)



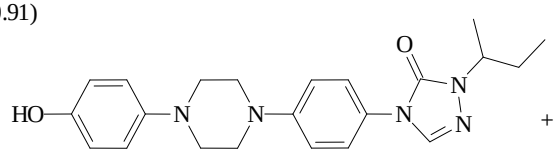
2,4-Dihydro-4-[4-[(4-methoxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one

$C_{23}H_{29}N_5O_2$ (407.51)

+ HBr

Hydrobromic acid

(80.91)



2,4-Dihydro-4-[4-[(4-hydroxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one

$C_{22}H_{27}N_5O_2$ (393.48)

+ CH_3Br (94.93)

ITRA-Stage-I/II/III

Charge water, potassium hydroxide, Cis-(2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl-methyl)-1,3-dioxalane-4-yl) methyl methane sulfonate and 2,4-Dihydro-4-[4-[(4-hydroxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one into the reactor. Heat the mass to 80-85°C and maintain for 6 hours. Cool the mass below 35°C and centrifuge. Charge the cake and DMF into a reactor and maintain for 1 hour ar room temperature. Centrifuge the mass and wash with DMF to produce Itraconazole Crude. The crude is treated with toluene, methanol and ethyl acetate and carbon to produce Itraconazole pure.

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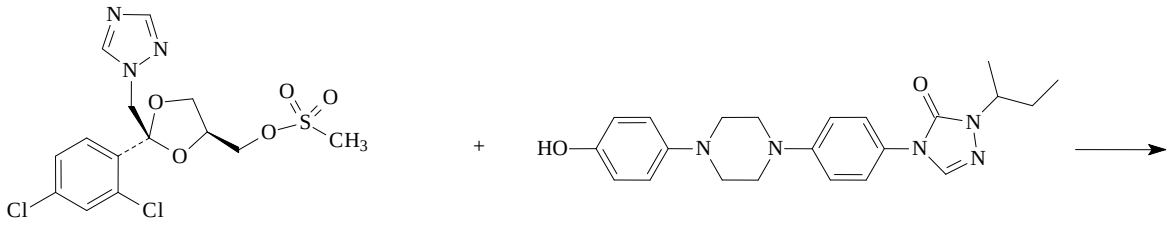
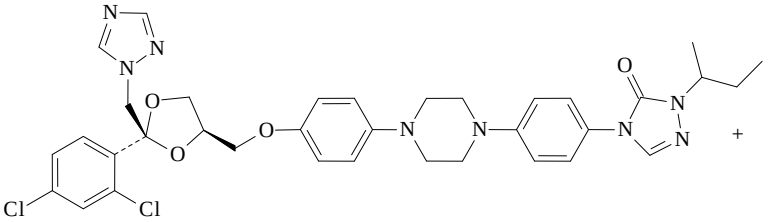


cis-[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl methyl)-1,3-dioxolan-4-yl] methyl methanesulphonate

$C_{14}H_{15}N_3O_5SCl_2$ (408.25)

2,4-Dihydro-4-[4-[(4-hydroxyphenyl)-1-piperazinyl] phenyl]-2-(1-methylpropyl)-3H-1,2,4-triazole-3-one

$C_{22}H_{27}N_5O_2$ (393.48)



Itraconazole

$C_{35}H_{38}N_8O_4Cl_2$ (705.64)

CH_3OH (32.04) + SO_2 (64.05)

Raw Material:

Raw Materials	Quantity	CC
1-(4-Methyxy) piperadine	86.9	1.02
1H,1,2,4-Triazole	70.4	0.83
2-Bromo butane	33.2	0.39
Acetone	5.5	0.06
Carbon	7.8	0.09
Cis-Bromobenzoate	111.3	1.31
Dimethyl formamide	44.5	0.52
Ethyl acetate	12	0.14
Formamidine acetate	63.6	0.75
Hydragin hydrate	65.0	0.77
Hydrobromic acid	26.4	0.31
Hydrochloric acid	38.4	0.45
Hydrogen gas	10	0.12
Hyflow supercell	6.7	0.08
Methane sulfonyl chloride	38.3	0.45
Methanol	25.3	0.30
Methylene chloride	12.8	0.15
n-Butanol	2.6	0.03

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Palladium carbon	0.1	0.00
Paranitro chlorobenzene	71.2	0.84
Phenyl chloroformate	78.6	0.93
Potassium carbonate	233.8	2.75
Potassium hydroxide	52	0.61
Soda ash	86.7	1.02
Sodium bicarbonate	71.0	0.83
Sodium hydroxide	17.5	0.21
Toluene	9.1	0.11
Triethyl amine	40.2	0.47
Itraconazole	85.0	1.00

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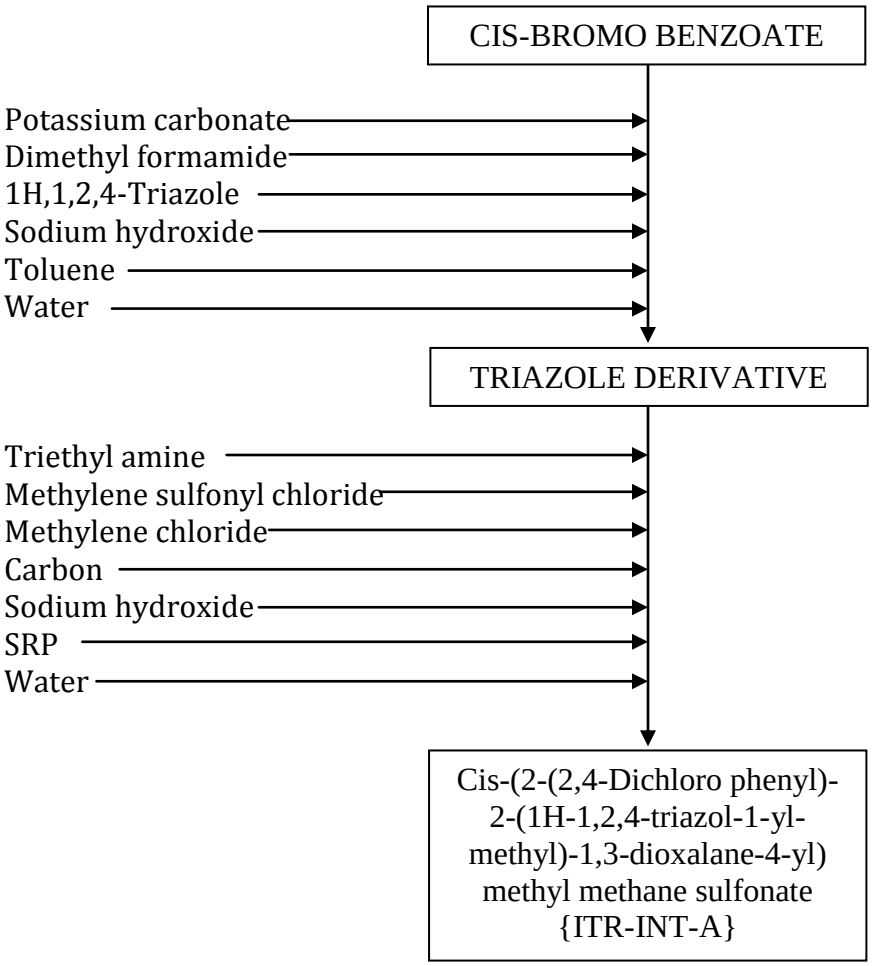
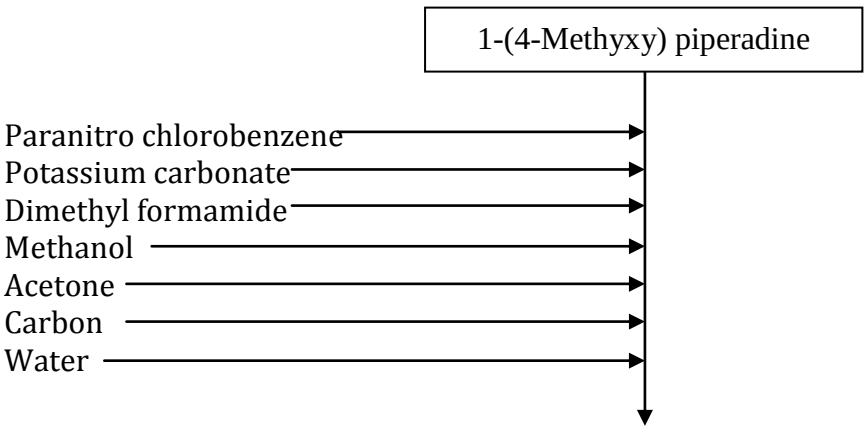
FLOW CHART OF {ITR-INT-A}:



FLOW CHART OF ITR-INT-B



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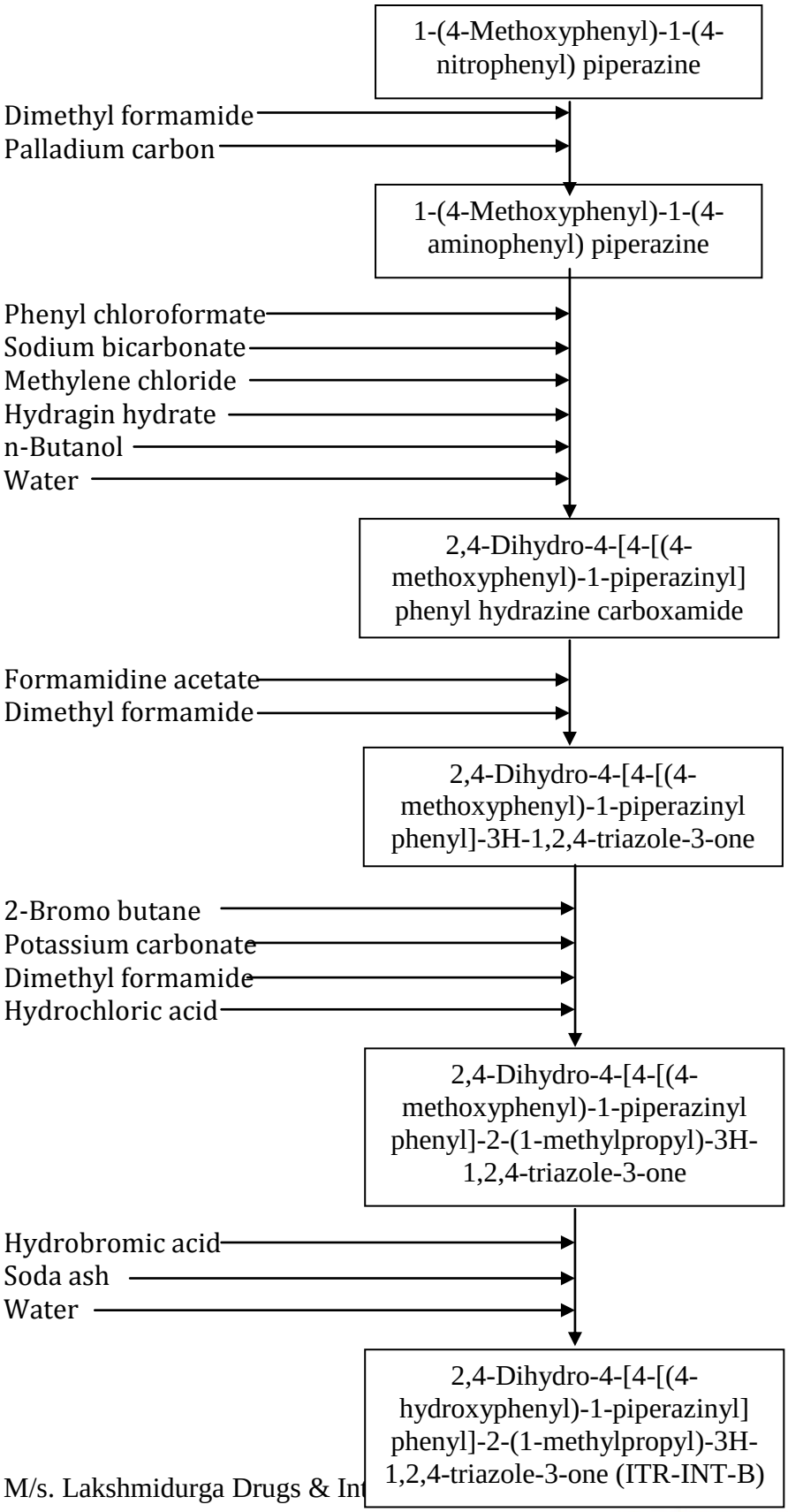

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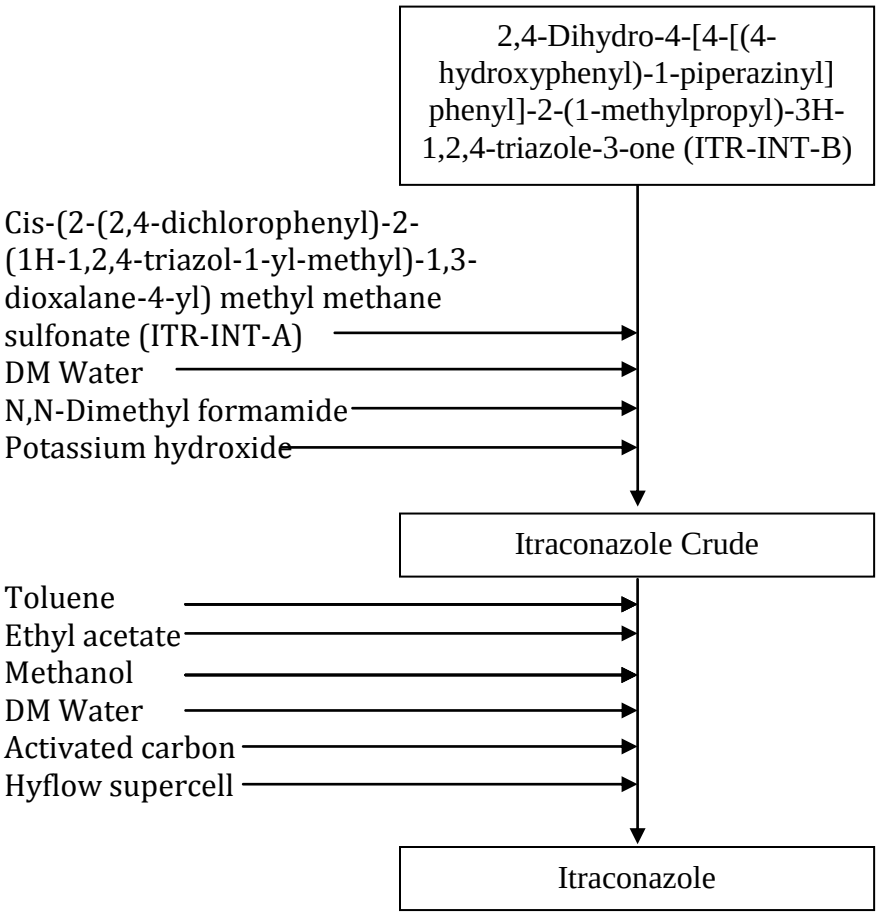
ITRACONAZOLE



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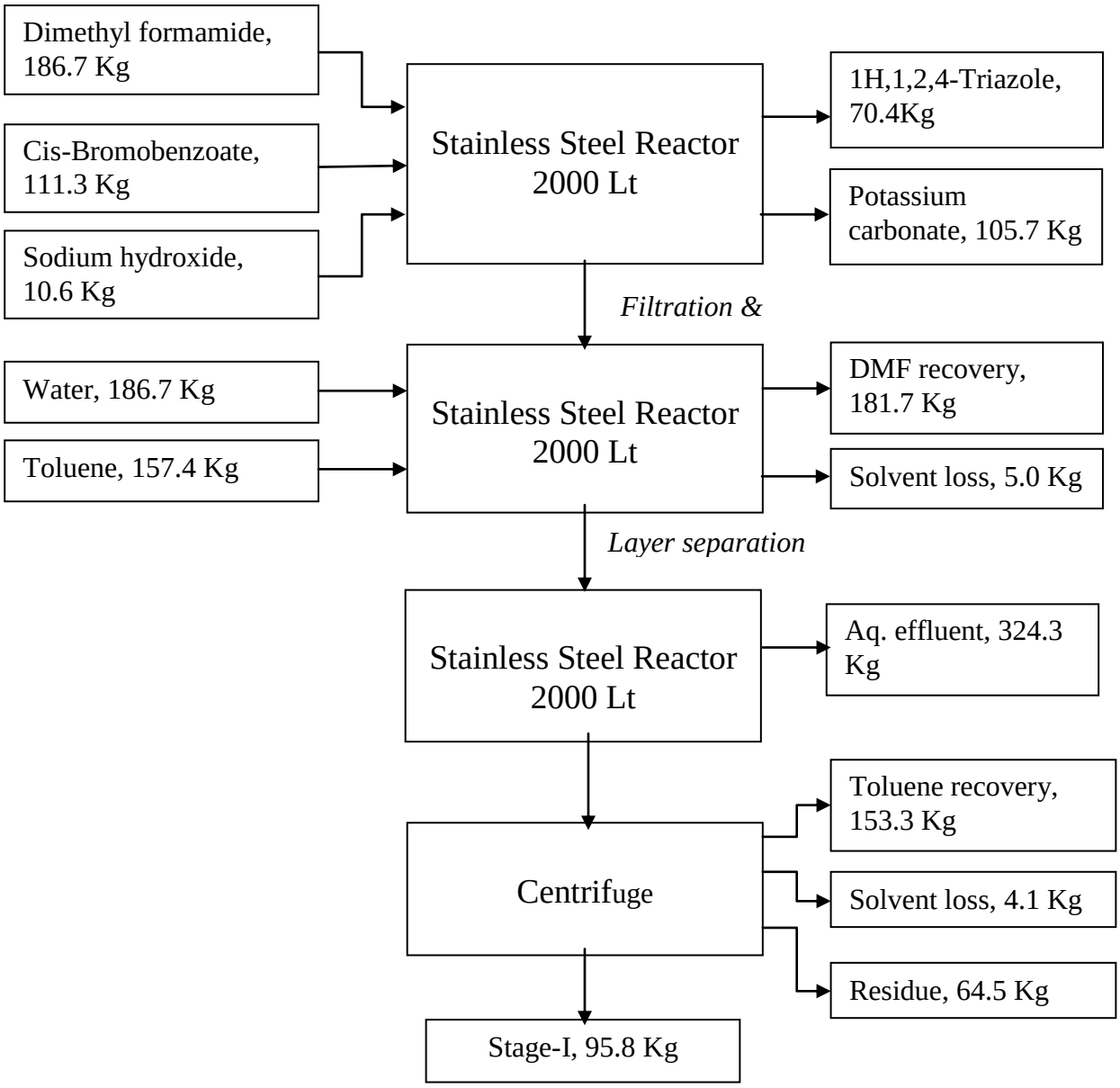
Stage-ITR-INT-A-1:



Batch Cycle Time:

Description	Time in hours
Reaction time	12
Workups	6
Centrifugation	4
Total	**22**
Drying time	6

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Solvent distillation	6
Total process time	**34**

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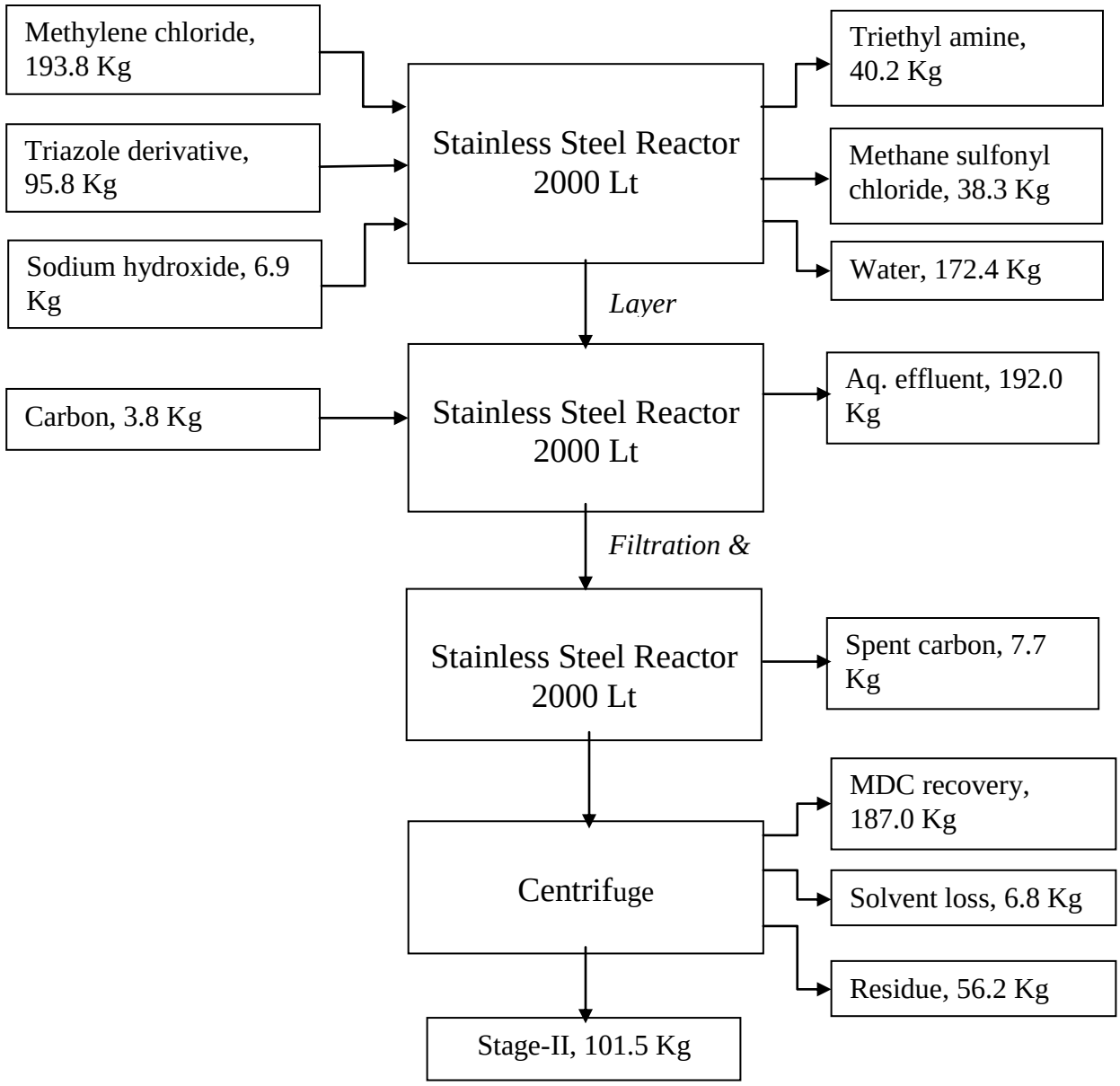
Stage-ITR-INT-A-2:



Batch Cycle Time:

Description	Time in hours
Reaction time	8
Workups	8
Centrifugation	2
Total	**18**
Drying time	6

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Solvent distillation	6
Total process time	**30**

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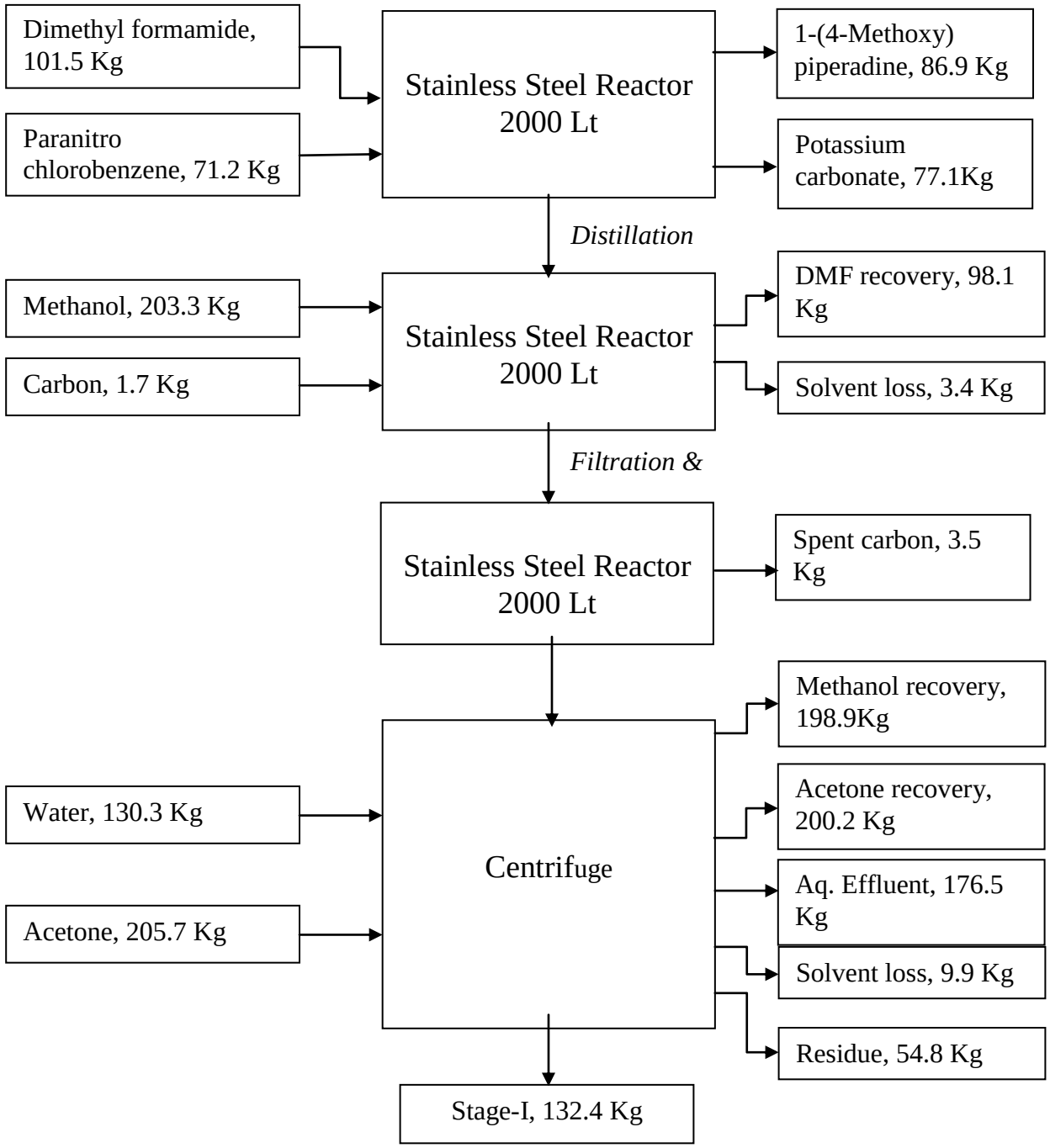
Stage-ITR-INT-B-1:



Batch Cycle Time:

Description	Time in hours
Reaction time	12
Workups	6

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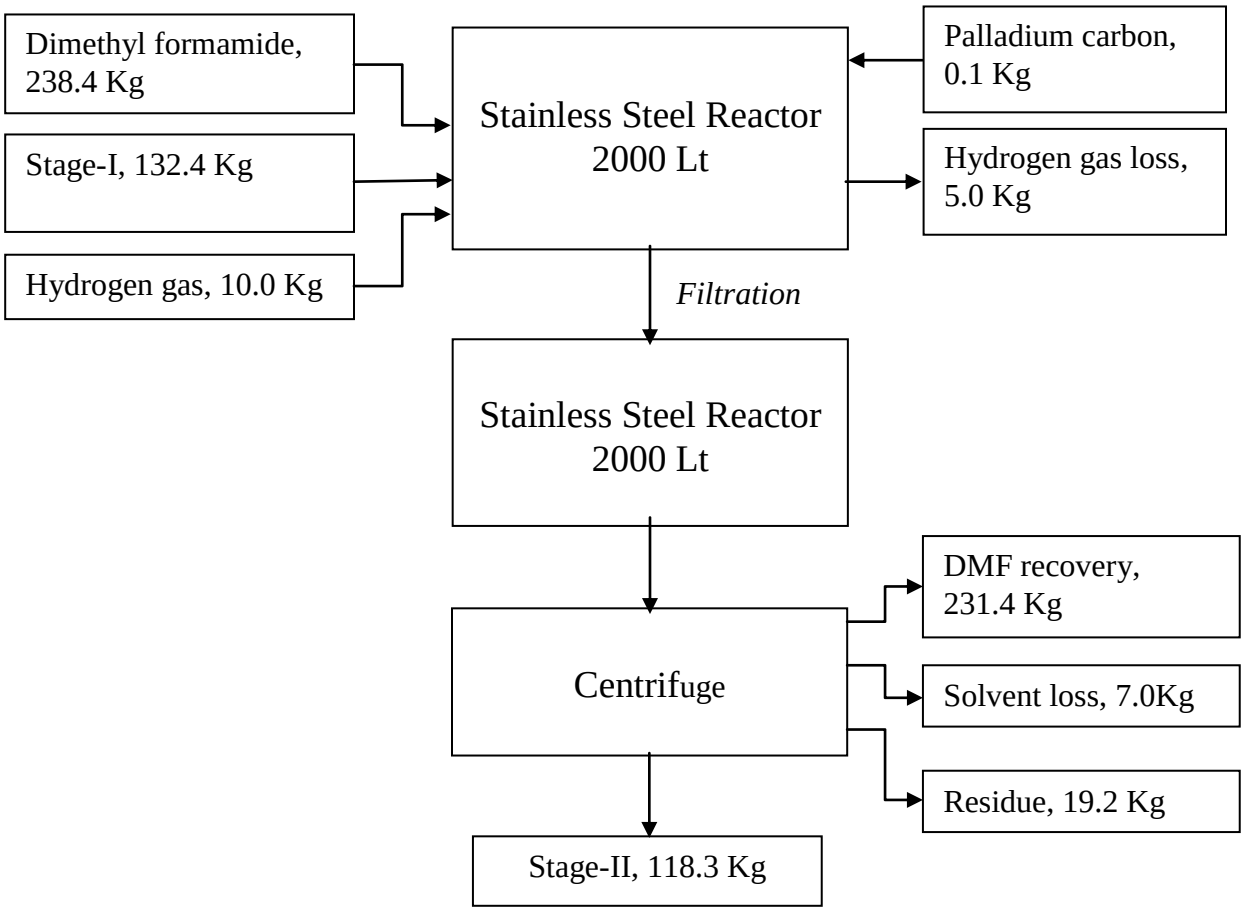
Centrifugation	4
Total	**22**
Drying time	6
Solvent distillation	6
Total process time	**34**

Stage-ITR-INT-B-2:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	20
Workups	6
Centrifugation	4
Total	**30**
Drying time	6

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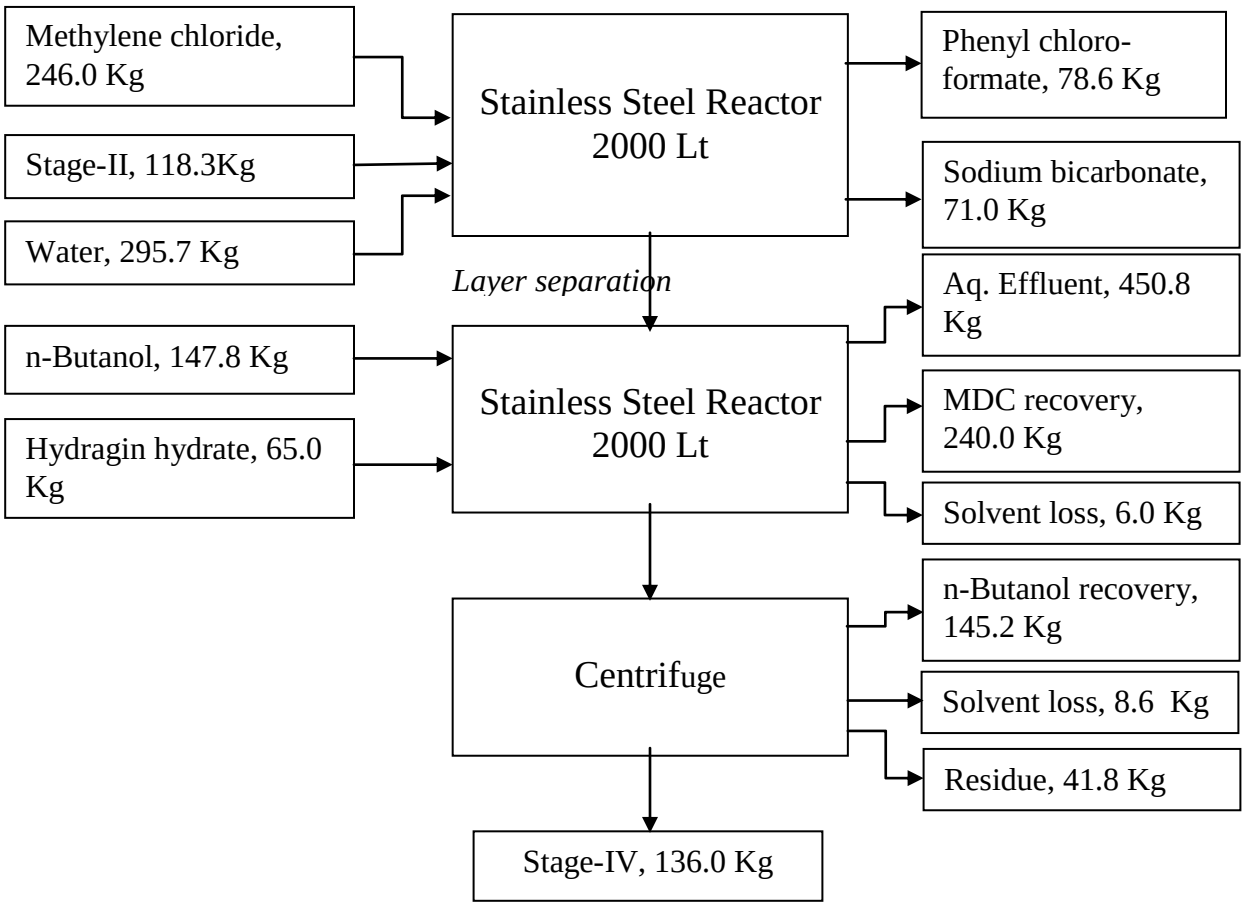
Solvent distillation	6
Total process time	**42**

Stage-ITR-INT-B-III+IV:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	18
Workups	6
Centrifugation	4
Total	**28**
Drying time	6
Solvent distillation	4
Total process time	**38**

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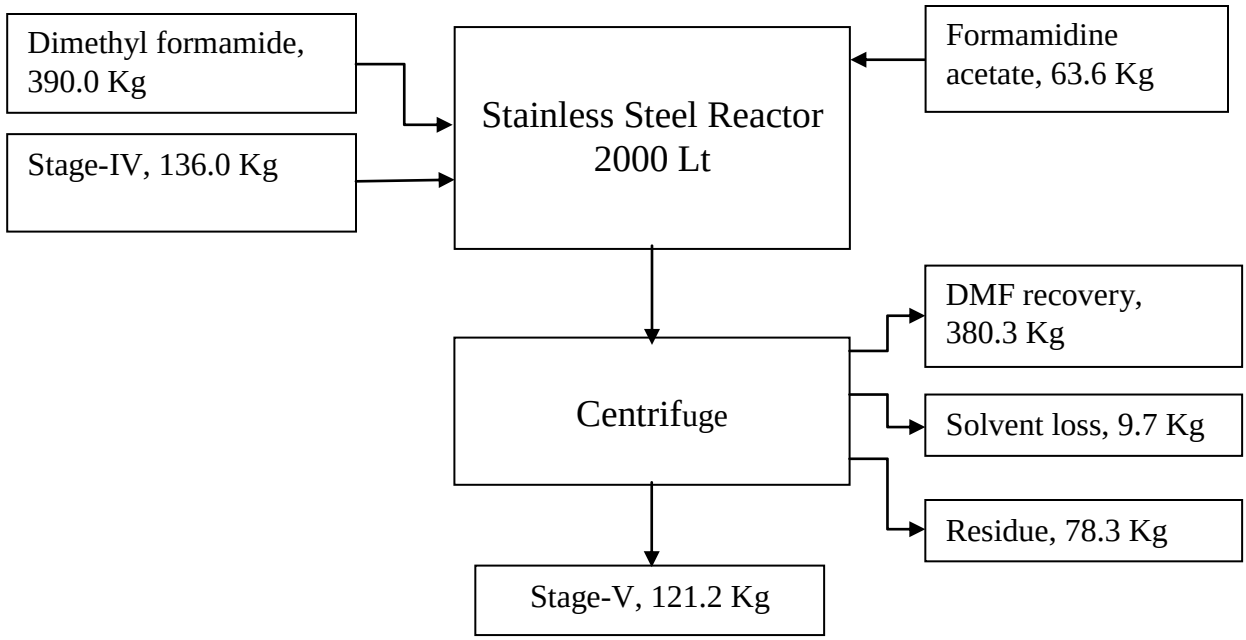
Stage-ITR-INT-B-V:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	8
Workups	2
Centrifugation	3
Total	**13**
Drying time	6
Solvent distillation	6
Total process time	**25**

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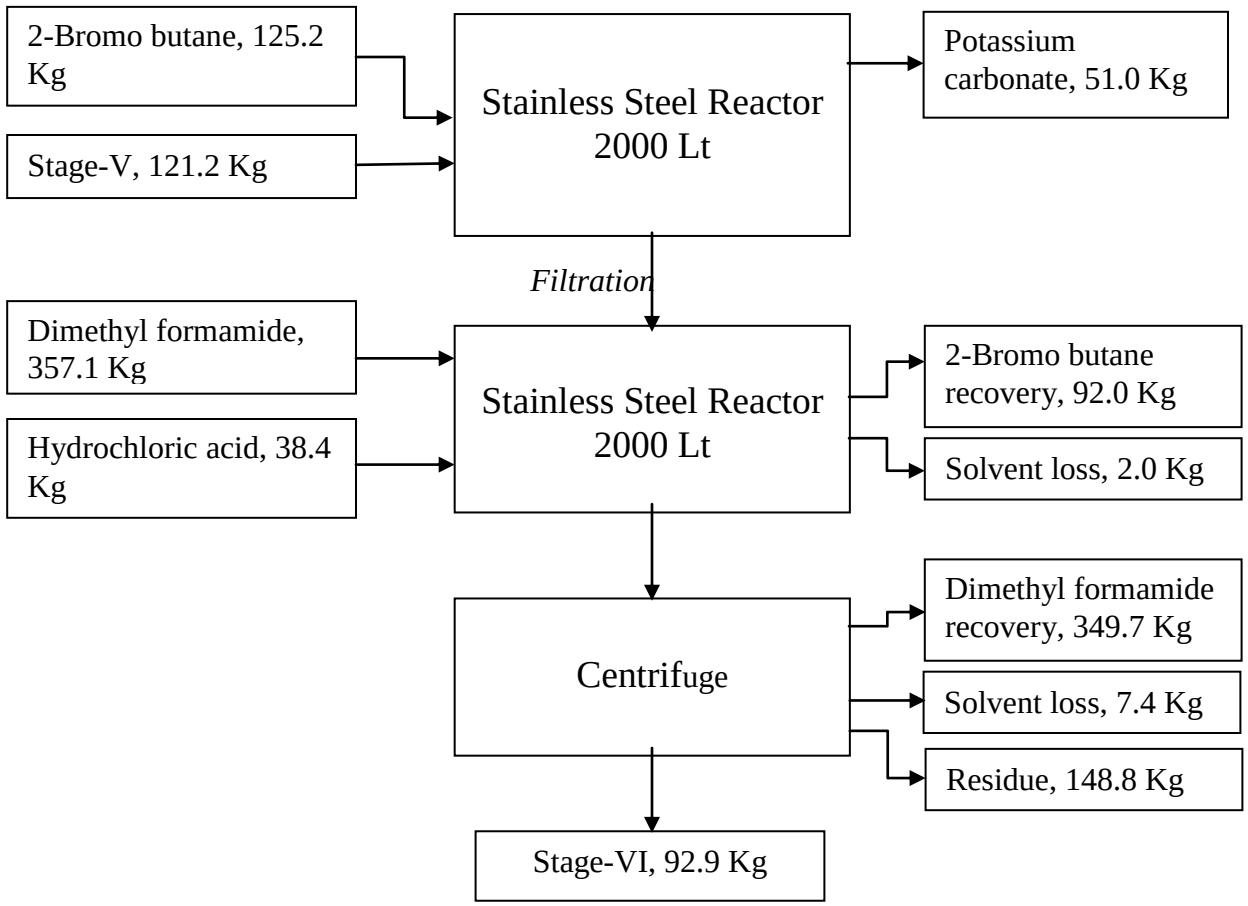
Stage-ITR-INT-B-VI:



Batch Cycle Time:

Description	Time in hours
Reaction time	14
Workups	4
Centrifugation	4
Total	**22**
Drying time	6
Solvent distillation	6
Total process time	**34**

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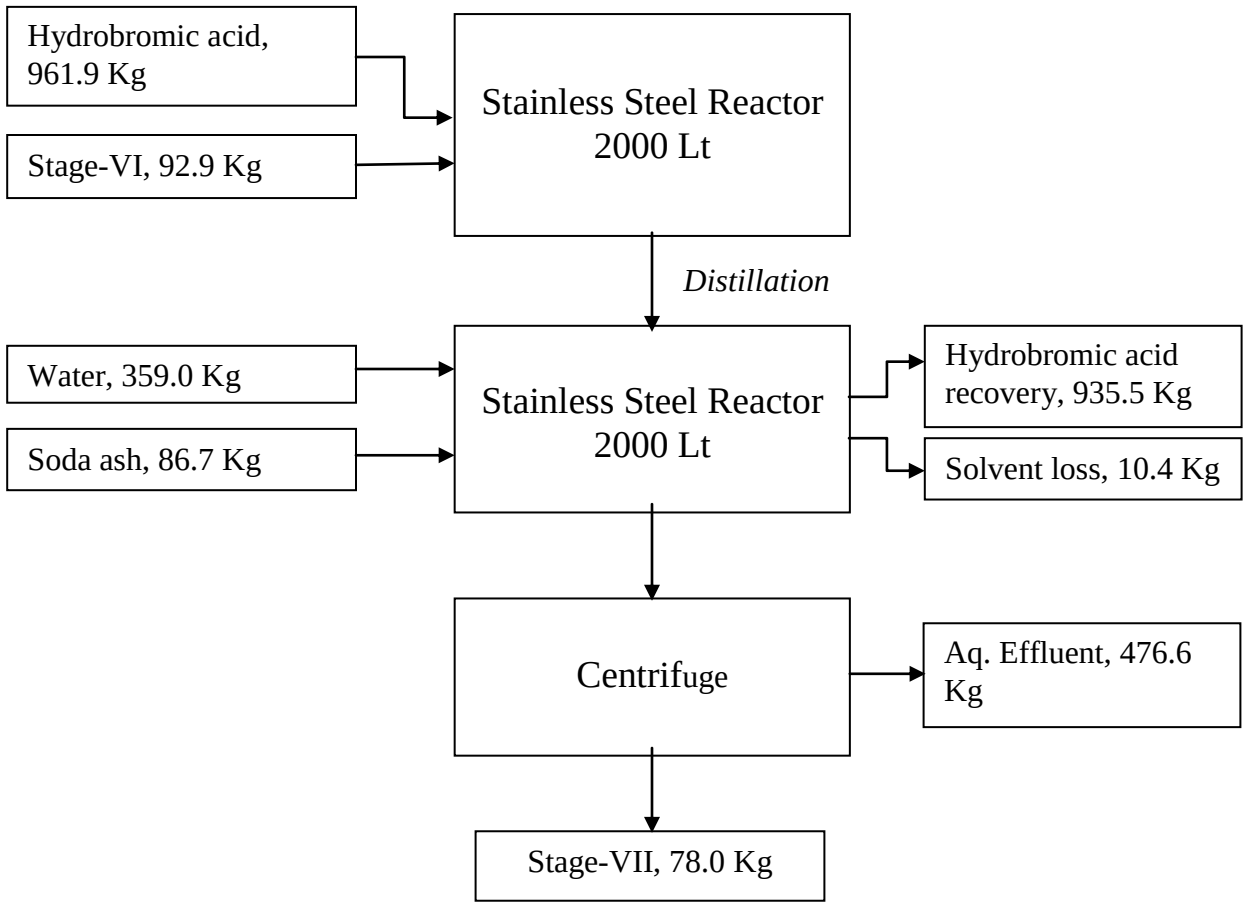
Stage-ITR-INT-B-VII:



Batch Cycle Time:

Description	Time in hours
Reaction time	24
Workups	6
Centrifugation	4
Total	**34**
Drying time	8
Total process time	**42**

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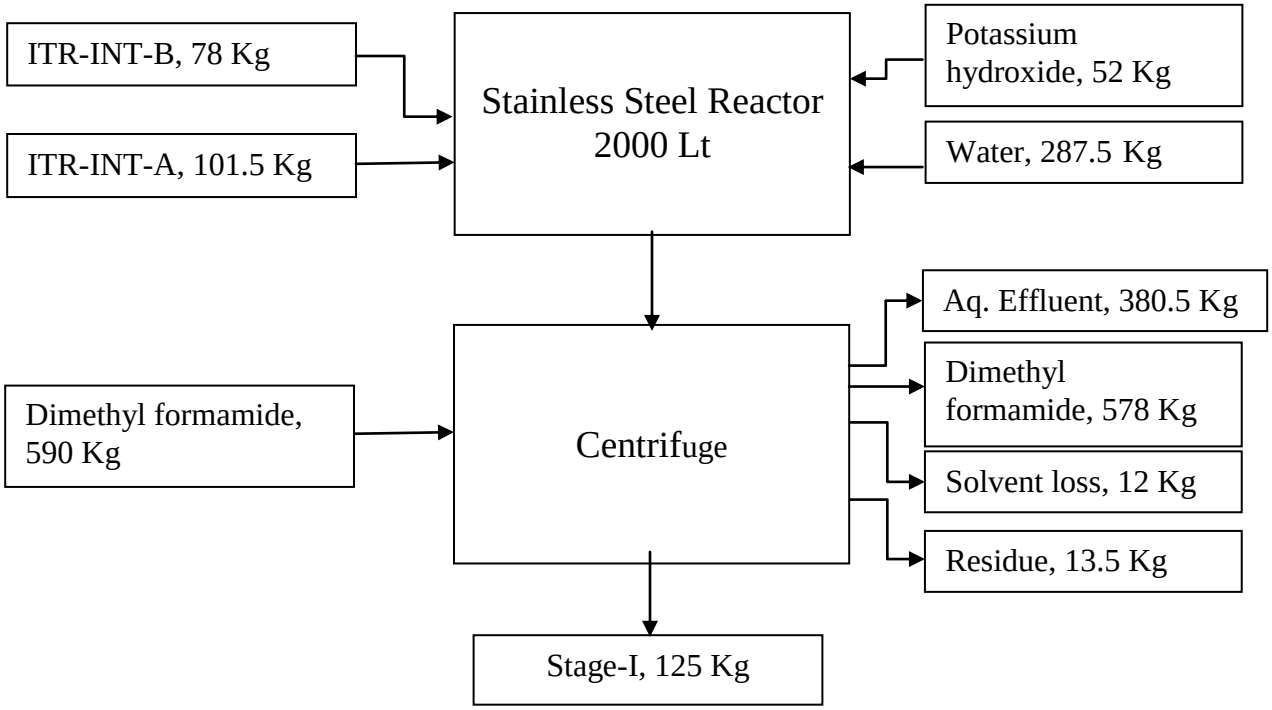
Stage-IT-I:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	10
Workups	3
Centrifugation	4
Total	**17**
Drying time	4
Solvent distillation	7
Total process time	**28**

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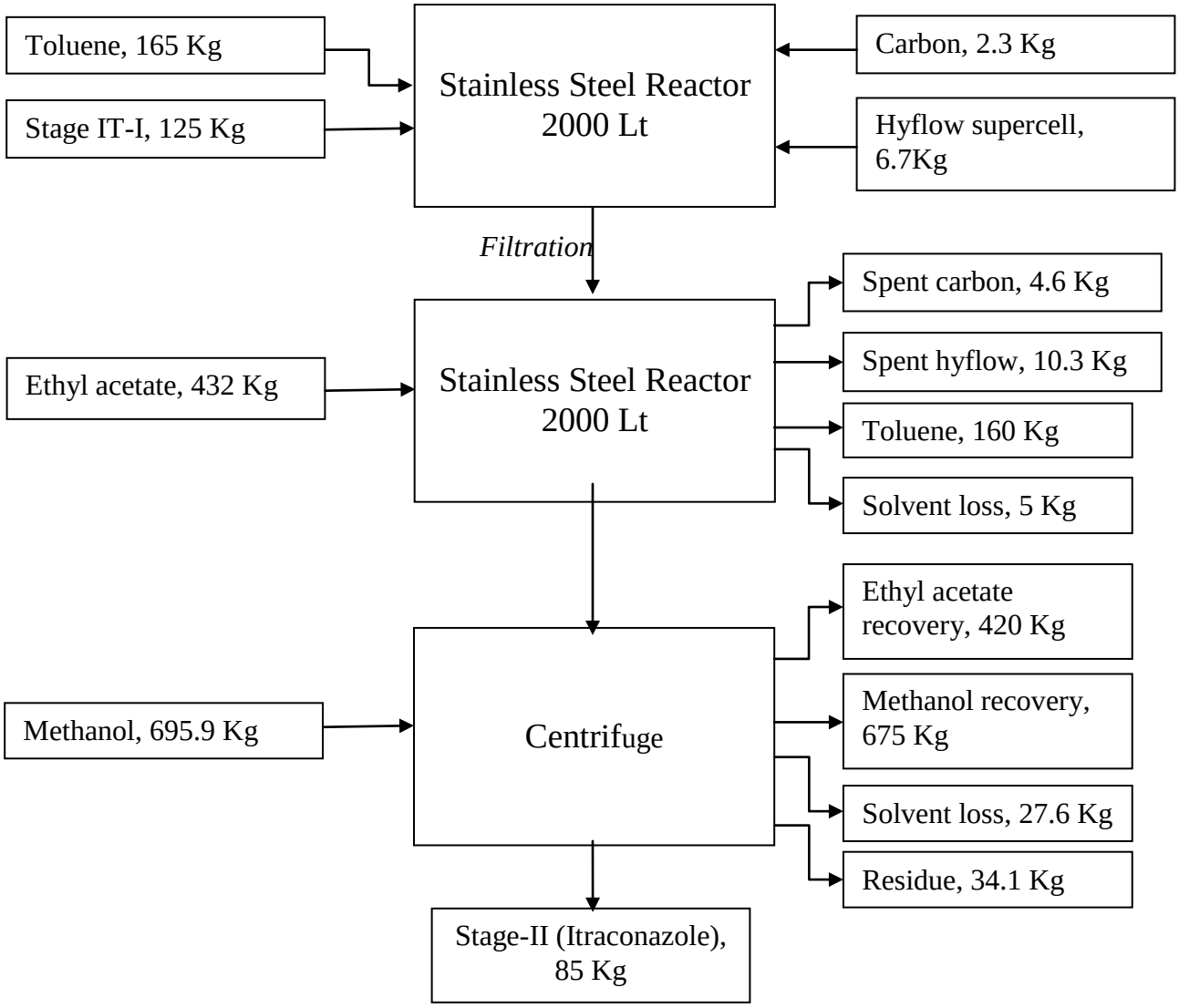
Stage-IT-II:



Batch Cycle Time:

Description	Time in hours
Reaction time	4
Workups	16
Centrifugation	4
Total	**24**
Drying time	10
Solvent distillation	8
Total process time	**42**

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Material balance:

ITR-INT-A
Stage-I

INPUT	Quantity	OUTPUT	Quantity
Cis-Bromobenzoate	111.3	Triazole derivative	95.8
1H,1,2,4-Triazole	70.4	Solvent rec (DMF)	181.7
Potassium carbonate	105.7	Solvent rec (Tol)	153.3
Dimethyl formamide	186.7	Aq. Effluent	324.3
Sodium hydroxide	10.6	Residue	64.5
Toluene	157.4		
Water	186.7	Solvent loss	9.1
Total	**828.7**	**Total**	**828.7**

Stage-II

INPUT	Quantity	OUTPUT	Quantity
Triazole derivative	95.8	ITR-INT-A	101.5
Triethyl amine	40.2	Solvent rec (MDC)	187.0
Methane sulfonyl chloride	38.3		
Methylene chloride	193.8	Aq.effluent	192.0
Carbon	3.8	Spent carbon	7.7
Sodium hydroxide	6.9	Residue	56.2
Water	172.4	Solvent loss	6.8
Total	**551.2**	**Total**	**551.2**

ITR-INT-B
Stage-I

INPUT	Quantity	OUTPUT	Quantity
1-(4-Methyxy) piperadine	86.9	Stage-I	132.4
Paranitro chlorobenzene	71.2	Solvent Rec (Methanol)	198.9
Potassium carbonate	77.1	Solvent Rec (Acetone)	200.2
Dimethyl formamide	101.5	Solvent Rec (DMF)	98.1
Methanol	203.3	Aq. Effluent	176.5
Acetone	205.7	Spent carbon	3.5
Carbon	1.7	Residue	54.8
Water	130.3	Solvent loss	13.3
Total	**877.7**	**Total**	**877.7**

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Stage-II

INPUT	Quantity	OUTPUT	Quantity
Stage-I	132.4	Stage-II	118.3
Dimethyl formamide	238.4	Solvent Rec (DMF)	231.4
Palladium carbon	0.1	Gas loss	5.0
Hydrogen gas	10	Residue	19.2
		Solvent loss	7.0
Total	**380.9**	**Total**	**380.9**

Stage-III+IV

INPUT	Quantity	OUTPUT	Quantity
Stage-II	118.3	Stage-IV	136.0
Phenyl chloroformate	78.6	Solvent Rec (MDC)	240.0
Sodium bicarbonate	71.0	Solvent Rec (Butanol)	145.2
Methylene chloride	246.0	Aq. Effluent	450.8
Hydragin hydrate	65.0	Residue	41.8
n-Butanol	147.8		
Water	295.7	Solvent loss	8.6
Total	**1022.4**	**Total**	**1022.4**

Stage-V

INPUT	Quantity	OUTPUT	Quantity
Stage-IV	136.0	Stage-V	121.2
Formamidine acetate	63.6	Solvent Rec (DMF)	380.3
Dimethyl formamide	390.0	Residue	78.3
		Solvent loss	9.7
Total	**589.5**	**Total**	**589.5**

Stage-VI

INPUT	Quantity	OUTPUT	Quantity
Stage-V	121.2	Stage-VI	92.9
2-Bromo butane	125.2	Solvent Rec (DMF)	349.7
Potassium carbonate	51.0	Solvent Rec (2-BB)	92.0
Dimethyl formamide	357.1	Residue	148.8
Hydrochloric acid	38.4		

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		Solvent loss	9.4
Total	**692.8**	**Total**	**692.8**

Stage-VII

INPUT	**Quantity**	**OUTPUT**	**Quantity**
Stage-VI	92.9	ITR-INT-B	78.0
Hydrobromic acid	961.9	Hydrobromic acid rec	935.5
Soda ash	86.7	Aq. Effluent	476.6
Water	359.0	Solvent loss	10.4
Total	**1500.5**	**Total**	**1500.5**

Itraconazole

Stage-I

INPUT	**Quantity**	**OUTPUT**	**Quantity**
ITR-INT-B	78	IT-I	125
ITR-INT-A	101.5	Solv. Recovery (DMF)	578
Water	287.5	Aq. Effluent	380.5
N,N-Dimethyl formamide	590	Residue	13.5
Potassium hydroxide	52	Solvent loss	12
Total	**1109**	**Total**	**1109**

Stage-II

INPUT	**Quantity**	**OUTPUT**	**Quantity**
Stage IT-I	125	Itraconazole	85
Toluene	165	Solv. Recovery (Tol)	160
Ethyl acetate	432	Solv. Recovery (EA)	420
Methanol	695.9	Solv. Recovery (Me)	675
Carbon	2.3	Residue	34.1
Hyflow supercell	6.7	Spent Carbon	4.6
		Spent hyflow	10.3
		Solv. Loss	37.9
Total	**1426.9**	**Total**	**1426.9**

Water Usage	**Quantity**
Int-A-I	186.7
Int-A-II	172.4

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Int-B-I	130.3
Int-B-II	0.0
Int-B-III+IV	295.7
Int-B-V	0.0
Int-B-VI	0.0
Int-B-VII	359.0
IT-I	287.5
IT-II	0.0
IT-III	0.0
Total	**1431.6**

Aqueous Effluent	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Int-A-I	324.3	7	900	1200	3500	600	100	
Int-A-II	192.0	8.5	1000	1100	2500	200	0	
Int-B-I	176.5	6.5	900	1000	2500	600	100	
Int-B-II	0.0	0	0	0	0	0	0	
Int-B-III+IV	450.8	7	1200	1000	3500	900	200	
Int-B-V	0	0	0	0	0	0	0	
Int-B-VI	0.0	0	0	0	0	0	0	
Int-B-VII	476.6	3.5	600	900	4500	0	0	
IT-I	380.5	9	1400	1200	3500	200	0	
IT-II	0	0	0	0	0	0	0	
Total	**2000.7**	**6.5**	**980.4**	**1043.7**	**3561.7**	**389.4**	**66.4**	**FE**

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Int-A-I	64.5	0	0	0
Int-A-II	56.2	7.7	0	0
Int-B-I	54.8	3.5	0	0
Int-B-II	19.2	0	0	0
Int-B-III+IV	41.8	0	0	0
Int-B-V	78.3	0	0	0
Int-B-VI	148.8	0	0	0
Int-B-VII	0	0	0	0
IT-I	13.5	0	0	0
IT-II	34.1	4.6	0	10.3
Total	**511.2**	**15.8**	**0.0**	**10.3**

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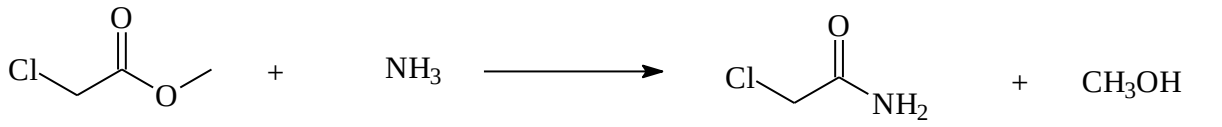
3. 2-CHLOROACETAMIDE

Stage-I:

Charge Ammonia solution into the reactor and cool to 0°C. Add Methyl 2-chloroacetate slowly in the reactor below 10°C. Maintain and centrifuge the mass. Wash the material with water and dry to produce 2-Chloroacetamide.

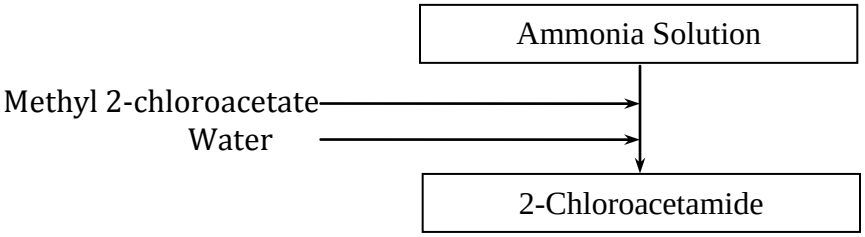


Methyl 2-chloroacetate	Ammonia	2-Chloroacetamide	Methanol
$C_3H_5O_2Cl$ (108.52)	H_3N (17.03)	C_2H_4NOCl (93.51)	CH_4O (32.04)

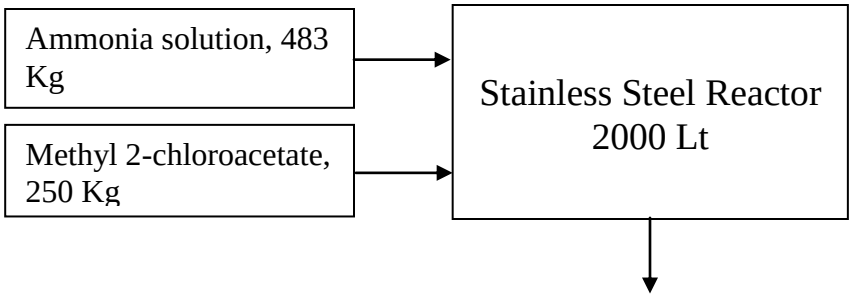
Raw material:

Raw Materials	Quantity	CC
Ammonia solution	483	2.42
Methyl 2-chloroacetate	250	1.25
2-Chloroacetamide	200	1.00

FLOW CHART OF 2-CHLOROACETAMIDE:



Stage-I:



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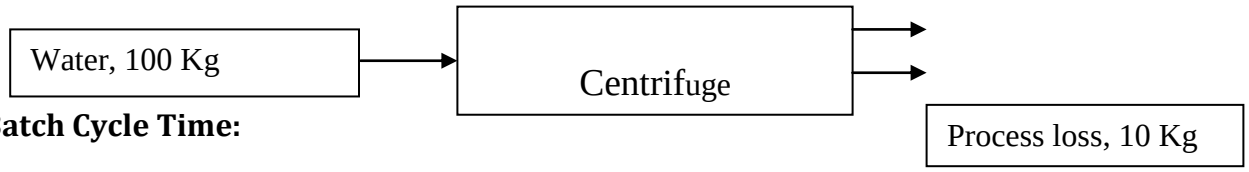

Batch Cycle Time:

Description	Time in hours
Reaction time	10
Centrifugation	4
Total	**14**
Drying time	8
Total process time	**22**

2-Chloroacetamide
Stage-I

Input		Output	
Ammonia solution 25%	483	2-Chloroacetamide	200
Methyl 2-chloroacetate	250		
Water	100	Aqueous effluent	623
		Process loss	10
Total	**833**	**Total**	**833**

Water Usage	Quantity
Stage-1	100
Total	**100**

Aqueous Effluent	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-I	623	8	70	200	300	0	0	
Total	**623**	8	70	200	300	0	0	**FE**

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Stage-I	0	0	0	0
Total	0	0	0	0

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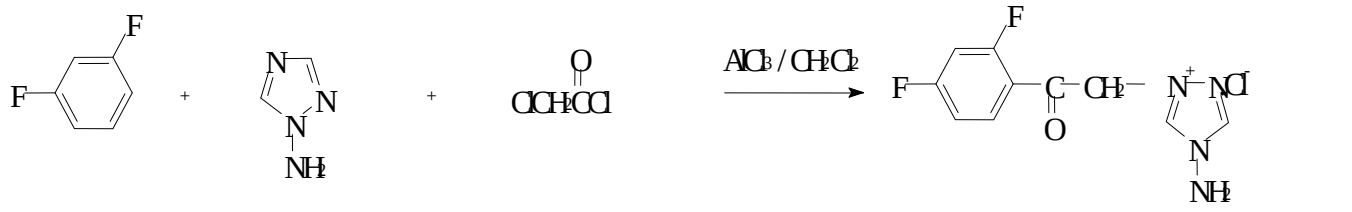
4. FLUCONAZOLE AND ITS INTERMEDIATES

Stage-I

Charge Methylene dichloride and aluminium chloride into the reactor. Cool the mass to below 5°C. charge 1,3-Difluorobenzene into the reactor. Add slowly chloroacetyl chloride into the reactor for 4 to 5 hours below 10°C. Charge water into another reactor and cool below 5°C. Charge the reaction mass to ice and hydrochloric acid, slowly maintaining the temperature below 10°C. Stir the reaction mass for 4 hours and separate the layers. Wash the organic layer with sodium bicarbonate solution. Distill off MDC completely below 50°C. Charge isopropyl alcohol and 4-amino-1,2,4-triazole into the reactor and maintain for 6 hours at 45-50°C. Cool the reaction mass to 10°C and centrifuge the material and dry to produce 2-(1H-1,2,4-triazole-1-yl)-2',4'-difluoroacetophenone salt.



1,3-Difluorobenzene — $C_6H_4F_2$ (114.09)

4-Amino-1,2,4-triazole — $C_2H_4N_4$ (84.08)

Chloroacetylchloride — $C_2H_2OCl_2$ (112.44)

2-(1H-1,2,4-Triazol-1-yl)-2',4'-difluoroacetophenone salt — $C_{10}H_9N_4OF_2Cl$ (274.70)

Stage-II

Charge water, sodium nitrite and 2-(1H-1,2,4-triazole-1-yl)-2',4'-difluoroacetophenone into the reactor and heat to 50-60°C. Slowly add hydrochloric acid at 50-60°C and maintain for 12 hours. Cool the mass below 20°C and neutralize the reaction mass with ammonia solution. Centrifuge the mass and wash with water. Dry the material to produce 1-(2,4-difluorophenyl)-2-(1H,1,2,4-Triazol-1-yl) ethanone.

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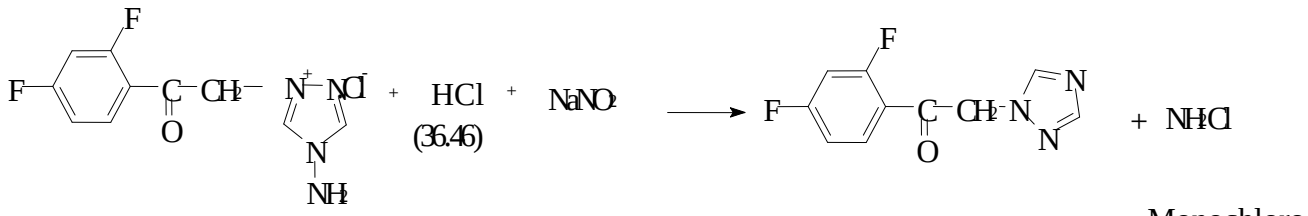

2-(1H-1,2,4-Triazol-1-yl)-2',4'-difluoroacetophenone salt

$C_{10}H_9N_4OF_2Cl$ (274.70)

HCl (36.46)

$NaNO_2$ (68.99)

1-(2.4-Difluorophenyl)-2-(1H-1,2,4-triazole-1-yl) ethanone

$C_{10}H_7N_3OF_2$ (223.18)

Monochloro amine NH_2Cl (51.47)

Stage-III & IV

Charge Toluene, 1-(2,4-difluorophenyl)- 2-(1H,1,2,4-Triazol-1-yl) ethanone, potassium hydroxide, 1,2,4,-Triazole and Trimethyl sulphoxinium iodide into the reactor. Heat to reflux and maintain for 12 hours. Distill off Toluene completely. Cool the reaction mass and charge water into the reactor. Charge toluene into the reactor and stir for 30 minutes. Settle the mass for 30 minutes. Separate the layers. Discard the bottom aqueous layer. Cool the mass to 10°C and centrifuge. Dry the material to produce Flucnazole crude.

Charge water, crude and ammonia solution into the reactor. Check complete dissolution and charge carbon. Stir for 30 minutes and filter over hyflow bed. Charge toluene and citric acid. Neutralize the mass with hydrochloric acid. Stir for 30 minutes and settle for 30 minutes. Separate the layers and discard aqueous layer. Cool the mass. Centrifuge the mass and wash with toluene. Dry the material to produce Fluconazole pharma.

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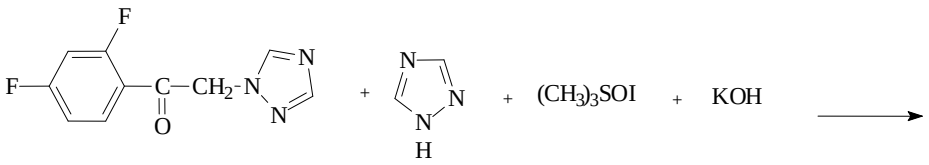


1-(2.4-Difluorophenyl)-2-(1H-1,2,4-triazole-1-yl) ethanone

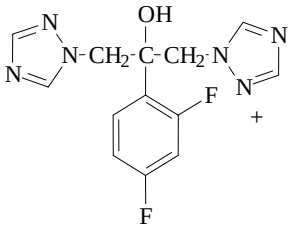
$C_{10}H_7N_3OF_2$ (223.18)

1,2,4-triazole

$C_2H_3N_3$ (69.06)

$(CH_3)_3SOI$ (220.26)

KOH (56.12)



Fluconazole

$C_{13}H_{12}N_6OF_2$ (306.27)

+ $(CH_3)_2SO$ C_2H_6OS (78.12)

+ H_2O (18.01)

+ KI (166.00)

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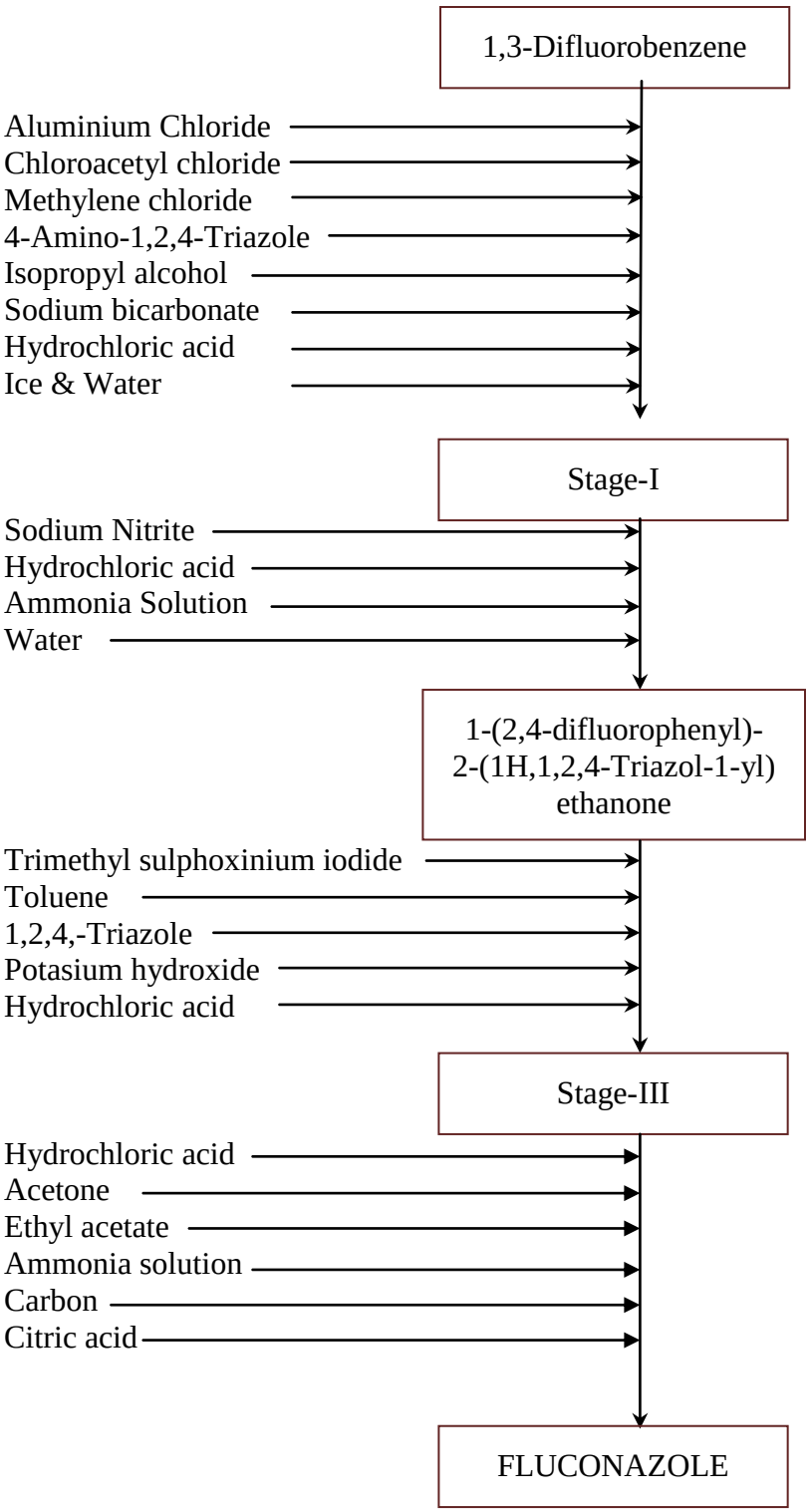
Flowchart:



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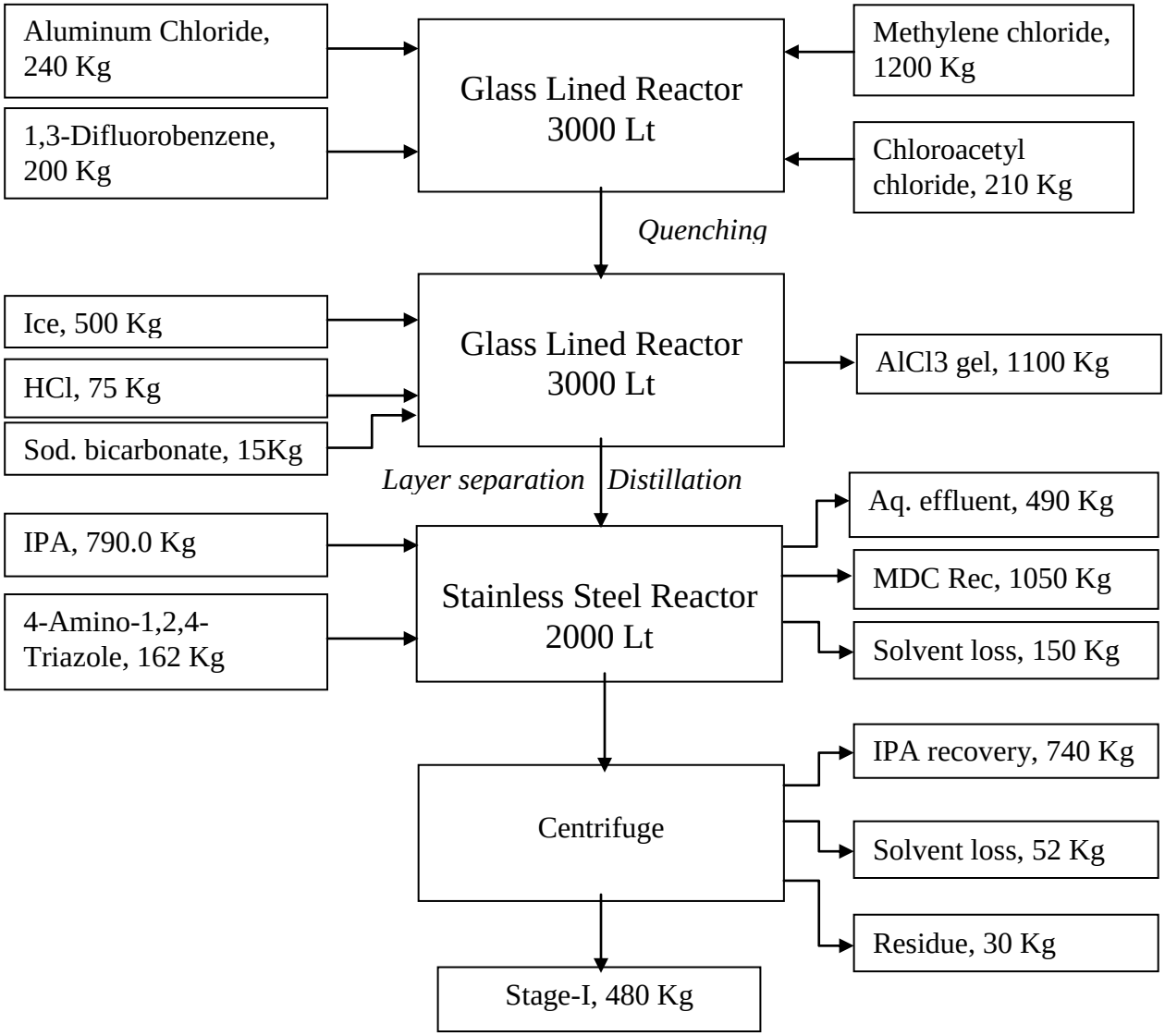
Stage-I:



Batch Cycle Time:

Description	Time in hours
Reaction time	40
Workups	10
Centrifugation	4
Total	**54**
Drying time	8
Solvent distillation	16

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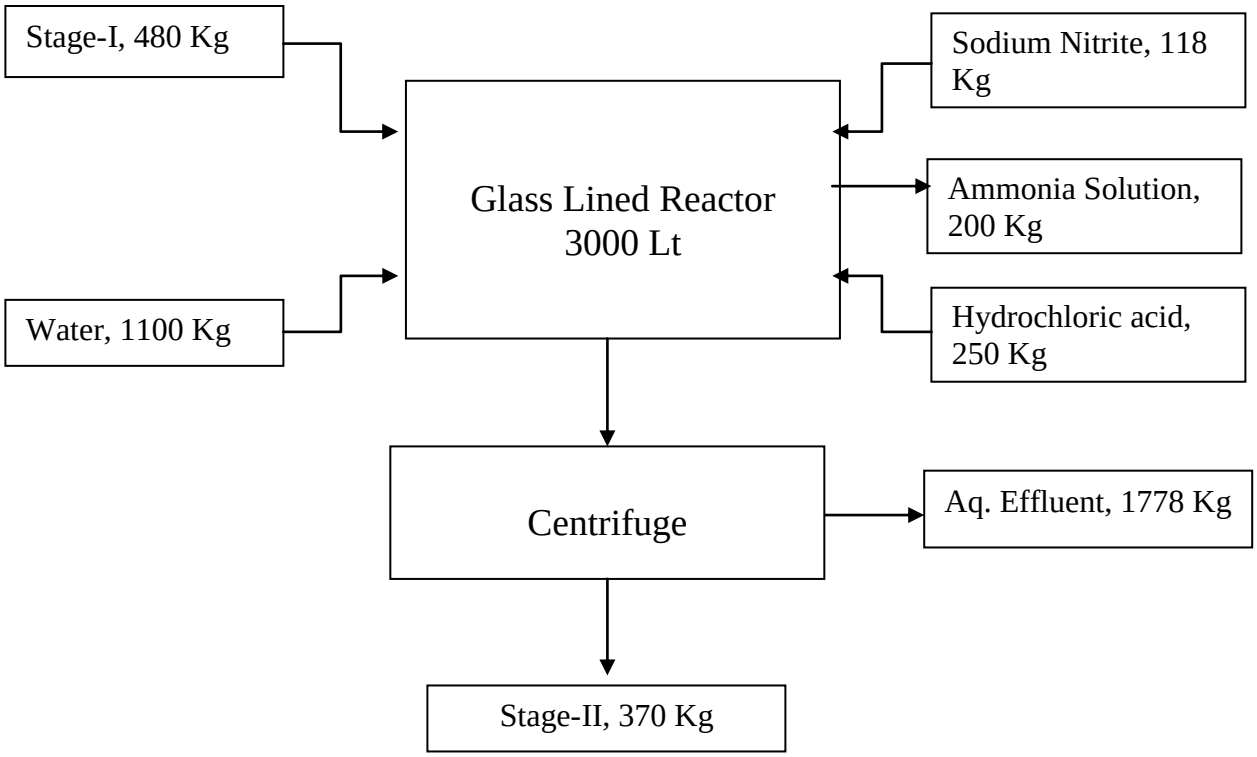
Total process time	**78**

Stage-II:



Batch Cycle Time:

Description	**Time in hours**
Reaction time	8
Workups	0
Centrifugation	4
Total	**12**
Drying time	12
Total process time	**24**

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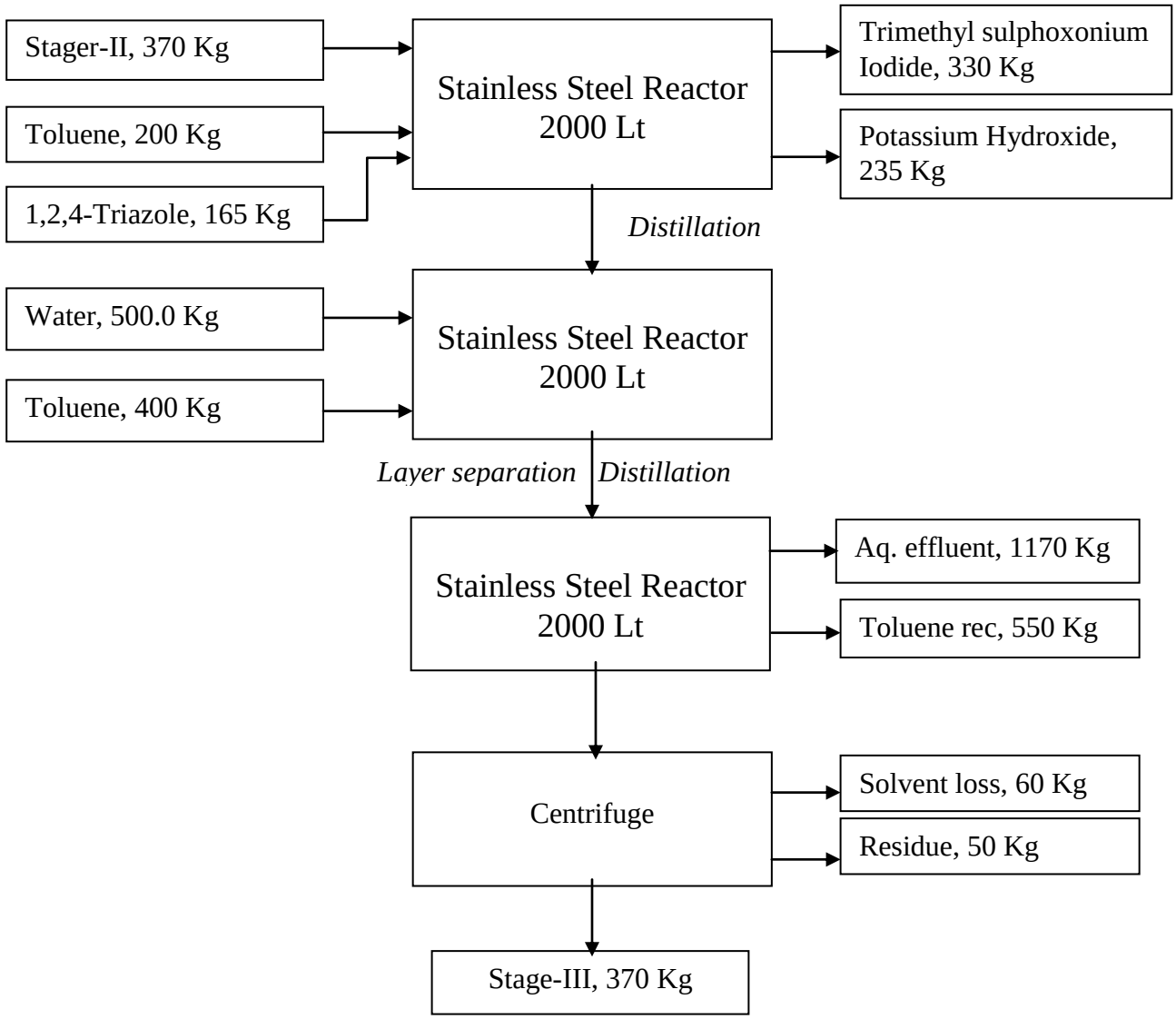
Stage-III:



Batch Cycle Time:

Description	Time in hours
Reaction time	26
Workups	16

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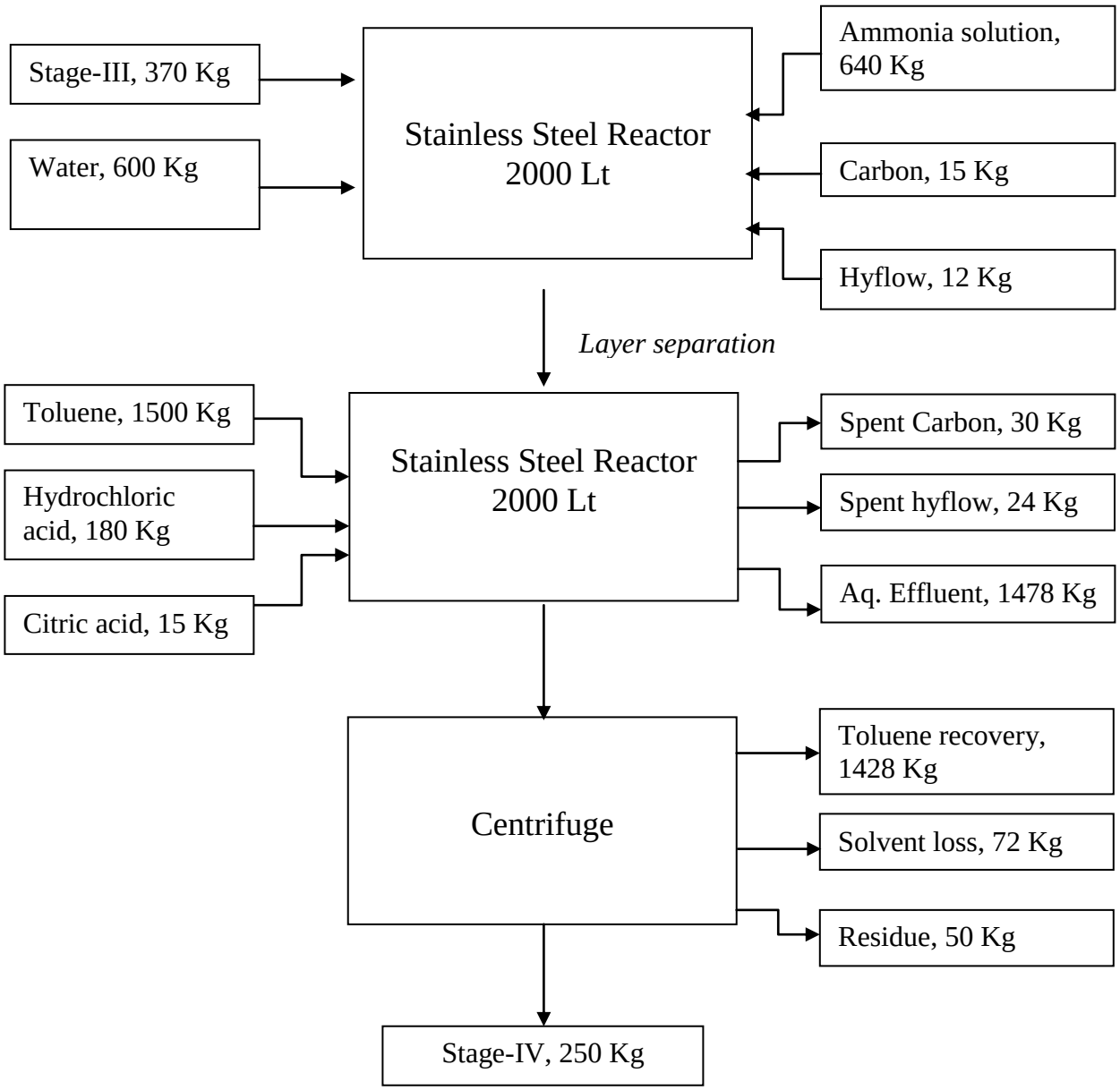
Centrifugation	2
Total	**44**
Drying time	6
Solvent distillation	10
Total process time	**60**

Stage-IV:



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Batch Cycle Time:

Description	Time in hours
Reaction time	8
Workups	4
Centrifugation	4
Total	**16**
Drying time	8
Solvent distillation	16
Total process time	**40**

Material Balance:

Stage-I			
Input		**Output**	
1,3-Difluorobenzene	200	Stage-I Compound	480
Aluminium Chloride	240	Solvent Recovery (MDC)	1050
Methylene chloride	1200	Solvent Recovery (IPA)	740
Chloroacetyl chloride	210		
4-Amino-1,2,4-Triazole	162	AlCl3 gel for Rec.	1100
IPA	790	Aq. Effluent	490
Sodium bicarbonate	15	Residue	30
Hydrochloric acid	75		
Ice & Water	1200	Solvent loss	202
Total	**4092**	**Total**	**4092**

Stage-II			
Input		**Output**	
Stage-I Compound	480	Stager-II	370
Sodium Nitrite	118		
Hydrochloric acid	250		
Water	1100	Aq. Effluent	1778
Ammonia Solution	200		
Total	**2148**	**Total**	**2148**

Stage-III			
Input		**Output**	
Stager-II	370	Stage-III	370

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Trimethyl sulphoxonium Iodide	330		
1,2,4-Triazole	165	Solvent recovery (Toluene)	550
Potassium Hydroxide	235	Aq. Effluent	1170
Toluene	600	Residue	50
Water	500	Solvent loss	60
Total	**2200**	**Total**	**2200**

Stage-IV			
Input		**Output**	
Stage-III Material	370	Fluconazole	250
Toluene	1500	Solvent rec (Tol)	1428
Carbon	15	Aq. Effluent	1478
Citric acid	15	Spent carbon	30
Ammonia solution	640	Spent hyflow	24
Hydrochloric acid (CP)	180	Residue	50
Hyflow supercell	12		
Water	600	Solvent loss	72
Total	**3332**	**Total**	**3332**

Water Usage	**Quantity**
Stage-I	1200
Stage-II	1100
Stage-III	500
Stage-IV	600
Total	**3400**

Raw Material	**Quantity**	**CC**
1,2,4-Triazole	165	0.66
1,3-Difluorobenzene	200	0.80
4-Amino-1,2,4-Triazole	162	0.65
Aluminium Chloride	240	0.96
Ammonia Solution	840	3.36
Carbon	15	0.06

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Chloroacetyl chloride	210	0.84
Citric acid	15	0.06
Hydrochloric acid	505	2.02
Hyflow supercell	12	0.05
IPA	790	3.16
Methylene chloride	1200	4.80
Potassium Hydroxide	235	0.94
Sodium bicarbonate	15	0.06
Sodium Nitrite	118	0.47
Toluene	2100	8.40
Trimethyl sulphoxonium Iodide	330	1.32
Fluconozole	250.0	1.00

Aqueous Effluent	**Qty**	**pH**	**TDS**	**BOD**	**COD**	**Chloride**	**Sulphate**	**Disposal**
Stage-I	490	6.0	750	1200	2200	600	200	MEE
Stage-II	1778	7.5	1100	1000	2500	0	0	MEE
Stage-III	1170	8.5	600	1000	1500	240	200	MEE
Stage-IV	1478	7.0	2100	1500	4500	900	100	MEE
Total	4916	7.4	1246.8	1170.3	2833.4	387.5	97.6	

Solid Waste	**Residue**	**Spent CB**	**Spent SS**	**Spent HF**
Stage-I	30.0	0.0	0.0	0.0
Stage-II	0.0	0.0	0.0	0.0
Stage-III	50.0	0.0	0.0	0.0
Stage-IV	50.0	30.0	0.0	24.0
Total	**130.0**	**30.0**	**0.0**	**24.0**

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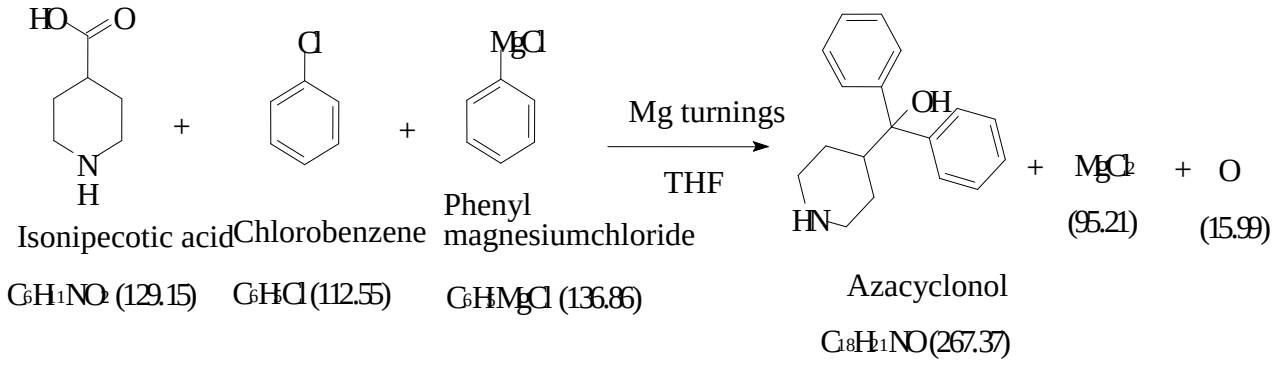
5. AZACYCLONOL

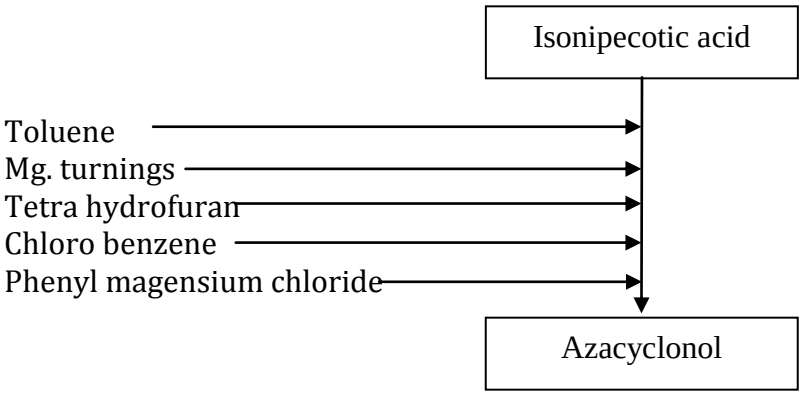
Stage-I

Charge tetrahydrofuran, Mg turnings, Isonipecotic acid and Chlorobenzene into a reactor. Heat the mass to reflux and maintain for 12 hours. Distill tetrahydrofuren completely. Cool the mass below 40°C. Charge toluene and filter. Charge phenyl magnesium chloride. Heat the mass to reflux and maintain for 12 hours. Cool the mass to 10°C. Centrifuge and wash with toluene. Dry the material to produce Azacyclonol.



Isonipecotic acid $C_6H_{11}NO_2$ (129.15) + Chlorobenzene C_6H_5Cl (112.55) + Phenyl magnesiumchloride C_6H_5MgCl (136.86) → Azacyclonol $C_{18}H_{21}NO$ (267.37) + $MgCl_2$ (95.21) + O (15.99)

FLOW CHART - AZACYCLONOL



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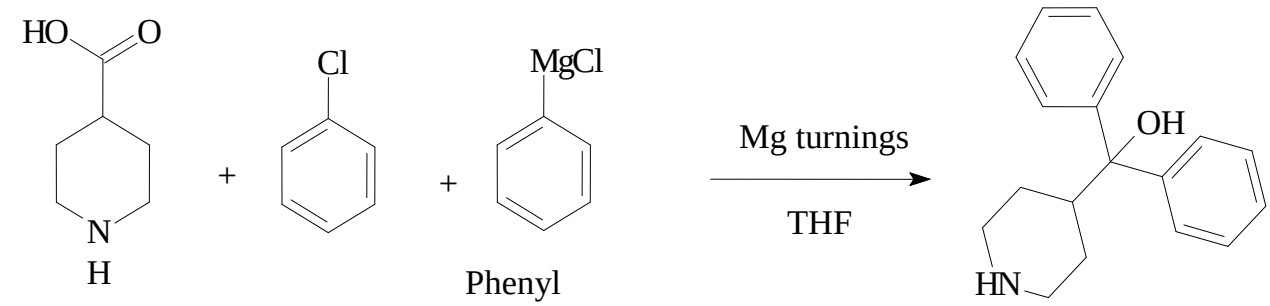
REACTION SCHEME - AZACYCLONOL



Isonipecotic acid + Chlorobenzene + Phenyl magnesiumchloride → Azacyclonol

Raw material

INPUT			OUTPUT	
Isonipecotic acid	200		Azacyclonol	408
Toluene	1184		Solv. Rec (Tol)	1105
Mg. turnings	188		Solv. Rec (THF)	705
Tetra hydrofuran	759		Residue	74
Chloro benzene	57			
Phenyl magensium chloride	37		Solvent loss	133
	2425			2425

Water Usage	Quantity
Stage-1	0
Total	0

Raw Matrial	Quantity	CC
Isonipecotic acid	200.0	0.49
Toluene	79.0	0.19
Mg. turnings	188.0	0.46
Tetra hydrofuran	54.0	0.13
Chloro benzene	57.0	0.14
Phenyl magensium chloride	37.0	0.09
Azacyclonol	408.0	1.00

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Stage-I	74.0	0.0	0.0	0.0

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Total	74.0	0.0	0.0	0.0
Disposal	**TSDF**	**TSDF**	**TSDF**	**TSDF**

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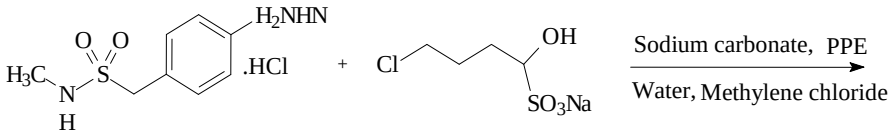
6. SUMATRIPTAN SUCCINATE AND ITS INTERMEDIATES

Stage-I:

Charge water, 4-Hydrazino-N-Methyl Benzene Methane Sulfonamide HCl, sodium bicarbonate and 4-Chloro Butyraldehyde Sodium Bisulphite Adduct into a reactor. Heat the mass to 75-80°C. Add slowly PPE into the reactor for 4 to 6 hours at 75-80°C. Maintain the mass for 12 hours at 75-80°C. Cool the mass below 40°C and charge MDC. Adjust the pH of the mass to neutral with sodium bicarbonate. Filter the mass. Maintain for 30 minutes and settle for 30 minutes. Separate the bottom organic layer and discard top aqueous layer. Dry the organic mass over sodium sulphate. Distill off MDC completely and charge ethyl acetate. Dry the organic layer over vacuum salt. Distill off ethyl acetate and keep the residue for further process.

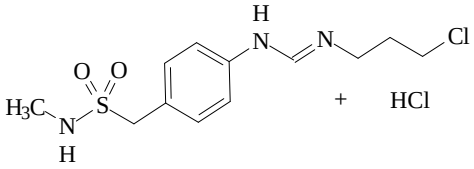


4-Hydrazino-N-methylbenzene methane sulfonamide HCl

$C_8H_{13}N_3O_2S$ (251.73)

4-Chlorobutyraldehyde sodium bisulphite adduct

$C_4H_8O_4SNaCl$ (210.60)



+ HCl + $NaHSO_4$ + H_2

(36.46) (120.05) (2.02)

$C_{12}H_{12}N_3O_2SCl$ (303.00)

Stage-II & III:

Charge dimethyl amine, stage-I residue, potassium iodide, sodium bicarbonate and TBAB into a reactor. Heat the mass to 55-60°C. Maintain the mass for 8 hours at 55-60°C. Cool the mass below 40°C. Charge ethyl acetate, water and vacuum salt. Separate the layers and discard the aqueous layer. Distill off ethyl acetate completely below 75°C. Cool the mass to RT and charge acetone. Cool the mass below 10°C. Centrifuge the material. Dry the material to produce Sumatriptan base.

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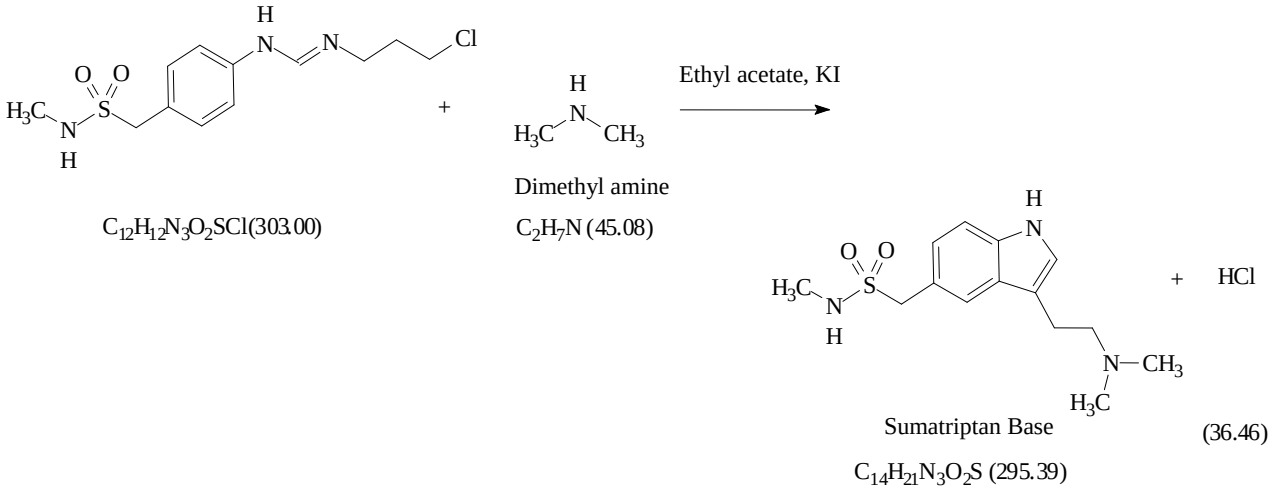
Charge acetone and Sumatripton base into a reactor. Heat the mass to dissolve. Charge carbon and maintain for 30 minutes. Filter over hyflow bed to another reactor. Cool the mass to 5°C. Centrifuge and wash with acetone. Dry the material to produce Sumatriptan base pure.



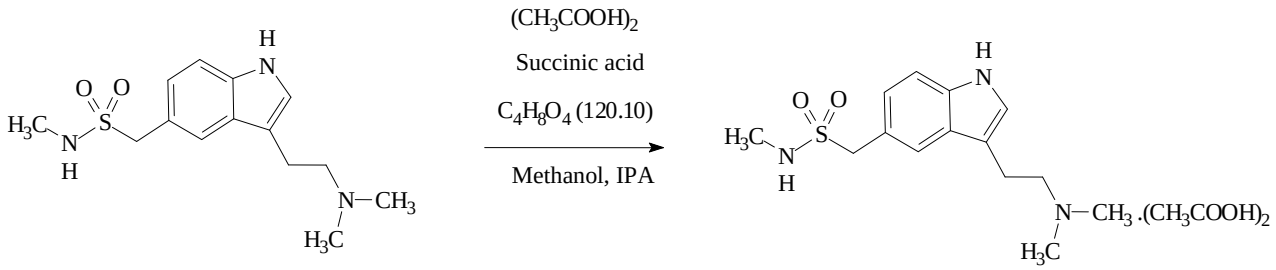
$C_{12}H_{12}N_3O_2SCl$(303.00)

C_2H_7N (45.08)

$C_{14}H_{21}N_3O_2S$ (295.39)

Stage-IV:

Charge methanol, base pure material and succinic acid into a reactor. Heat to reflux and maintain for 4 hours. Distill off methanol completely. Cool the mass and charge isopropyl alcohol. Cool the mass and centrifuge and wash with IPA. Dry the material to produce Sumatriptan succinate.



$C_{14}H_{21}N_3O_2S$ (295.39)

$C_{18}H_{29}N_3O_6S$ (415.49)

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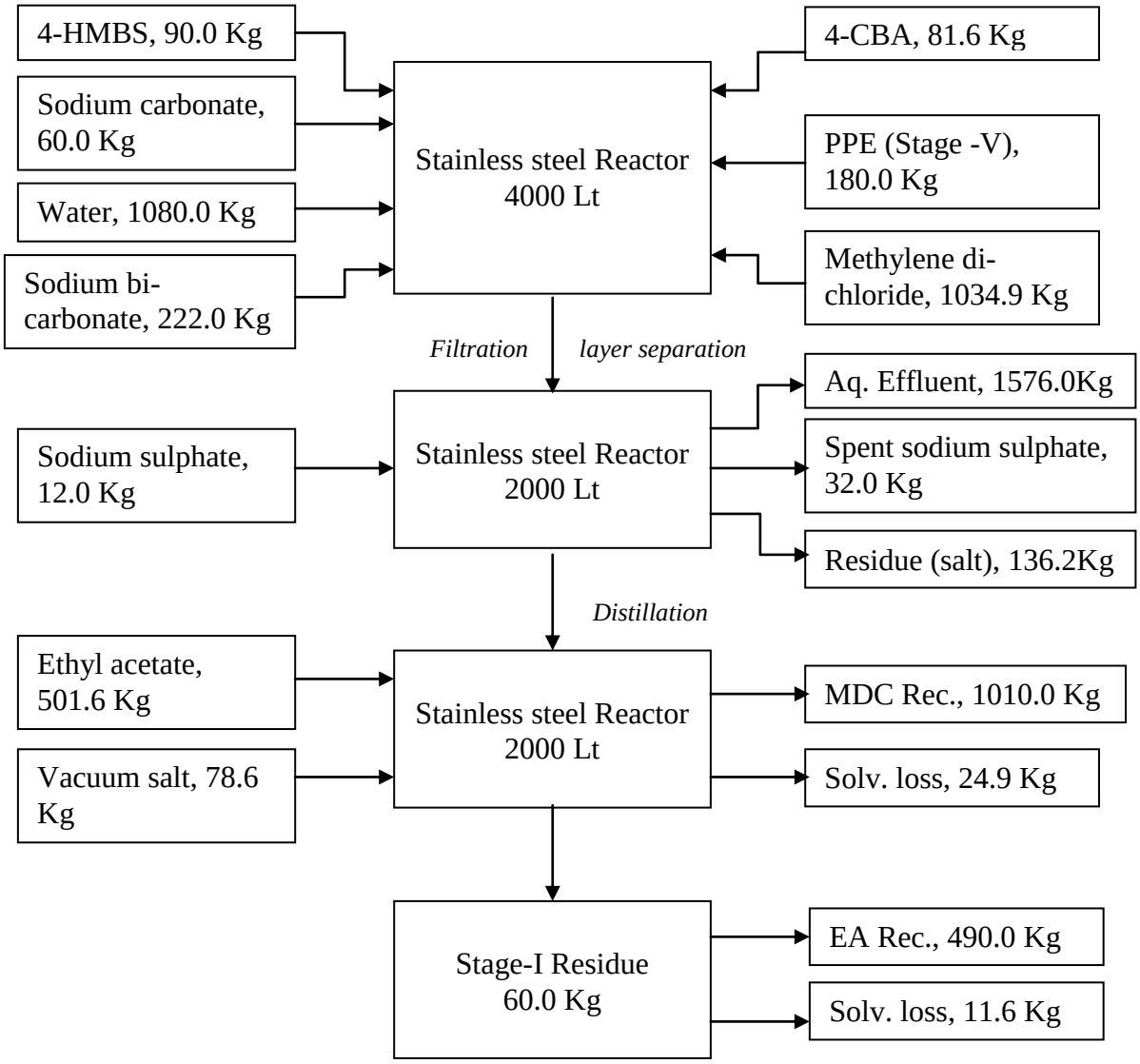
Stage-I:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	18
Work ups	21
Total	**39**
EA distillation	6
Total Process time	**45**

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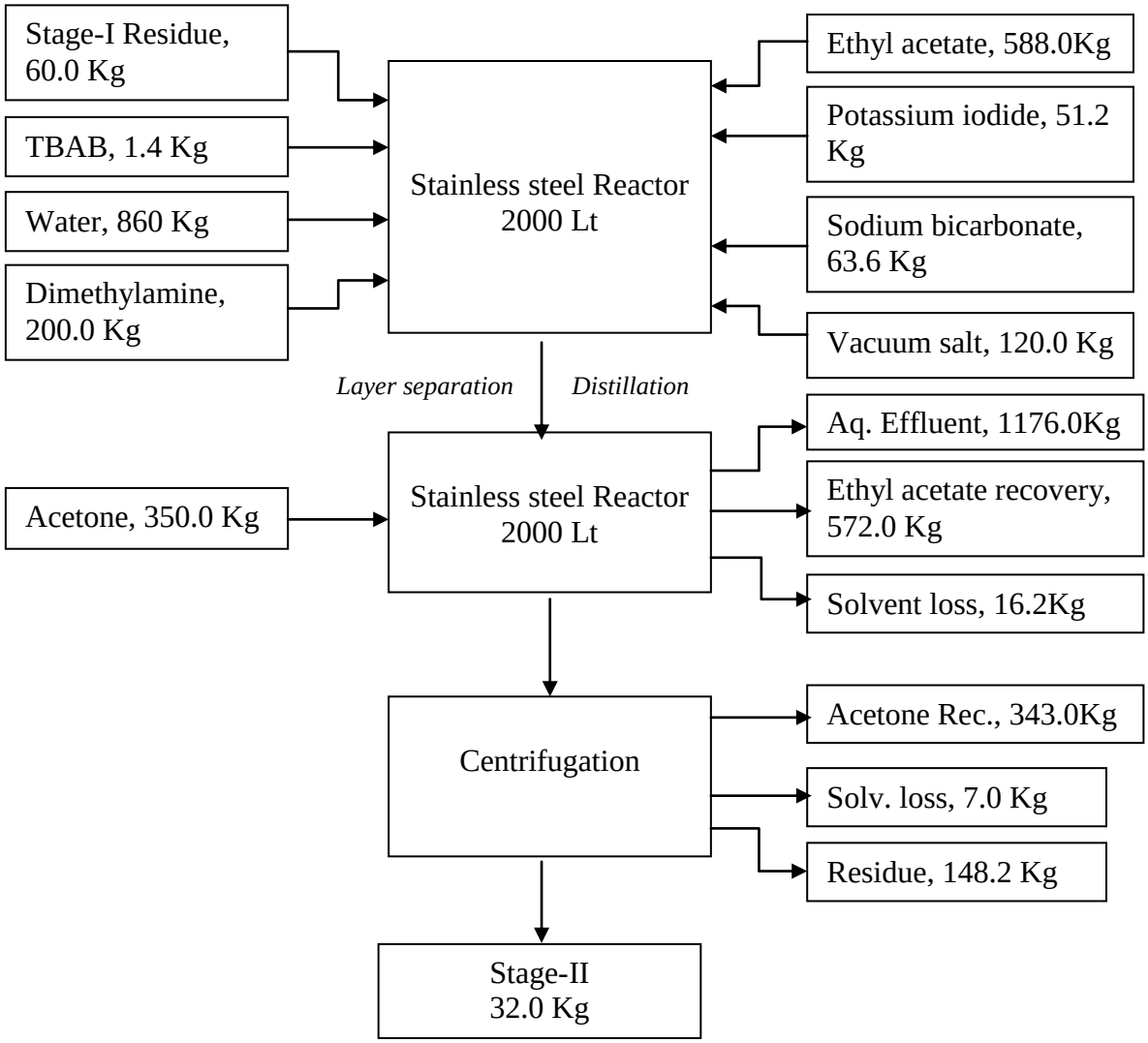
Stage-II:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	12
Work ups	20
Centrifugation	2
Total	**34**
Drying	6
Acetone distillation	6
Total Process time	**42**

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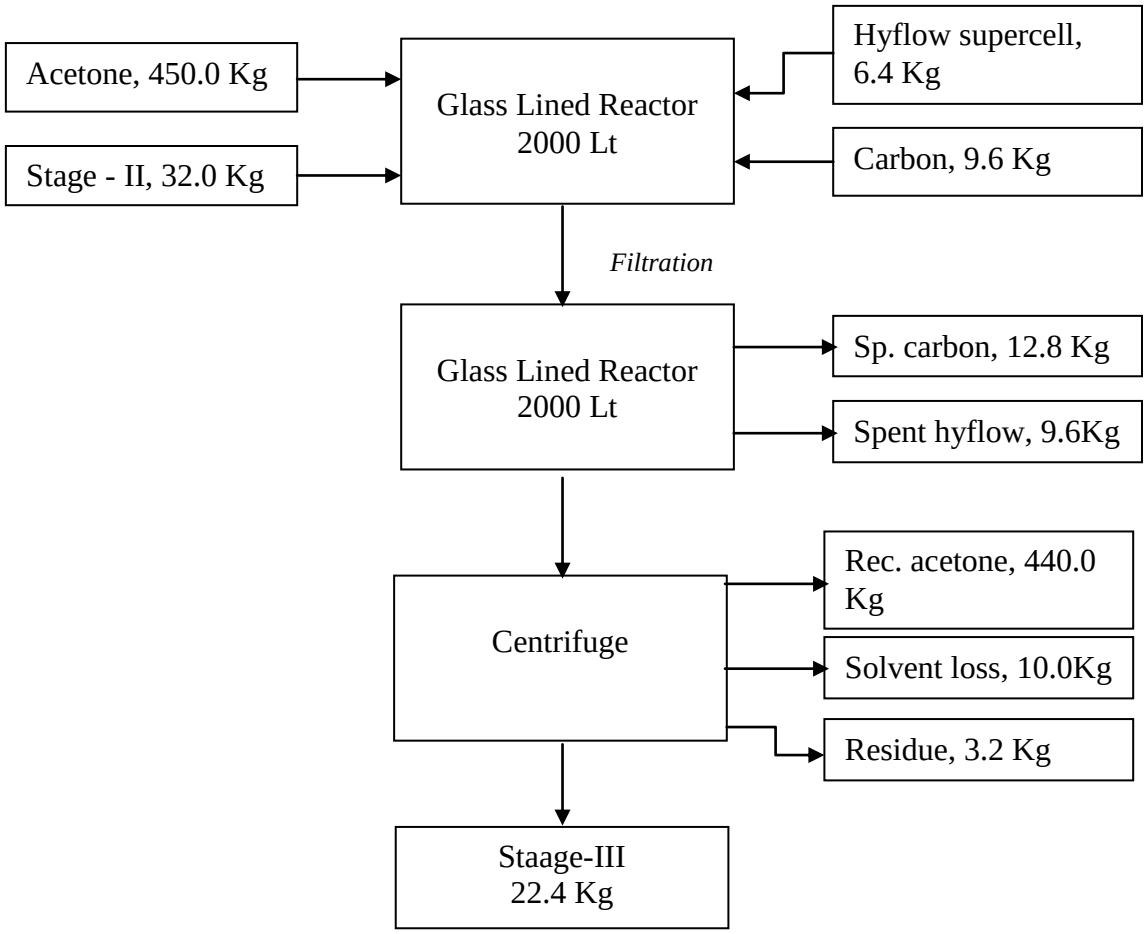
Stage-III:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	4
Work ups	2
Centrifugation	2
Total	**8**
Drying	6
Acetone distillation	6
Total Process time	**20**

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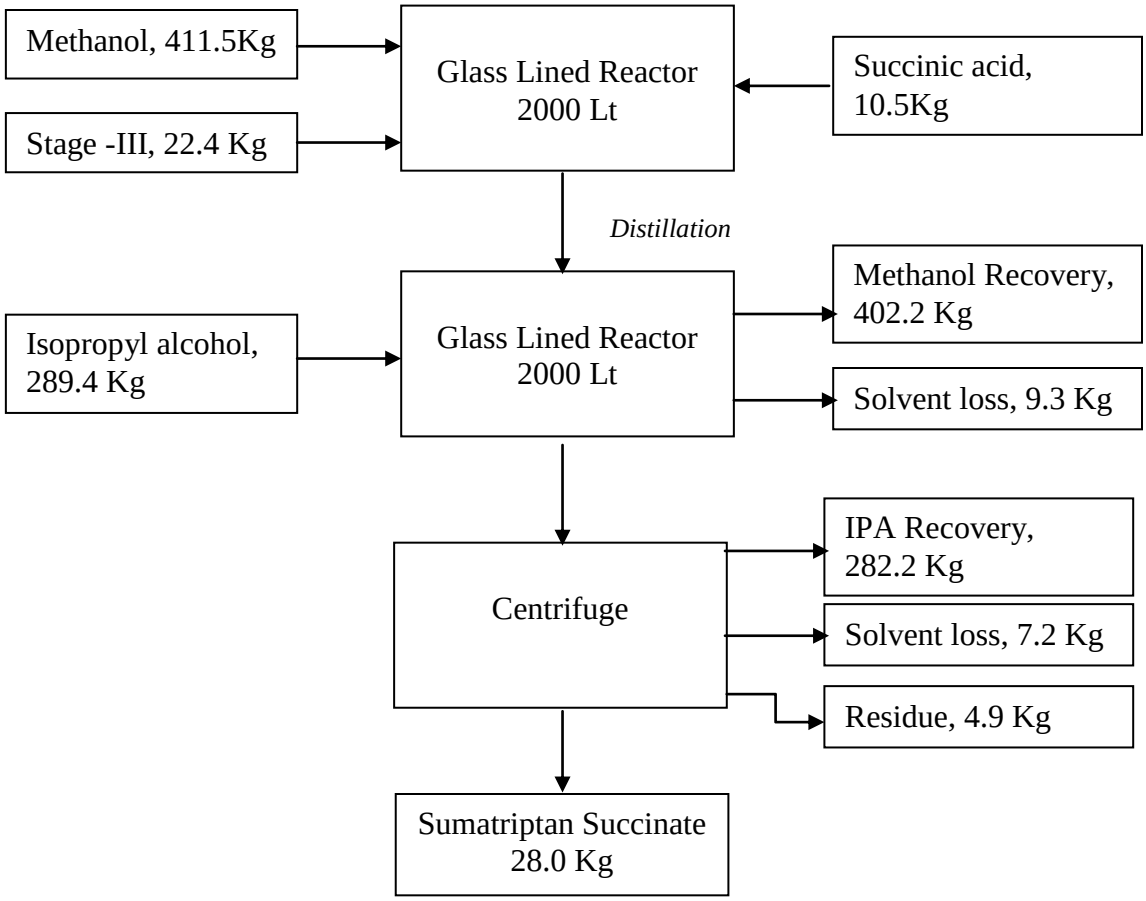
Stage-IV:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	6
Work ups	8
Centrifugation	2
Total	**16**
Drying	8
IPA distillation	6
Total Process time	**30**

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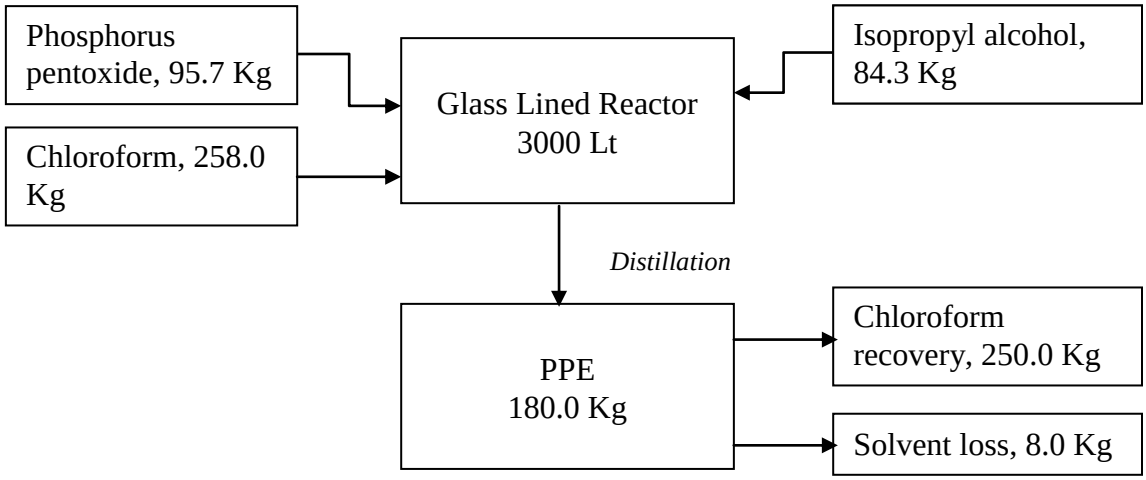
Stage-V:

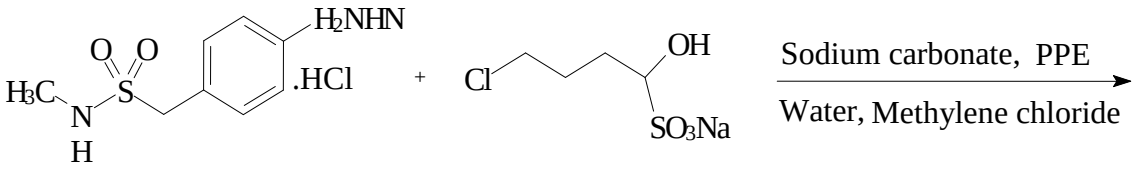


Batch Cycle Time:

Particulars	Time in hours
Reaction time	12
Work ups	6
Total	**18**

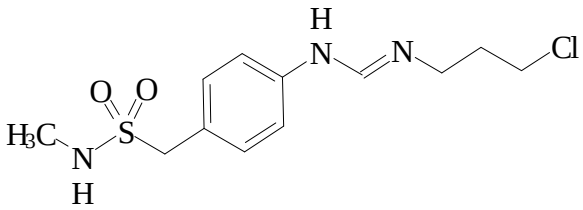
Reaction Scheme – Sumatriptan Succinate

Stage-I



4-Hydrazino-N-methylbenzene methane sulfonamide HCl

4-Chlorobutyraldehyde sodium bisulphite adduct



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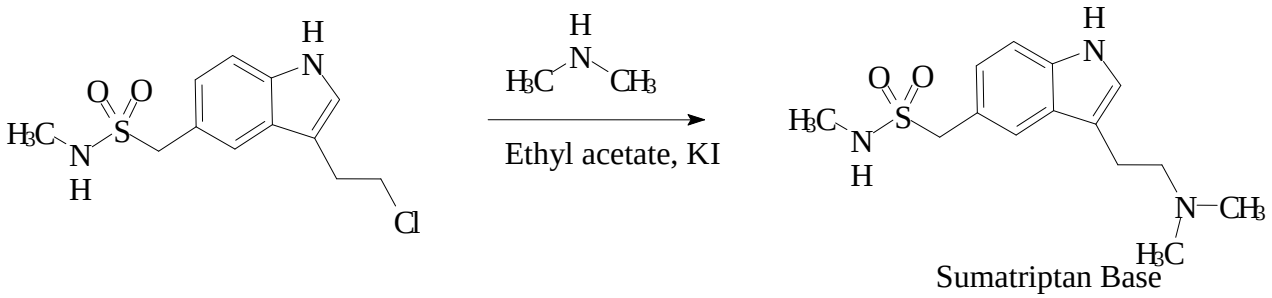
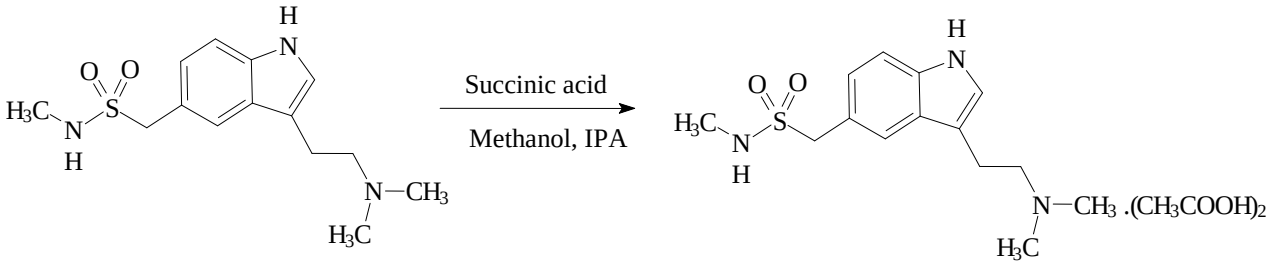
Stage-II & Stage-III



Sumatriptan Base

Stage-IV



Sumatriptan Base

Sumatriptan succinate

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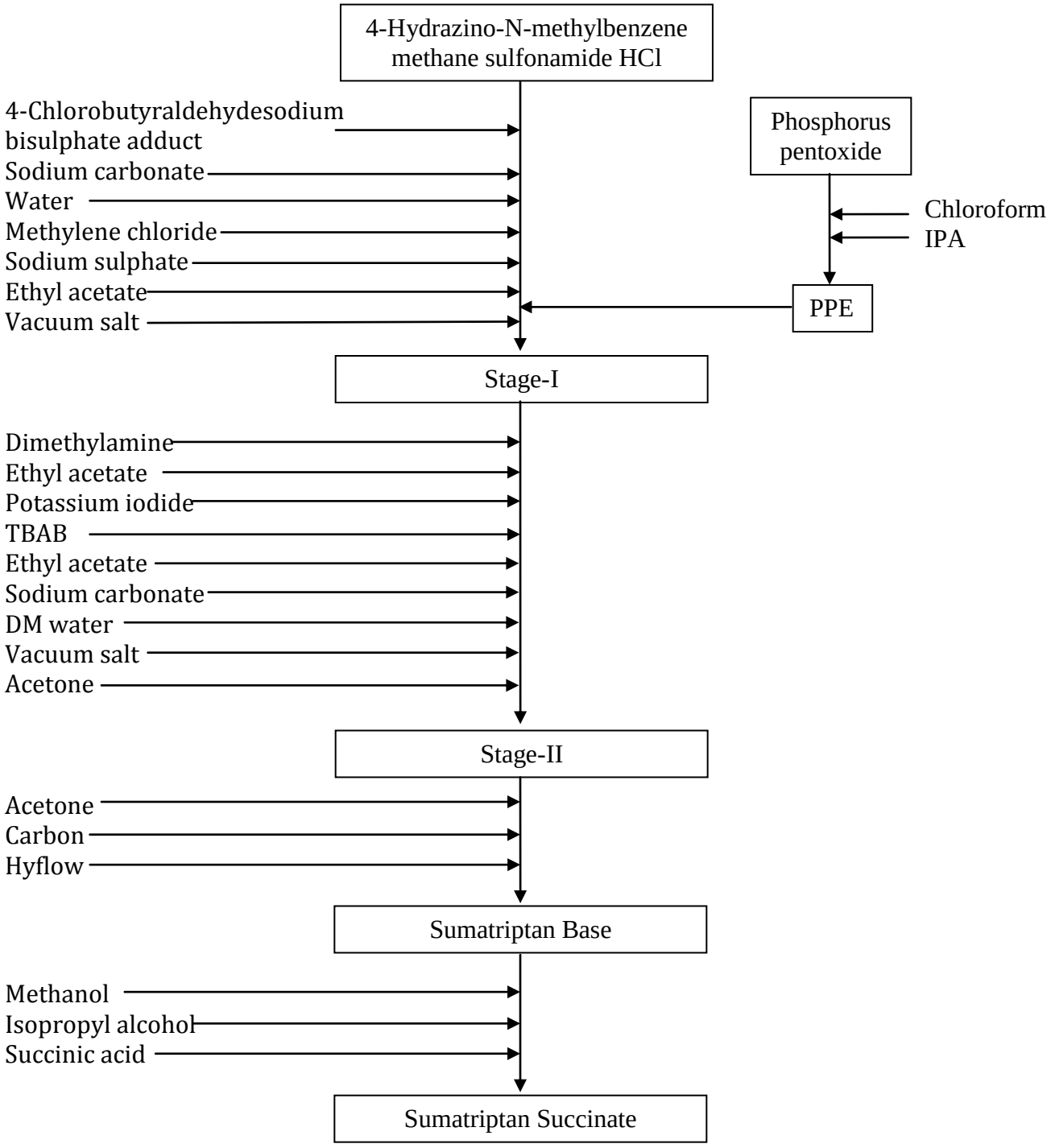
Flow Chart – Sumatriptan Succinate



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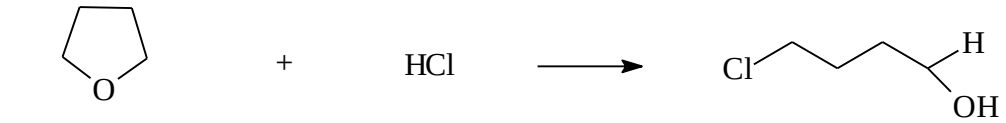
CBA

Stage-I:

Charge tetrahydrofuran and hydrochloric acid into a reactor. Heat to reflux and maintain for 2 hours. Cool the mass to RT and further below 0°C. Neutralize the mass with CS lye solution. Charge MDC to the reactor. Stir the mass for 1 hour and settle for 30 minutes. Separate the layers and discard the aqueous layer. Wash the organic layer with water.



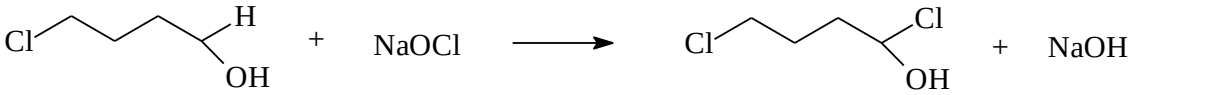
Tetrahydrofuran
C_4H_8O (72.10)

Hydrochloric acid (36.46)

4-Chlorobutanol
C_4H_9OCl (108.56)

Stage-II:

Charge stage-I organic layer and MDC into a reactor. Cool the mass to -15°C. Charge tempo, sodium thiosulphate, sodium bicarbonate and potassium bromide into the reactor. Add sodium hypochlorite slowly into the reactor. Filter the salts on a nutch filter, and charge the filtrates into the reactor. Charge vacuum salt and water into the reactor. Stir the mass for 1 hour and settle. Separate the layers and discard the aqueous layer. Distill off MDC completely below 50°C and unload the mass.



4-Chlorobutanol
C_4H_9OCl (108.56)

Sodioum hypochlorite (74.44)

1,4-Dichlorobutanol
$C_4H_8OCl_2$ (143.01)

Sodium hydroxic (39.99)

Stage-III:

Charge stage-II residue into a reactor. Add sodium metabisulphite solution in water into the reactor for 4 to 5 hours. Centrifuge the material and wash with methanol. Dry the material at 60-65°C.

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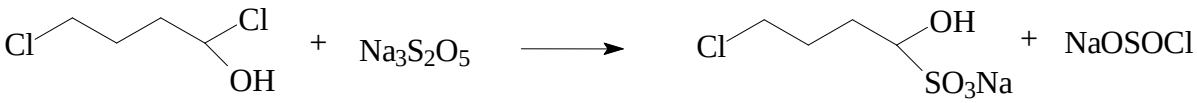


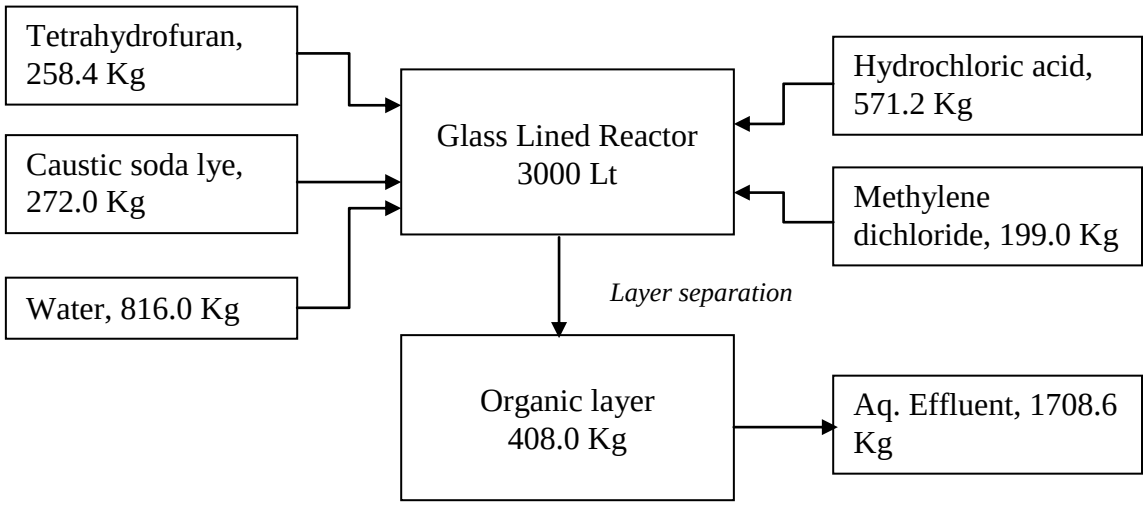
1,4-Dichlorobutanol
$C_4H_8OCl_2$ (143.01)

Sodium metabisulphite
(213.08)

4-Chlorobutyraldehyde sodium bisulphite adduct
$C_4H_8O_4SNaCl$ (210.60)

(213.08)

CBA Stage-I:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	4
Work ups	4
Total	**8**
Total Process time	**8**

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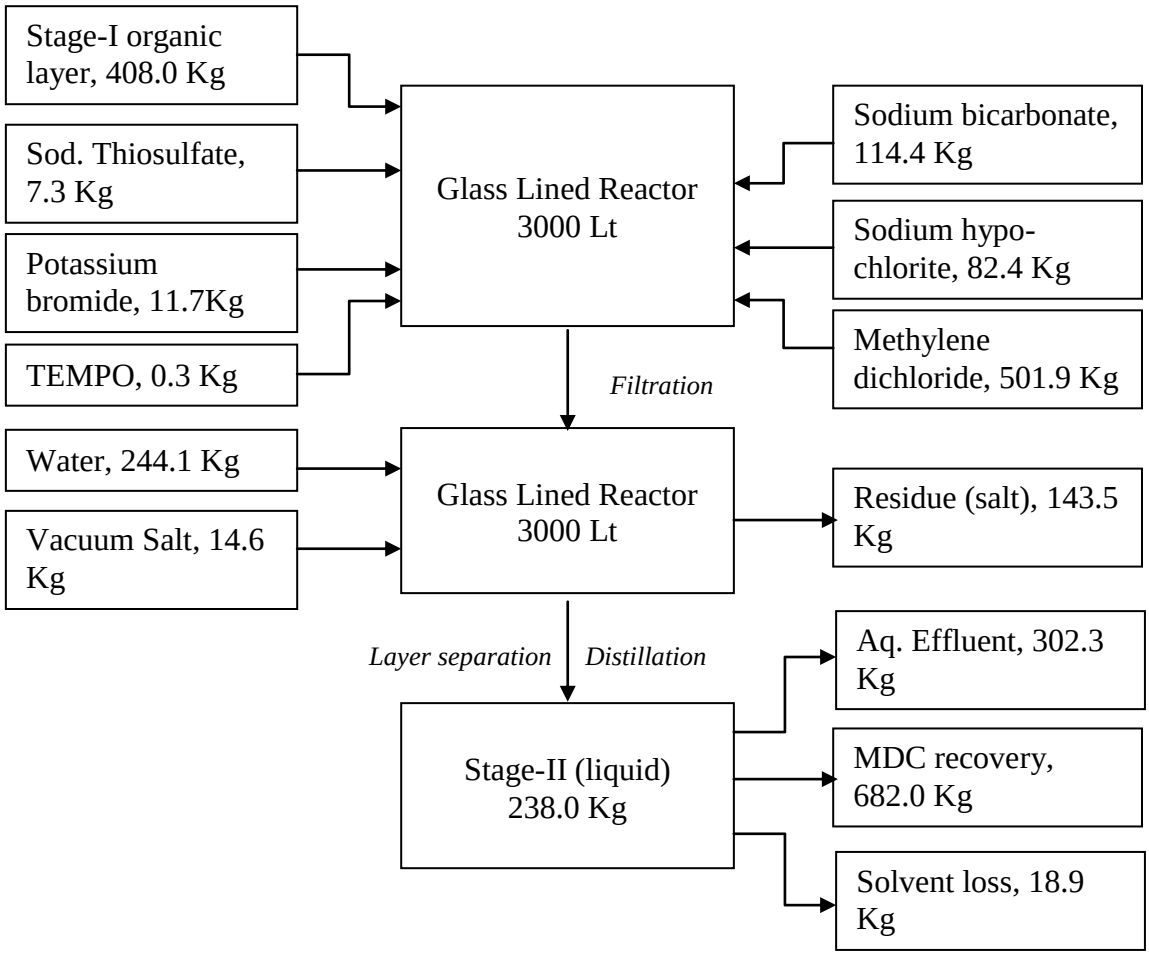
CBA Stage-II:



Batch Cycle Time:

Particulars	Time in hours

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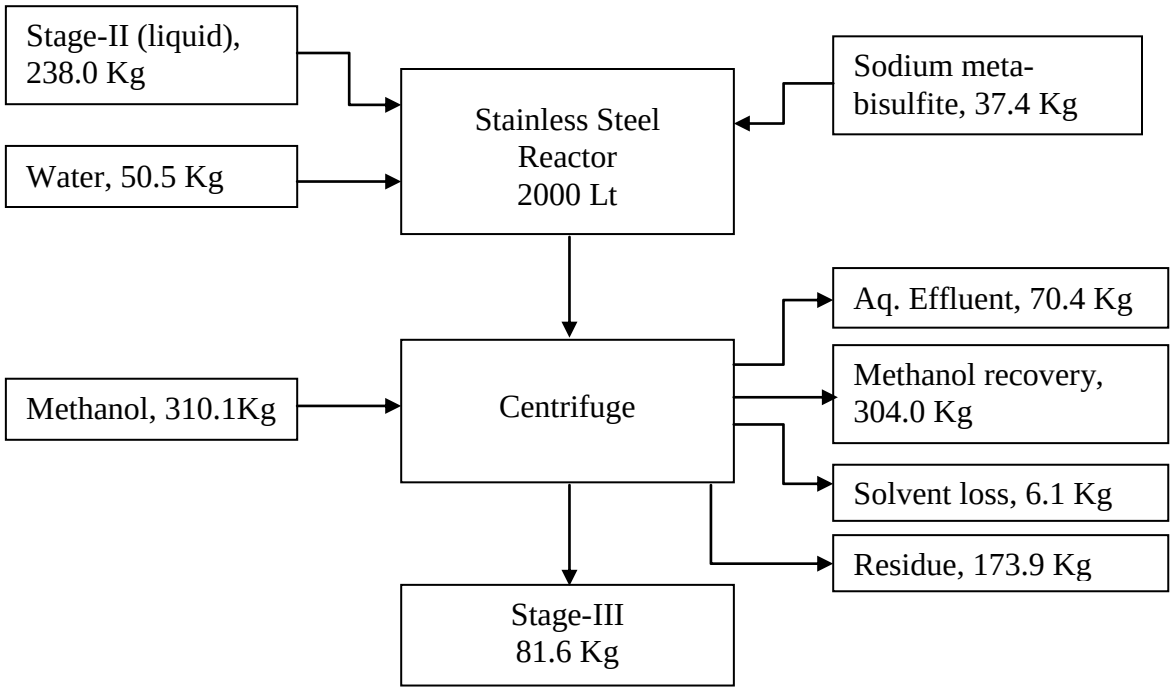
Reaction time	14
Work ups	10
Total	**24**
MDC distillation	8
Total Process time	**32**

CBA Stage-III:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	5
Work ups	4
Centrifugation	4
Total	**13**
Drying	6

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MDC distillation	6
Total Process time	**25**

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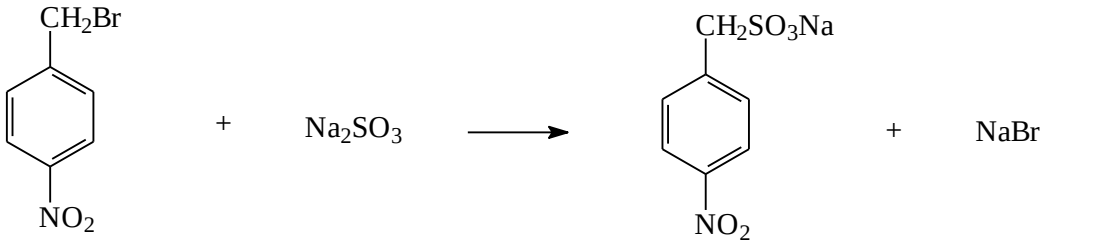
HMBS

Stage-I:

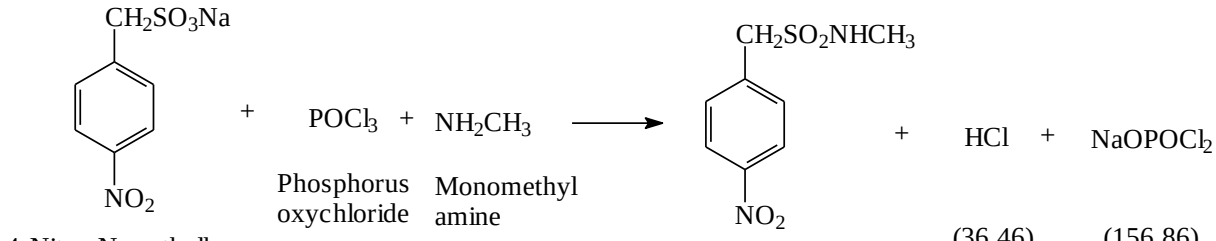
Charge water, para-nitrobenzyl bromide and sodium sulphite into a reactor. Heat the mass to 70-75°C and maintain for 5 hours. Cool the mass to RT and further below -5°C. Centrifuge the material and dry.



p-Nitrobenzylbromide $C_7H_6NO_2Br$ (216.03) | Sodium sulphite (126.04) | 4-Nitro-N-methylbenzene sodium bisulphite adduct $C_7H_6NO_5SNa$ (239.71) | Sodium bromid (102.89)

Stage-II:

Charge toluene and stage-I material into a reactor. Add slowly POCl3 into the reactor at 25-35°C. Heat the mass to reflux and reflux for 12 hours. Cool the mass to RT and further below 5°C. Add the reaction mass into crushed ice slowly. Stir the mass and settle. Separate the layers and discard the bottom aq. Layer. Wash the organic layer with salt solution. Add mono-methyl amine into reactor slowly. Maintain and centrifuge. Wash the mass with water and dry.



4-Nitro-N-methylbenzene sodium bisulphite adduct $C_7H_6NO_5SNa$ (239.71) | Phosphorus oxychloride (153.33) | Monomethyl amine (31.05) | 4-Nitro-N-methylbenzene methane sulfonamide $C_8H_{10}N_2O_4S$ (230.23) | (36.46) | (156.86)

Stage-III:

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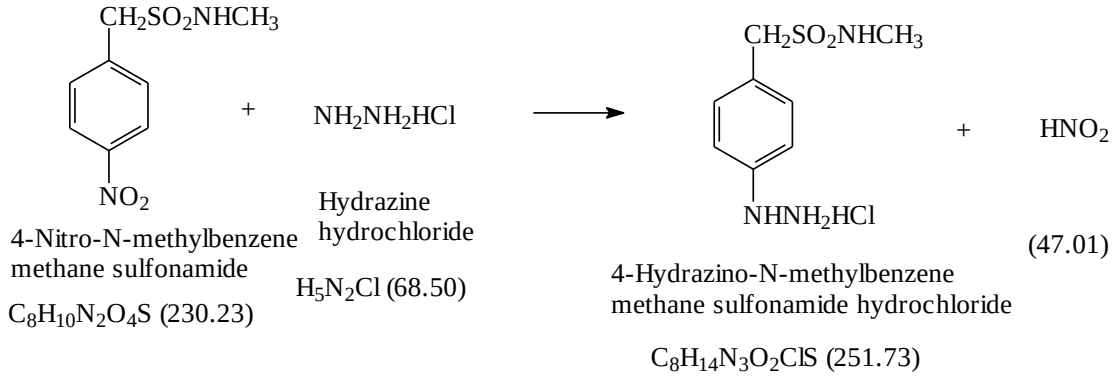
Charge methanol, stage-II material, dimethyl carbonate and carbon into a reactor. Heat the reflux. Add slowly hydrazine HCl into the reactor maintaining the reaction mass under reflux. Reflux for 10 hours. Filter the mass and distill off methanol completely. Charge toluene into the reactor. Cool the mass below 0°C. Centrifuge and wash with toluene. Dry the material.



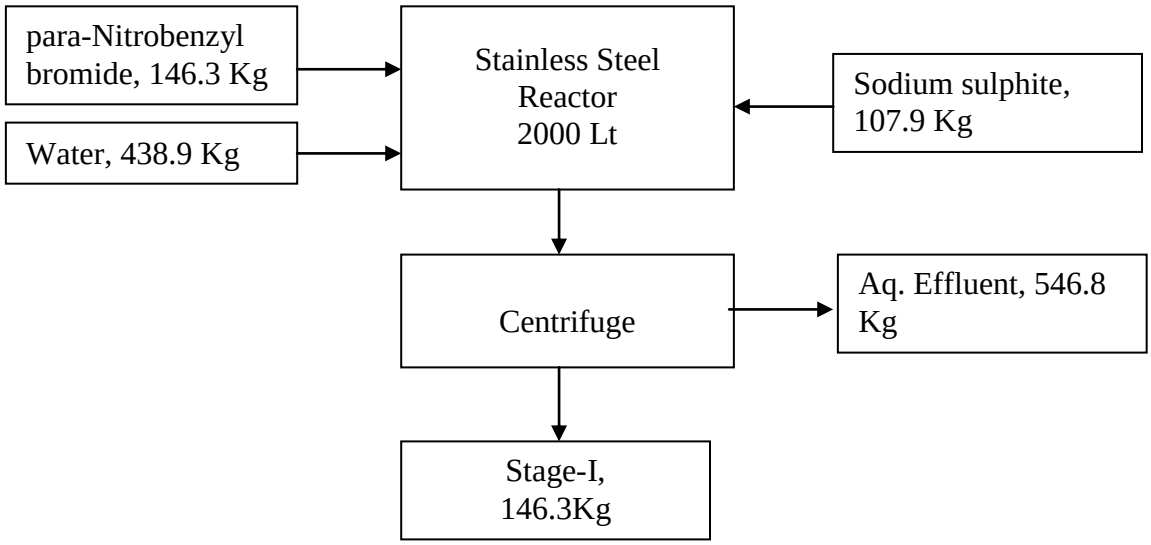
4-Nitro-N-methylbenzene methane sulfonamide

$C_8H_{10}N_2O_4S$ (230.23)

4-Hydrazino-N-methylbenzene methane sulfonamide hydrochloride

$C_8H_{14}N_3O_2ClS$ (251.73)

HMBS Stage-I:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	7
Work ups	7
Centrifugation	4
Total	**18**

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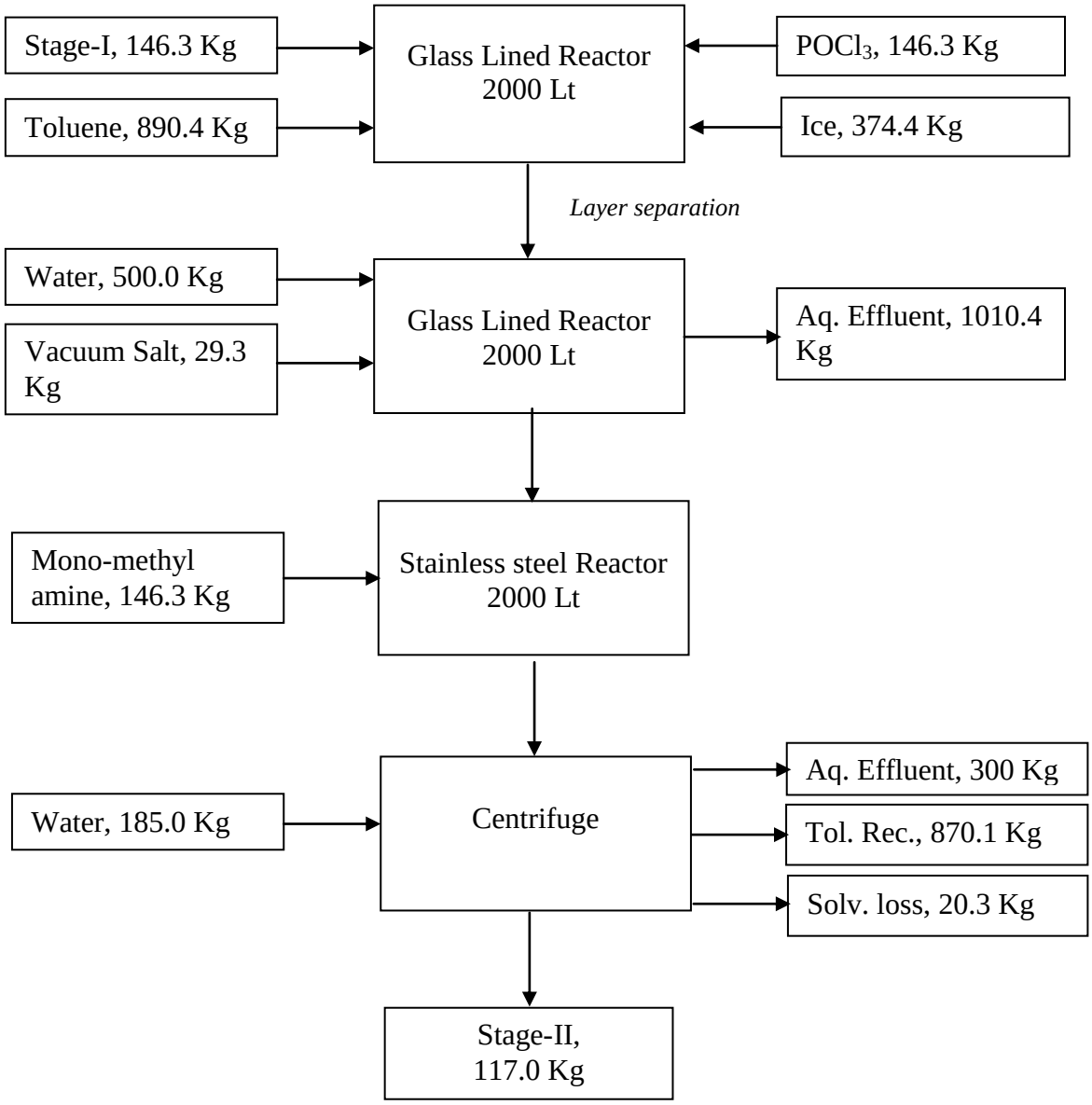
Drying	8
Total Process time	**26**

HMBS Stage-II:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	20
Work ups	8

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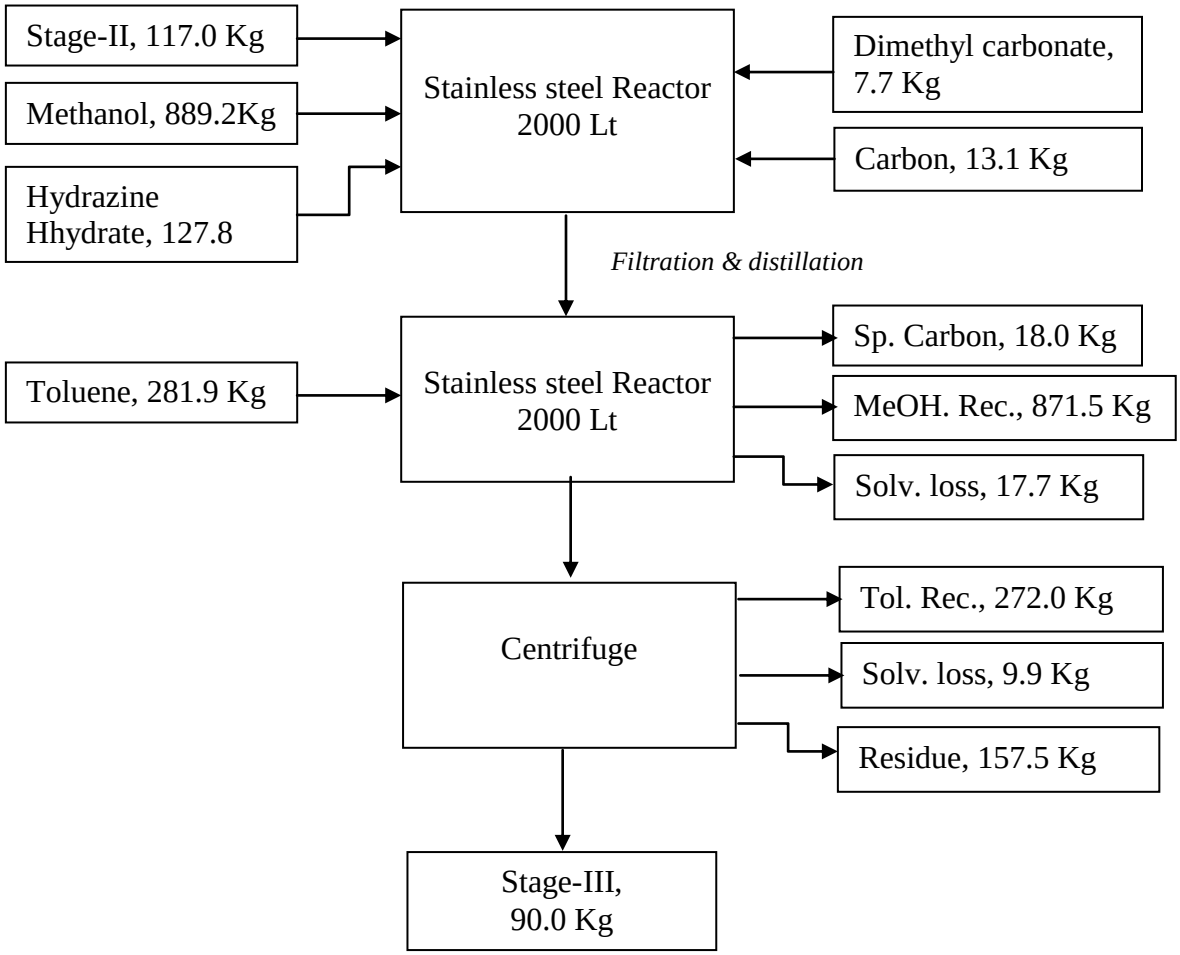
Centrifugation	4
Total	**32**
Drying	6
Toluene distillation	10
Total Process time	**48**

HMBS Stage-III:



Batch Cycle Time:

Particulars	Time in hours
Reaction time	15
Work ups	15

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Centrifugation	6
Total	**36**
Drying	8
Toluene distillation	6
Total Process time	**50**

Sumatriptan Succinate
4-HMBS
Stage-1

Input	Quantity	Output	Quantity
para-Nitrobenzyl bromide	146.3	Stage-I	146.3
DM Water	438.9	Aq. Effluent	546.8
Sodium sulphite	107.9		
Total	**693.1**	**Total**	**693.1**

Stage-II

Input	Quantity	Output	Quantity
Stage-I	146.3	Stage-II	117.0
Toluene	890.4	Solvent rec. (Tol)	870.1
$POCl_3$	146.3		
Ice	374.4	Aq. Effluent	1310.4
Mono-methylamine (40%)	146.3		
DM Water	585.0		
Vacuum Salt	29.3	Solvent loss	20.3
Total	**2317.8**	**Total**	**2317.8**

Stage-III

Input	Quantity	Output	Quantity
Stage-II	117.0	Stage-III	90.0
Methanol	889.2	Solvent rec (Methanol)	871.5
Dimethyl carbonate	7.7	Solvent rec (Tol)	272.0
Carbon	13.1	Spent Carbon	18.0
Hydrazine hydrate	127.8	Residue	157.5
Toluene	281.9	Solvent loss	27.6
Total	**1436.6**	**Total**	**1436.6**

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4-CBA

Stage-I

Input	Quantity	Output	Quantity
Tetrahydrofuran	258.4	Stage-I (Organic layer)	408.0
Hydrochloric acid	571.2		
Caustic soda lye	272.0	Aq. Effluent	1708.6
Methylene dichloride	199.0		
Water	816.0		
Total	**2116.6**	**Total**	**2116.6**

Stage-II

Input	Quantity	Output	Quantity
Stage-I organic layer	408.0	Stage-II (liquid)	238.0
Methylene dichloride	501.9	Solvent Rec. (MDC)	682.0
TEMPO-2,2,6,6-Tetramethylpiperidine 1-oxyl	0.3		
Sodium bicarbonate	114.4	Aq. Effluent	302.3
Potassium bromide	11.7	Residue	143.5
Sodium hypochlorite	82.4		
Vacuum Salt	14.6		
Water	244.1		
Sod. Thiosulfate	7.3	Solvent loss	18.9
Total	**1384.7**	**Total**	**1384.7**

Stage-III

Input	Quantity	Output	Quantity
Stage-II	238.0	Stage-III	81.6
Sodium meta-bisulfite solution	37.4	Solv Recovered (MeOH)	304.0
Water	50.5	Aq. effluent	70.4
Methanol	310.1	Residue	173.9
		Solvent loss	6.1
Total	**636.0**	**Total**	**636.0**

Suma

Stage-I

Input	Quantity	Output	Quantity

4-HMBS	90.0	Stage-I Residue	60.0
4-CBA	81.6	Solvent Rec. (MDC)	1010.0
DM Water	1080.0	Solvent Rec. (EA)	490.0
Sodium carbonate	60.0		
Methylene dichloride	1034.9		
Sodium sulphate	12.0	Aq. Effluent	1576.0
PPE (Stage -V)	180.0	Residue	136.2
Sodium bicarbonate	222.0	Spent sodium sulphate	32.0
Ethyl Acetate	501.6		
Vacuum Salt	78.6	Solvent loss	36.5
Total	**3340.7**	**Total**	**3340.7**

Stage-II

Input	**Quantity**	**Output**	**Quantity**
Stage-I Residue	60.0	Stage-II	32.0
Dimethylamine (40%)	200.0	Solvent Rec. (EA)	572.0
Potassium iodide	51.2	Solvent Rec. (Ace)	343.0
TBAB	1.4		
Ethyl Acetate	588.0	Aq. Effluent	1176.0
Sodium carbonate	63.6		
DM Water	860.0	Residue	148.2
Vacuum Salt	120.0		
Acetone	350.0	Solvent loss	23.0
Total	**2294.2**	**Total**	**2294.2**

Stage-III

Input	**Quantity**	**Output**	**Quantity**
Stage - II	32.0	Stage-III	22.4
Acetone	450.0	Solvent Rec. (Acetone)	440.0
Carbon	9.6	Spent carbon	12.8
Hyflow supercell	6.4	Spent hyflow	9.6
		Residue	3.2
		Solvent loss	10.0
Total	**498.0**	**Total**	**498.0**

Stage-IV

Input	**Quantity**	**Output**	**Quantity**
Stage - III	22.4	Stage-IV (Sumatriptan	28.0

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		Succinate)	
Methanol	411.5	Solvent Rec. (MeOH)	402.2
Succinic acid	10.5	Solvent Rec. (IPA)	282.2
Isopropyl alcohol	289.4	Residue	4.9
		Solvent loss	16.5
Total	**733.8**	**Total**	**733.8**

Stage-V (PPE)

Input	**Quantity**	**Output**	**Quantity**
Phosphorus pentoxide	95.7	PPE	180
Chloroform	258	Solvent Rec. (Chloroform)	250
Isopropyl alcohol	84.3	Solvent loss	8
Total	438	**Total**	438

Raw Material:

Raw Material	**Quantity**	**CC**
Acetone	17.0	0.61
Hydrazine hydrate	127.8	4.56
C.S. Lye	272.0	9.71
Carbon	22.7	0.81
Chloroform	8.0	0.29
CP HCl	571.2	20.40
Dimethyl carbonate	7.7	0.35
Dimethylamine (40%)	200.0	7.14
Ethyl Acetate	27.6	0.99
Hyflow supercell	6.4	0.23
Isopropyl alcohol	91.5	3.27
Methanol	33.1	1.18
Methylene dichloride	43.8	1.56
Mono-methylamine (40%)	146.3	5.22
para-Nitrobenzyl bromide	146.3	5.23
Phosphorus pentoxide	95.7	3.42
$POCl_3$	146.3	5.22
Potassium bromide	11.7	0.42
Potassium iodide	51.2	1.83
Sod. Thiosulfate	7.3	0.26
Sodium bicarbonate	336.4	12.01

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Sodium carbonate	123.6	4.41
Sodium hypochlorite	82.4	2.94
Sodium meta-bisulfite	37.4	1.34
Sodium sulphate	12.0	0.43
Sodium sulphite	107.9	3.85
Succinic acid	10.5	0.38
TBAB	1.4	0.05
TEMPO-2,2,6,6-Tetramethylpiperidine 1-oxyl	0.3	0.01
Tetrahydrofuran	258.4	9.23
Toluene	30.2	1.08
Vacuum Salt	242.5	8.66
Suma. Succinate	28.0	1.00

Water usage	**Quantity**
HMBS-I	438.9
HMBS-II	585.0
HMBS-III	0.0
CBA-I	816.0
CBA-II	244.1
CBA-III	50.5
Suma-I	1080.0
Suma-II	860.0
Suma-III	0.0
Suma-IV	0.0
Suma-V	0.0
Total	**4074.5**

Waste water	**Kg**	**pH**	**TDS**	**BOD**	**COD**	**Chloride**	**Sulphate**	**Disposal**
HMBS-I	546.8	6.5	1650	2200	1500	600	100	
HMBS-II	1310.4	7	1100	1500	3500	900	100	
HMBS-III	0	0	0	0	0	0	0	
CBA-I	1708.6	7.5	1200	2500	2500	300	0	
CBA-II	302.3	6.5	900	900	3500	600	100	
CBA-III	70.4	0	0	0	0	0	0	
Suma-I	1576	7	1200	1100	3500	0	0	
Suma-II	1176	7.5	900	1250	2800	400	100	
Suma-III	0	0	0	0	0	0	0	

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Suma-IV	0	0	0	0	0	0	0	
Suma-V	0	0	0	0	0	0	0	
Total	**6690.5**	**7.1**	**1138.3**	**1631.5**	**2921.3**	**399.3**	**49.9**	**FE**

Solid waste	**Residue**	**Spent CB**	**Spent SS**	**Spent HF**
HMBS-I	0.0	0.0	0.0	0.0
HMBS-II	0.0	0.0	0.0	0.0
HMBS-III	157.5	18.0	0.0	0.0
CBA-I	0.0	0.0	0.0	0.0
CBA-II	143.5	0.0	0.0	0.0
CBA-III	173.9	0.0	0.0	0.0
Suma-I	136.2	0.0	32.0	0.0
Suma-II	148.2	0.0	0.0	0.0
Suma-III	3.2	12.8	0.0	9.6
Suma-IV	4.9	0.0	0.0	0.0
Suma-V	0.0	0.0	0.0	0.0
Total	767.4	30.8	32.0	9.6
Disposal	**TSDF**	**TSDF**	**TSDF**	**TSDF**

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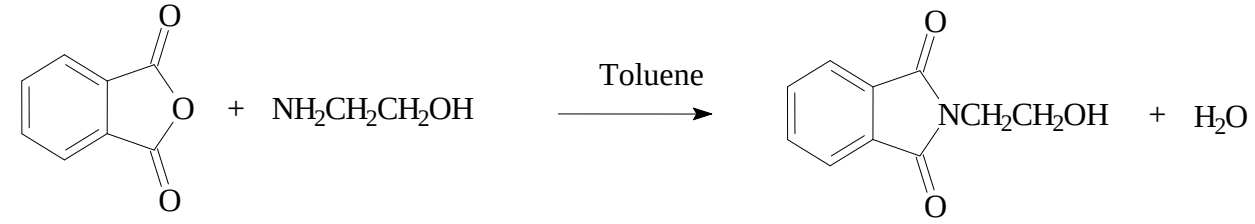
7. AMLODIPINE BESYLATE

STAGE – I:

Charge toluene, phthalic anhydride and mono-ethanol amine into the reactor. Heat the mass to reflux. Maintain for 4 hours at reflux. After completion of the reaction, cool the mass below 35°C and charge water. Stir the mass and settle for 1 hour. Discard bottom aqueous layer to ETP. Cool the mass to 10-15°C. Centrifuge the material and wash with toluene.



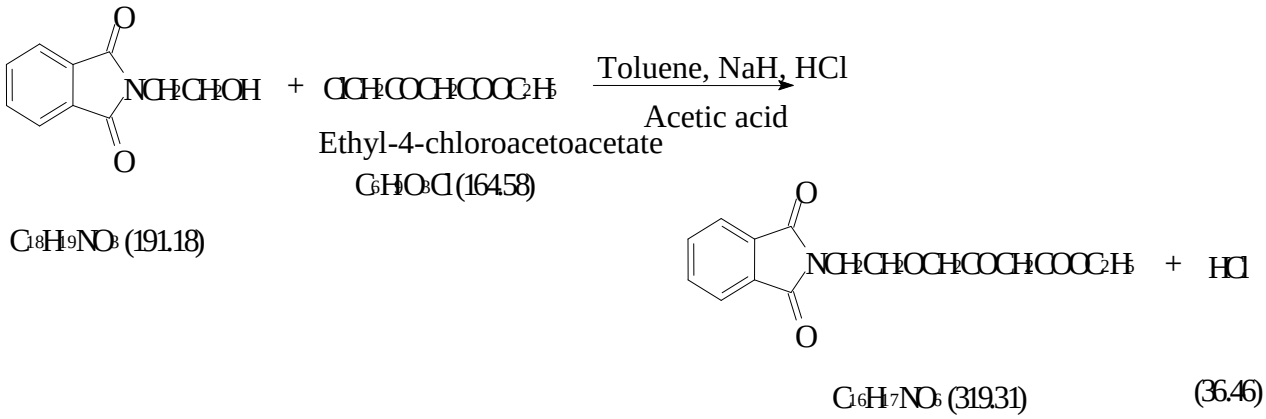
Phthalic anhydride — $C_8H_{14}O_3$ (148.11)

Monoethanol amine — C_2H_7NO (61.08)

$C_{18}H_{19}NO_3$ (191.18) (18.01)

STAGE – II:

Charge toluene, sodium hydride and Stage I compound into the reactor. Cool the mass to 0-5°C. Add ethyl 4-chloro acetoacetate into the reactor maintaining the temperature of the reaction mass at 0-5°C. After completion of the reaction, charge diluted hydrochloric acid and sodium chloride. Filter the mass and distil off toluene about 50% of volume and cool the mass slowly to 10-15°C. Centrifuge the mass and wash with toluene.



Ethyl-4-chloroacetoacetate

$C_6H_9O_3Cl$ (164.58)

$C_{18}H_{19}NO_3$ (191.18)

$C_{16}H_{17}NO_5$ (319.31) (36.46)

STAGE – III :

Charge hexane, and pyridine into the reactor. Heat the reaction mass to 50°C. Add orthochloro benzaldehyde into the reactor for 4 to 5 hours at 50-55°C. Maintain the mass for 4 hours and

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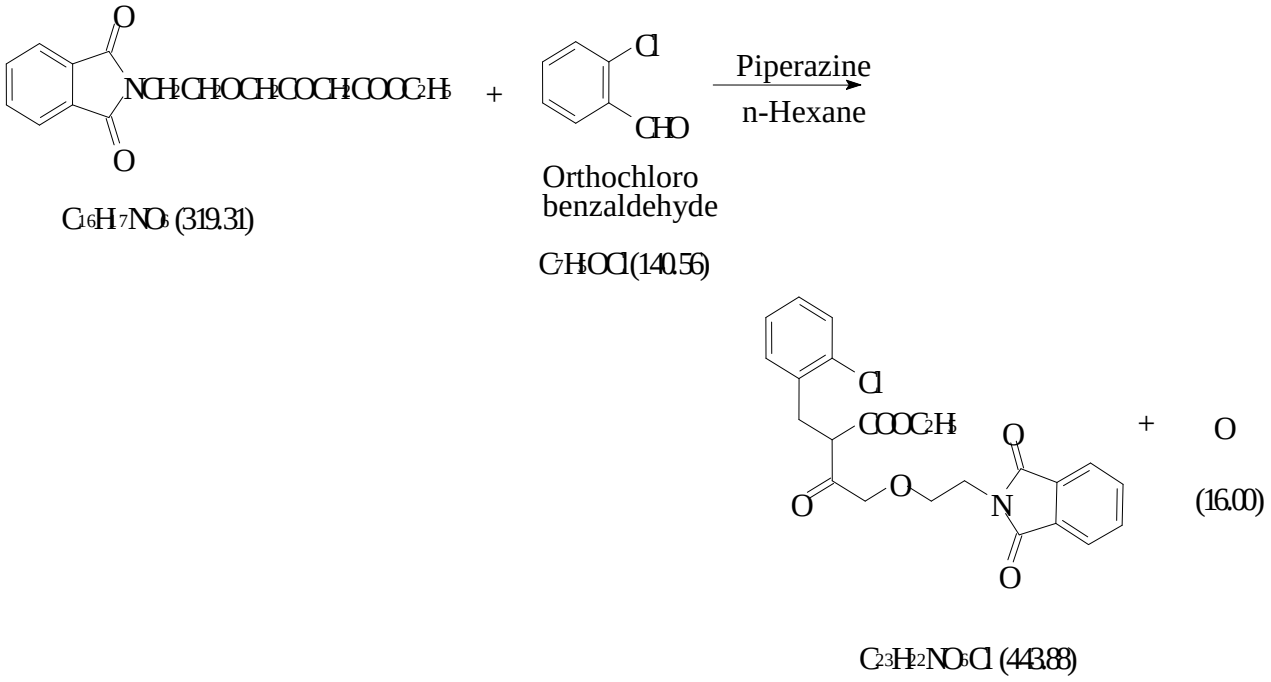
distil off hexane completely below 55°C. Cool the mass and charge toluene into the reactor followed by acetic acid. Charge stage-II compound into the reactor and maintain for 4 hours at room temperature. After completion of the reaction, charge water into the reactor and stir. Discard the bottom aqueous layer to ETP. Distill off toluene completely under vacuum below 85°C. Cool the mass and charge ethyl acetate. Stir and cool the mass to 0-5°C. Centrifuge the material and wash with ethyl acetate.



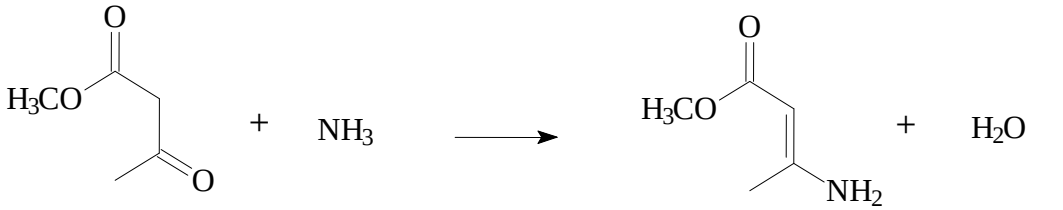
$C_{16}H_{17}NO_5$ (319.31)

C_7H_5OCl (140.56)

$C_{23}H_{22}NO_6Cl$ (443.88)

STAGE – 1A

Charge Methyl aceteoacetate and ammonia solution into the reactor and maintain for 6 hours. Filter the mass.



$C_5H_8O_3$ (116.11)

$C_5H_9NO_2$ (115.13)

STAGE – IV :

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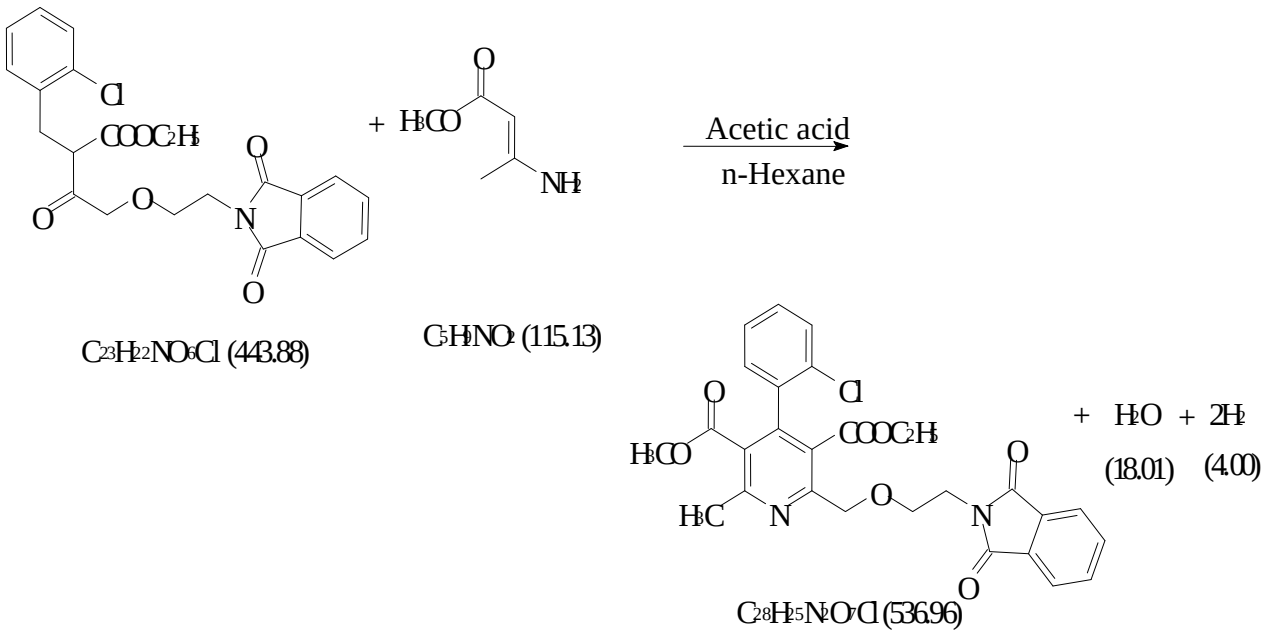
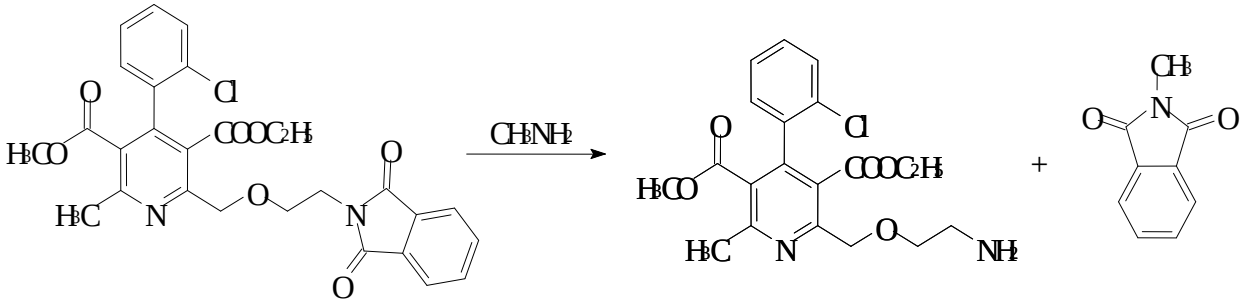
Charge hexane, Stage III compound and Stage-1A compound into the reactor. Heat the reaction mass to reflux and maintain for 4 hours. Cool the mass to 25-30°C. Centrifuge the material and wash with hexane.



$C_{23}H_{22}NO_6Cl$ (443.88) $C_5H_9NO_2$ (115.13) $C_{28}H_{25}N_2O_7Cl$ (536.96)

STAGE – V:

Charge monomethyl amine and Stage IV material into a reactor and heat to 75-80°C. After completion of the reaction, cool the mass to room temperature. Centrifuge the material to produce Amlodipine Base compound.



$C_{28}H_{25}N_2O_7Cl$ (536.96) $C_{20}H_{23}N_2O_5Cl$ (406.86) $C_9H_7NO_2$ (161.16)

STAGE – VI:

Charge methanol, Amlodipine Base compound into a reactor and add Benzene sulphonic acid slowly for 3-4 hours at 45-50°C. After completion of reaction, distil off methanol completely.

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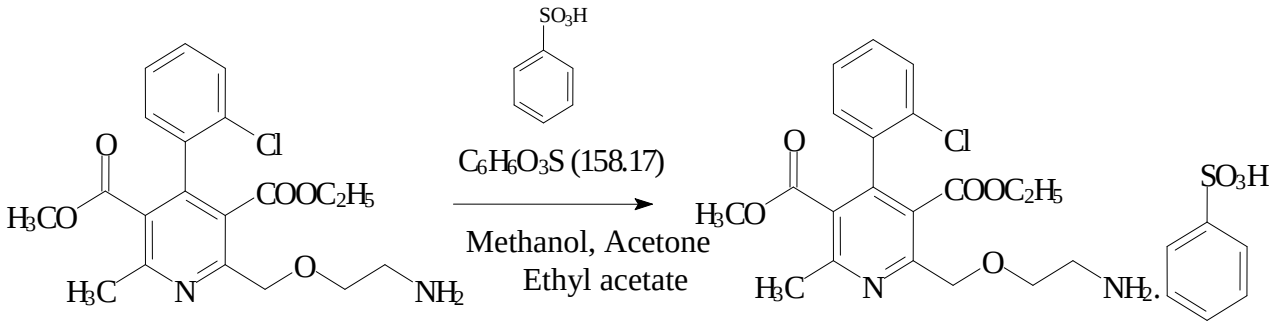
Charge ethyl acetate into the reactor and cool to 0-5°C. Centrifuge the material and wash with water followed by ethyl acetate. Dry the material at 50-55°C to give Amlodipin besylate.

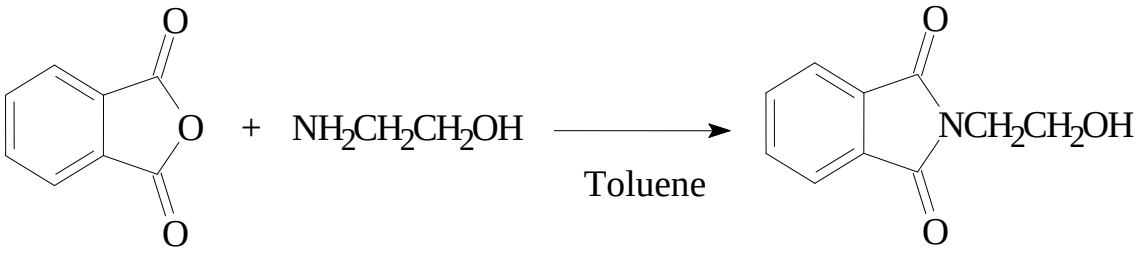


$C_{20}H_{23}N_2O_5Cl$ (406.86)

$C_{26}H_{29}N_2O_8SCl$ (565.03)

REACTION SCHEME OF AMLODIPINE BESYLATE

Stage-I



Phthalic anhydride Monoethanol amine

Stage-II

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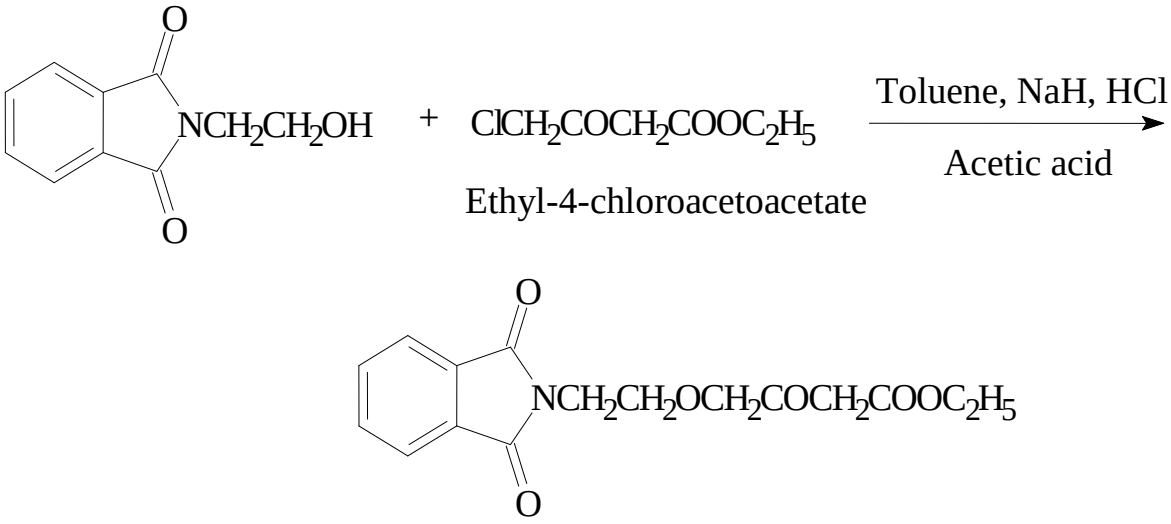
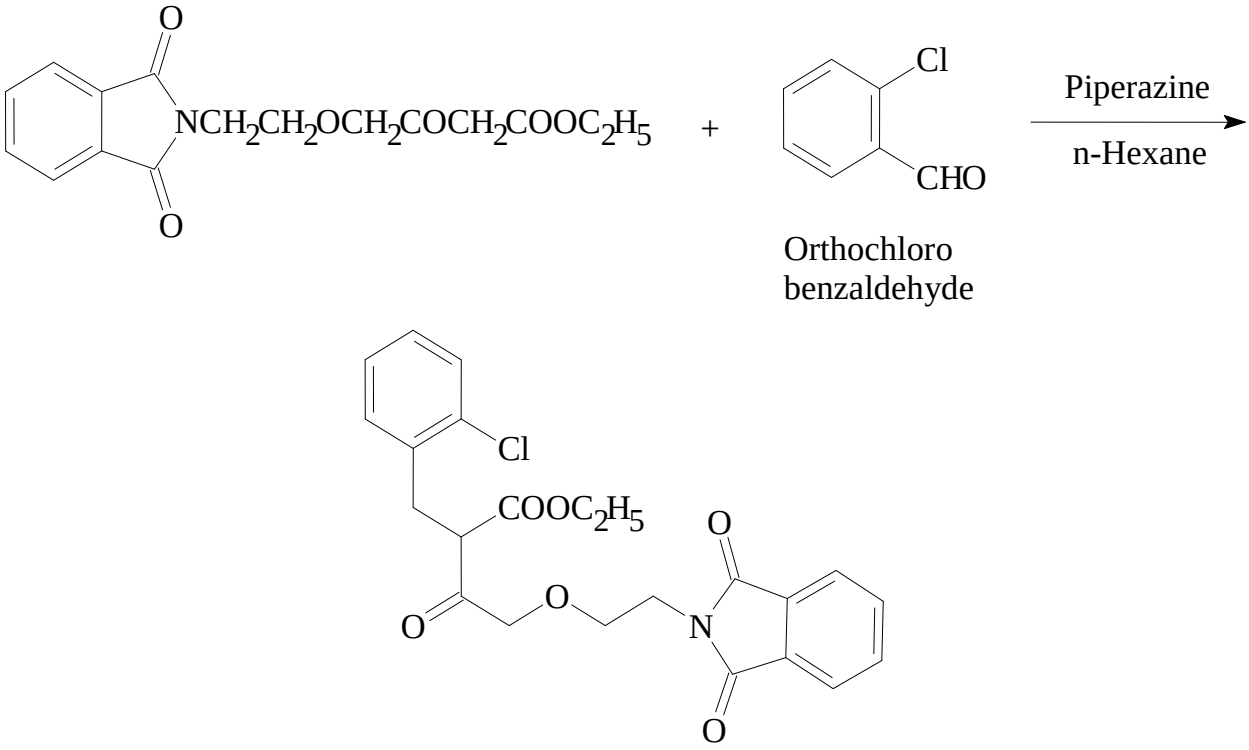


Stage-III



Stage-IV

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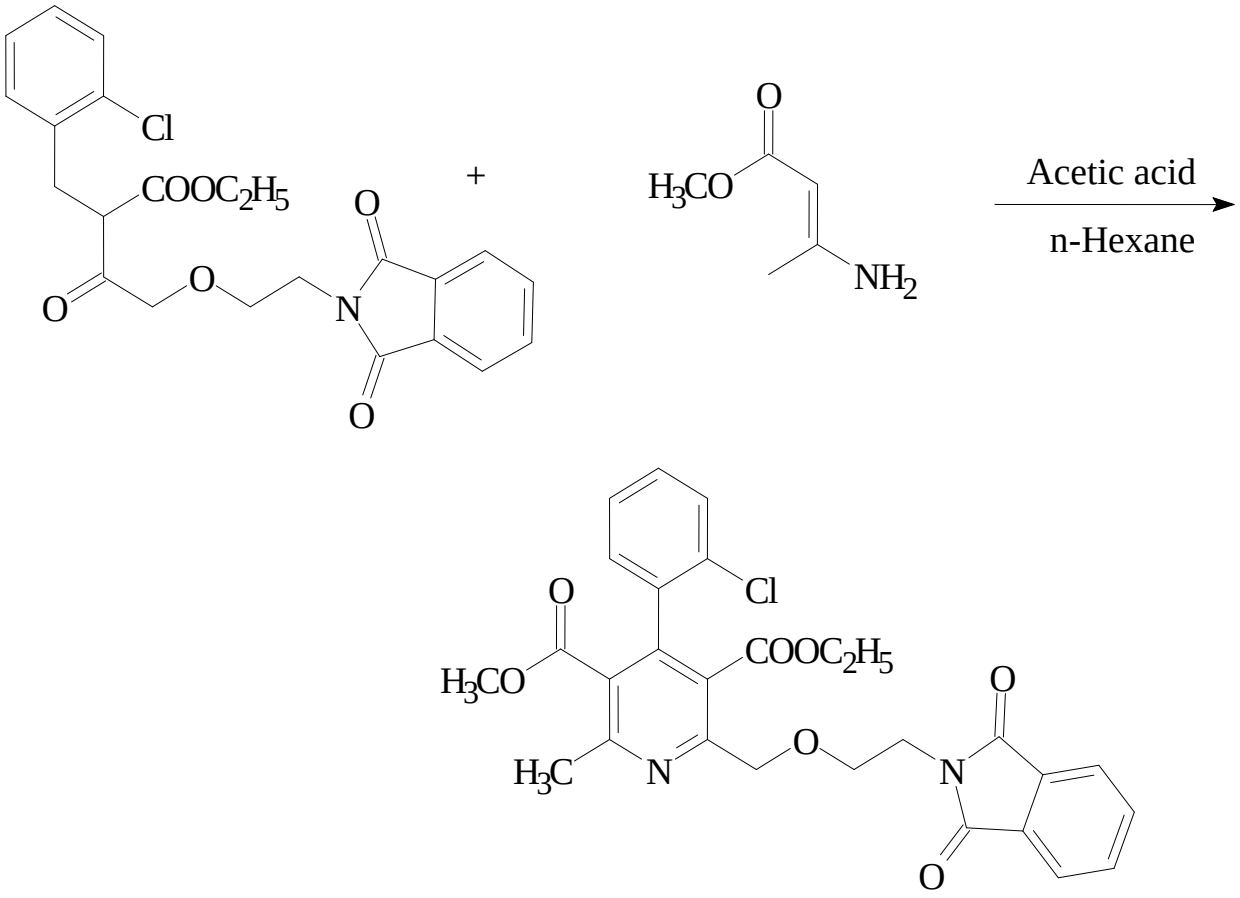
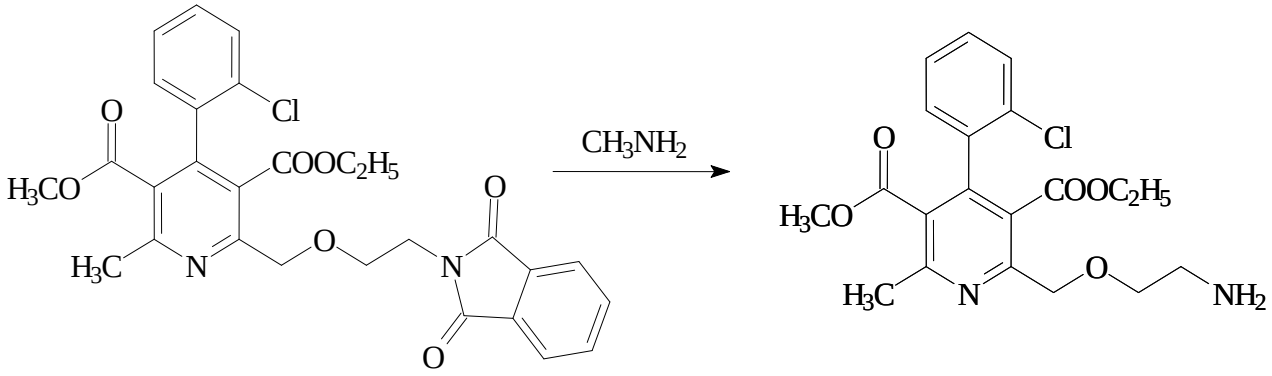


Stage-V



Stage-VI

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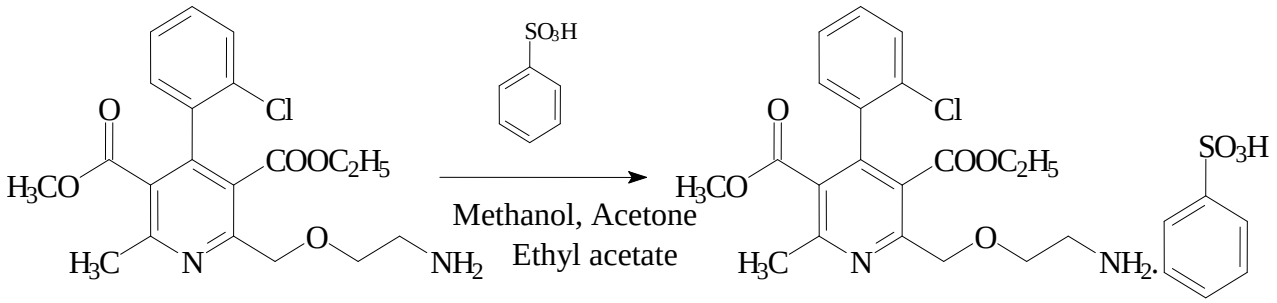
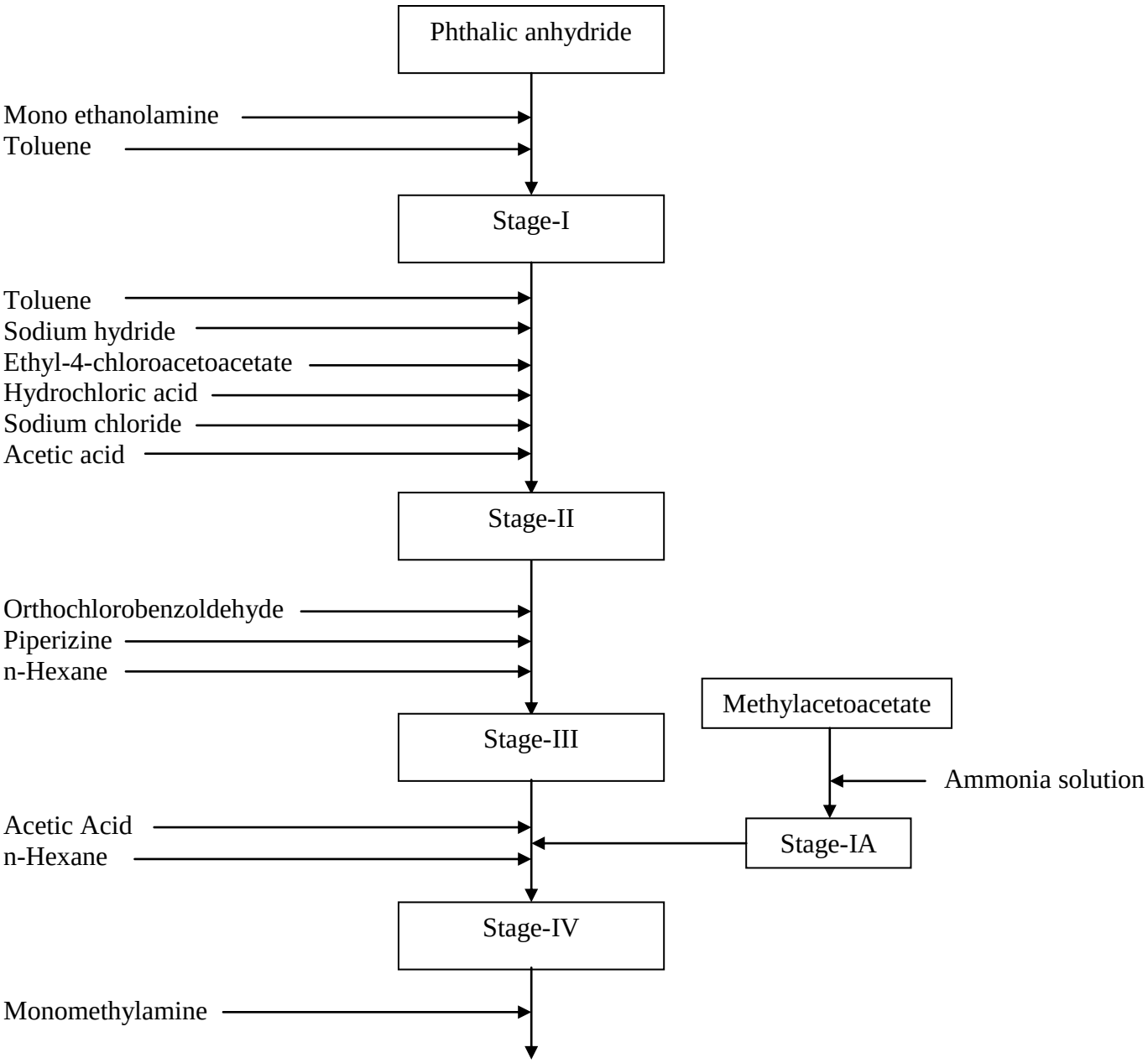


FLOW CHART



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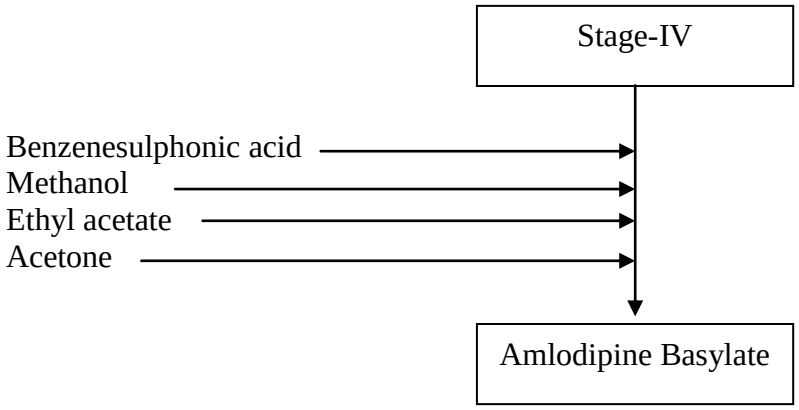

Amlodipine basylate

Stage-I

INPUT	QUANTITY	OUTPUT	QUANTITY
Phthalic anhydride	100	Stage-I	100
Monoethanol amine	45	Solv Rec (Toluene)	190
Toluene	196	Aq. Effluent	270
Purified water	250	Residue	25
		Solvent loss	6
TOTAL	**591**	**TOTAL**	**591**

Stage-II

INPUT	QUANTITY	OUTPUT	QUANTITY
Stage-I	100	Stage-II	125
Ethyl chloro aceto acetate	55	Solv Rec (Toluene)	210
HCl	5		
Acetic acid	18	Residue	131
Sodium chloride	50		
Sodium hydride	28		
Toluene	215	Solvent loss	5
TOTAL	**471**	**TOTAL**	**471**

Stage-IA

INPUT	QUANTITY	OUTPUT	QUANTITY
Methyl aceto acetate	50	Stage-1A	35
Liq ammonia	96	Aq. Effluent	111
TOTAL	**146**	**TOTAL**	**146**

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Stage-III

INPUT	QUANTITY	OUTPUT	QUANTITY
Ortho chloro benzaldehyde	40	Stage-III	150
Hexane	191	Solv. Rec (Tol)	488
Piperidine	2	Solv. Rec (EA)	343
Acetic acid	25	Solv. Rec (Hex)	183
Toluene	500	Aq. Effluent	267
Purified water	250	Residue	25
Stage-II	125		
Ethyl acetate	350	Solvent loss	27
TOTAL	**1483**	**TOTAL**	**1483**

Stage-IV

INPUT	QUANTITY	OUTPUT	QUANTITY
Stage-III	150	Stage-IV	150
Stage-IA	35	Solv. Rec (Hex)	342
Hexane	356	Residue	35
		Solvent loss	14
TOTAL	**541**	**TOTAL**	**541**

Stage-V

INPUT	QUANTITY	OUTPUT	QUANTITY
Stage-IV	150	Stage-V	100
MMA	375	Aq. Effluent	425
TOTAL	**525**	**TOTAL**	**525**

Stage-VI

INPUT	QUANTITY	OUTPUT	QUANTITY
Stage-V	100	Stage-VII	100
Benzerne Sulfonic acid	64	Solv. Rec (MeOH)	195
Methanol	200	Solv. Rec (EA)	243
Ethyl acetate	250	Aq. Effluent	144
Purified water	100	Residue	20
		Solvent loss	12
TOTAL	**714**	**TOTAL**	**714**

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Water usage	Quantity
Stage-I	250
Stage-II	0
Stage-III	250
Stage-IV	0
Stage-V	0
Stage-VI	100
Stage-IA	0
Total	**600**

Raw Materials	Quantity	CC
Acetic acid	43	0.43
Benzerne Sulfonic acid	64	0.64
Ethyl acetate	14	0.14
Ethyl chloro aceto acetate	55	0.55
HCl	5	0.05
Hexane	22	0.22
Liq ammonia	96	0.96
Methanol	5	0.05
Methyl aceto acetate	50	0.50
MMA	375	3.75
Monoethanol amine	45	0.45
Ortho chloro benzaldehyde	40	0.40
Phthalic anhydride	100	1.00
Piperidine	2	0.02
Sodium chloride	50	0.50
Sodium hydride	28	0.28
Toluene	23	0.23
Amlo. Basylate	100	1.00

Waste water	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-I	270.0	7.5	800.0	500.0	1200.0	200.0	0.0	
Stage-II	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Stage-III	267.0	6.0	600.0	700.0	2500.0	100.0	100.0	
Stage-IV	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Stage-V	425.0	8.0	600.0	800.0	1500.0	0.0	0.0	

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Stage-VI	144.0	6.5	1200.0	800.0	2550.0	100.0	0.0	
Stage-IA	111.0	9.0	350.0	500.0	100.0	0.0	0.0	
Total	**1217.0**	**7.4**	**692.6**	**684.1**	**1649.4**	**78.1**	**21.9**	**FE**

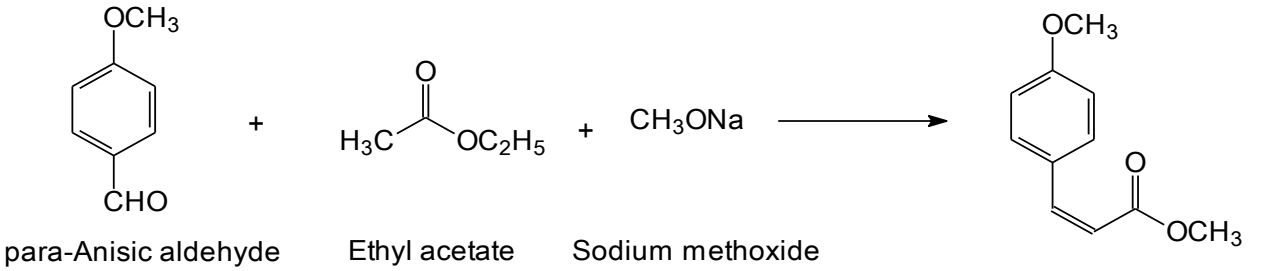
Solid waste	**Residue**	**Spent CB**	**Spent SS**	**Spent HF**
Stage-I	25.0	0.0	0.0	0.0
Stage-II	131.0	0.0	0.0	0.0
Stage-III	25.0	0.0	0.0	0.0
Stage-IV	35.0	0.0	0.0	0.0
Stage-V	0.0	0.0	0.0	0.0
Stage-VI	20.0	0.0	0.0	0.0
Stage-IA	0.0	0.0	0.0	0.0
Total	236.0	0.0	0.0	0.0
Disposal	**TSDF**	**TSDF**	**TSDF**	**TSDF**

8. OCTYL METHOXY CINNAMATE

Stage-I & II

p-Anisic aldehyde is condensed with ethyl acetate in presence of Sodium methoxide and the ethyl-4-methoxy cinnamate obtained as intermediate is transesterified with 2-ethylhexanol to furnish Octyl methoxy cinnamate which is purified by distillation under vacuum.

Reaction Scheme:



para-Anisic aldehyde (136) | Ethyl acetate (88) | Sodium methoxide (54) | Ethyl methoxy cinnamat (206)

Reaction scheme:

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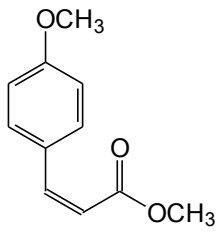
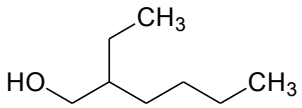
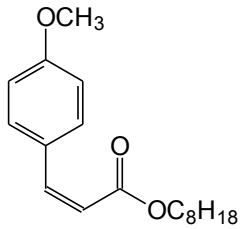


Ethyl methoxy cinnamate
(206)



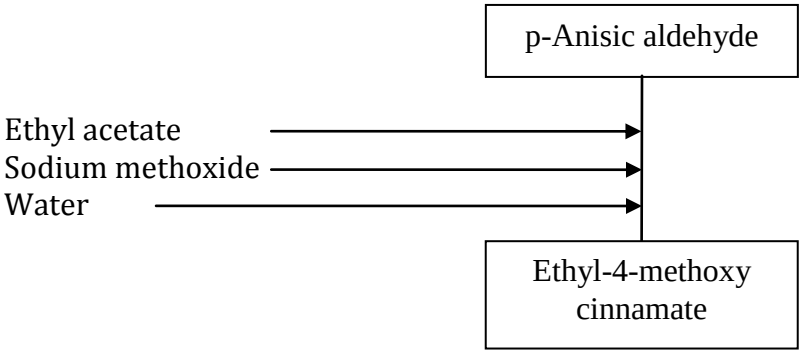
2-Ethylhexanol
(130)



Octyl methoxy cinnamate
(290)

FLOW CHART – **OCTYL METHOXY CINNAMATE**

Stage-I:



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Stage-II:

OCTYL METHOXY CINNAMATE

Stage-I			
INPUT		OUTPUT	
Para anisic aldehyde	300	EMC	1525
Ethyl acetate	1300		
Sodium methoxide	150	Effluent	700
Water	500		
		Solvent loss	25
	2250		2250

EMC = Ethyl methoxy cinnamate

Stage-II			
INPUT		OUTPUT	
EMC	1525	OMC	605
2-Ethyl hexanol	350	Sol. Rec. (ET)	1225
		Solvent loss	20
		Residue	25
	1875		1875

Water Usage	**Quantity**
Stage-1	500
Stage-2	0
Total	500

Raw Material	**Quantity**	**CC**
Para anisic aldehyde	300	0.50
Ethyl acetate	1300	2.15
Sodium methoxide	150	0.25
Water	500	0.83

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2-Ethyl hexanol	350	0.58
OMC	605	1.00

Waste water	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-I	700.0	8.0	600.0	1000.0	1000.0	0.0	0.0	FE
Stage-II	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total	**700.0**	**8.0**	**600.0**	**1000.0**	**1000.0**	**0.0**	**0.0**	

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Stage-I	0.0	0.0	0.0	0.0
Stage-II	25.0	0.0	0.0	0.0
Total	25.0	0.0	0.0	0.0
Disposal	**TSDF**	**TSDF**	**TSDF**	**TSDF**

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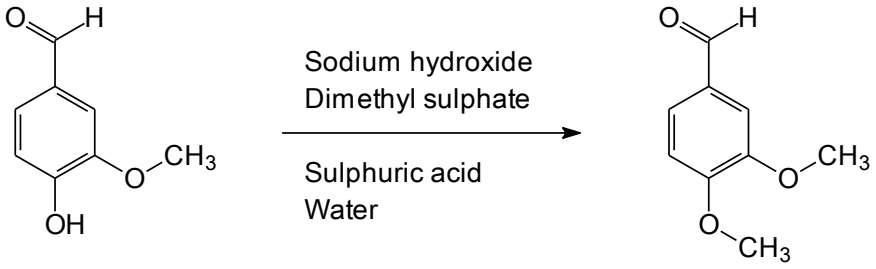
9. VERATRIC ACID

Stage-I

Vanilline is dissolved in water in alkaline medium at 90-95°C in a reactor. Sodium hydroxide solution and Dimethyl sulphate are added into the reactor simultaneously maintaining the temperature 80-90°C. After completion of addition the reaction mass is maintained. The pH of the rection mass is adjusted with Sulphuric acid. The mass is stirred and settled. The bottom aqueous layer is discarded and the top product layer is collected to produce Veratraldehyde.

Reaction Scheme:



Vanillin
(152)

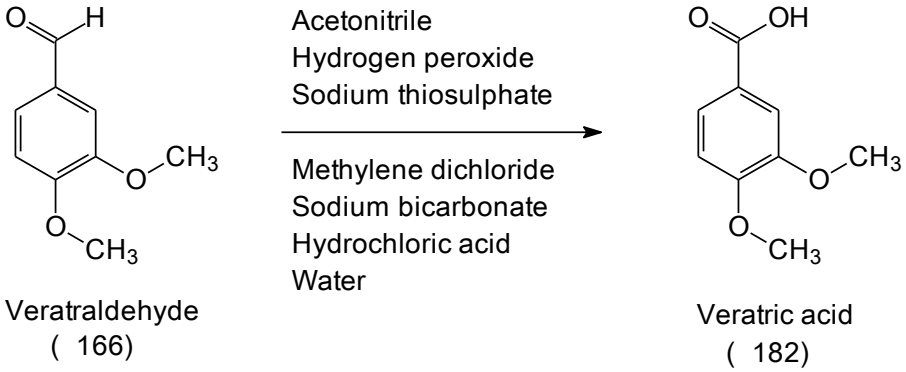
Veratraldehyde
(166)

Stage-II:

Acetonitrile and Veratraldehyde are charged into a reactor and the mass is stirred. Hydrogen peroxide is added slowly into the reactor. After completion of addition, the mass is heated. The mass is quenched in Sodium Thiosulphte solution and the product is extracted into Methylene dichloride (MDC). MDC is distilled out to produce crude mass.

The crude mass is washed with Sodium bicarbonate solution and extracted with MDC. The aqueous layer further acidified with Hydrochloric acid and then extracted with MDC. Both the MDC layers are combined and subjected to MDC distillation to produce Veratric acid.

Reaction scheme:

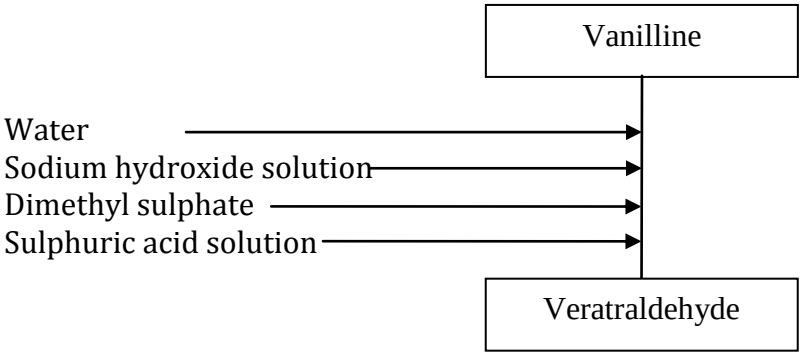


Veratraldehyde
(166)

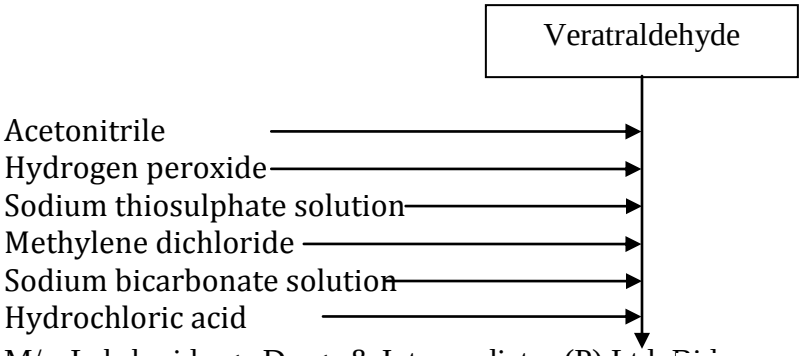
Veratric acid
(182)

FLOW CHART – Veratric acid

Stage-I:



Stage-II:



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Veratric acid

Veratric acid

Stage-I			
INPUT		OUTPUT	
Vanilline	212	Veratraldehyde	212
Sodium hydroxide	69		
Dimethyl sulphate	180	Effluent	588
Sulphuric acid	14		
Water	325		
	800		800

Stage-II			
INPUT		OUTPUT	
Veratraldehyde	212	Veratric acid	204
Hydrogen peroxide	636	Sol. Rec. (AC)	1000
Acetonitrile	1060	Sol. Rec. (MDC)	1600
Sodium thiosulphate	185	Effluent	2770
Methylene dichloride	1800		
Hydrochloric acid	64		
Sodium bicarbonate	77		
Water	1800	Solvent loss	260
	5834		5834

Water Usage	Quantity
Stage-1	325
Stage-2	1800
Total	2125

Raw Material	Quantity	CC
Vanillin	212	1.04
Sodium hydroxide	69	0.34
Dimethyl sulphate	180	0.88
Sulphuric acid	14	0.07
Hydrogen peroxide	636	3.12
Acetonitrile	60	0.29
Sodium thiosulphate	185	0.91
Methylene dichloride	200	0.98
Hydrochloric acid	64	0.31
Sodium bicarbonate	77	0.38
Veratric acid	204	1.00

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Waste water	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-I	588.0	6.5	600.0	1200.0	1200.0	0.0	200.0	FE
Stage-II	2770.0	7.5	1300.0	1200.0	2600.0	100.0	350.0	FE
Total	**588.0**	**6.5**	**600.0**	**1200.0**	**1200.0**	**0.0**	**200.0**	

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10. CLOPIDOGREL INTERMEDIATES

Intermediate-I: 2-Chlorophenyl glycine methyl ester tartarate

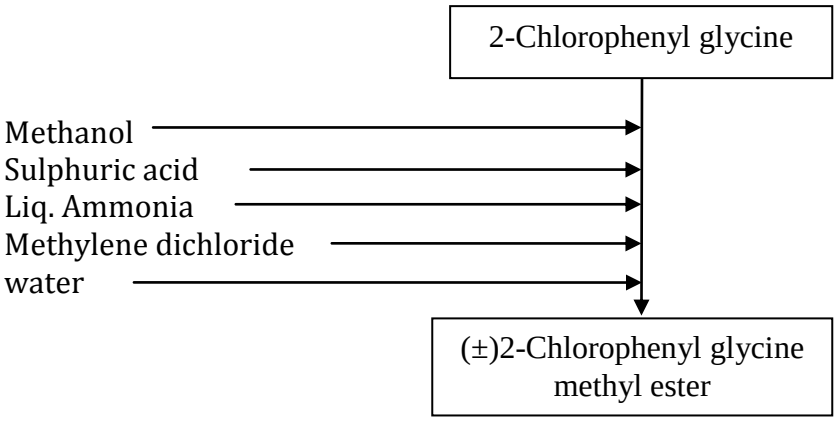
Stage-IA

Charge methanol and 2-Chlorophenyl glucine into a reactor and add sulphuric acid. Heat the mass and maintain. After completion of the reaction distill off methanol and dilute the mass with water. Charge Methylene dichloride and adjust pH with Liquor ammonia. Separate the MDC layer and distill off MDC completely. Cool the mass and unload. The mass is (±)2-Chlorophenyl glycine methyl ester.

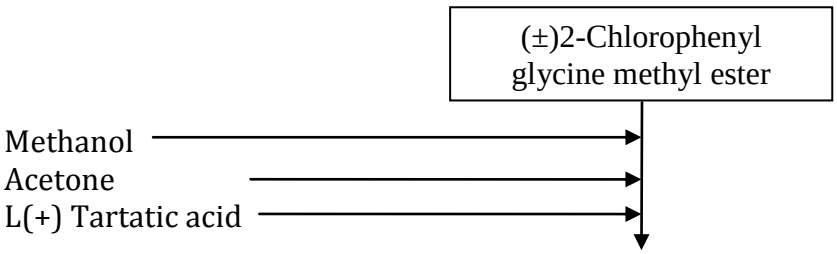
Stage-IB

Charhe Methanol, Acetone and L(+) Tartaric acid into a reactor and check dissolution. Charge Stage-IA into the reactor. Heat the mass and maintain. After completion of reaction, cool the mass and centrifuge. Wash the mass with methanol and dry to produce (+)-2-Chlorophenyl glycine methyl ester tartarate.

FLOW CHART – Stage-IA



FLOW CHART – Stage-IB



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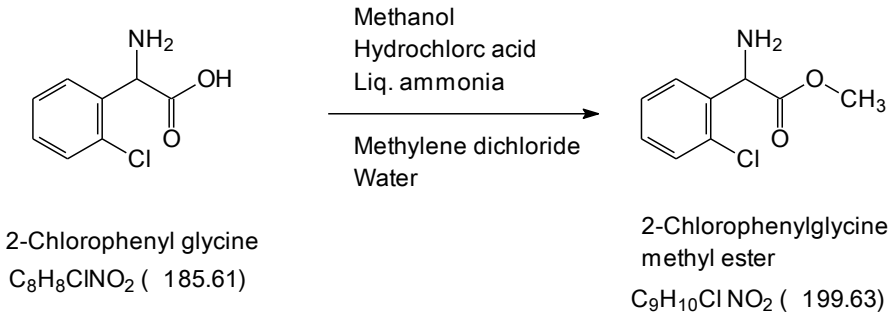
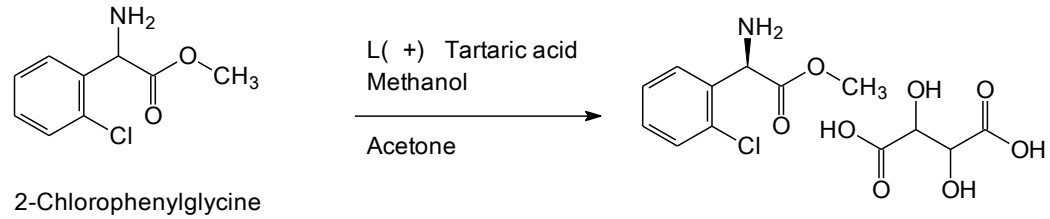
(+)-2-Chlorophenyl glycine methyl ester tartarate **-IA**



2-Chlorophenyl glycine
$C_8H_8ClNO_2$ (185.61)

2-Chlorophenylglycine methyl ester
$C_9H_{10}Cl\,NO_2$ (199.63)

REACTION SCHEME – Stage-IB



2-Chlorophenylglycine methyl ester
$C_9H_{10}Cl\,NO_2$ (199.63)

2-Chlorophenylglycine methyl ester tartarate
$C_{13}H_{16}Cl\,NO_8$ (379.72)

Clopidogrel Bisulphate Intermediate-I: 2-Chlorophenyl glycine methyl ester tartarate
Stage-IA

INPUT		OUTPUT	
Methanol	960	Stage-IA	290
2-Chlorophenyl glysine	300	Solv Rec (Methanol)	850
Sulphuric acid	300	Solv Rec (MDC)	1800
Liquor ammonia	270	Aq. Effluent	2140
Methylene dichloride	1980		
Water	1560	Solvent loss	290
TOTAL	5370	TOTAL	5370

Stage-IB

INPUT		OUTPUT	
Stage-IA	290	Stage-II	370
L(+) Tartaric acid	240	Solv Rec (Methanol+Acetone)	2000

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Methanol	1800		
Acetone	420	Residue	160
		Solvent loss	220
TOTAL	2750	TOTAL	2750

Water usage	Quantity
Stage-IA	1560
Stage-IB	0
Total	**1560**

Raw Material	Quantity	CC
2-Chlorophenyl glysine	300.0	0.81
Acetone	70.0	0.19
L(+) Tartaric acid	240.0	0.65
Liquor ammonia	270.0	0.73
Methanol	260.0	0.70
Methylene dichloride	180.0	0.49
Sulphuric acid	300.0	0.81
Intermediate-I	370.0	1.00

Waste water	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-IA	0.0	7.2	1000.0	600.0	1000.0	200.0	600.0	
Stage-IB	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total	**0.0**	**7.2**	**1000.0**	**600.0**	**1000.0**	**200.0**	**600.0**	

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Stage-IA	0.0	0.0	0.0	0.0
Stage-IB	160.0	0.0	0.0	0.0
Total	160.0	0.0	0.0	0.0

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Intermediate-II: (+)-N-(2-(2-Thionyl) ethyl)-2-chlorophenyl glycine methyl ester hydrochloride

Stage-IC

Charge Toluene, Stage-IB and Water into a reactor, and charge slowly Liquor ammonia. Separate the organic layer dry on sodium sulphate. Keep organic layer aside for further process. The product in organic layer is (+)2-Chlorophenyl glycine methyl ester.

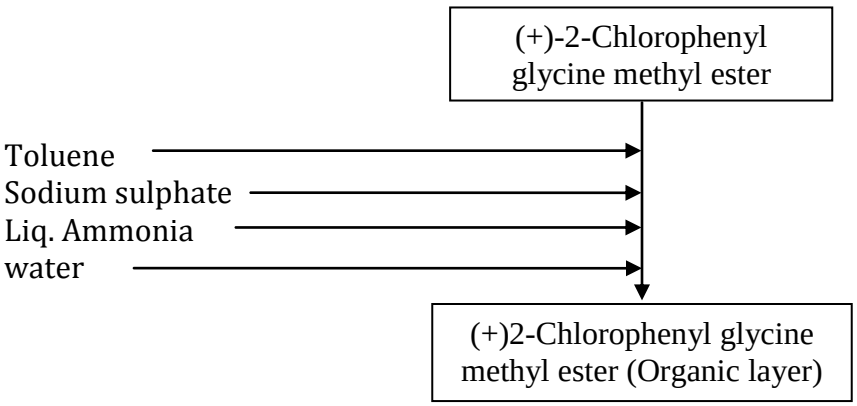
Stage-II

Charge Water and CS flakes into a reactor and check dissolution. Charge Thiophen-2-ethanol into the reactor. Add slowly para-Toluene sulfonyl chloride. Charge Trtrabutyl ammonium bromide and maintain. After completion of the reaction, separate the organic layer and keep aside for further process. The product in organic layer is Toluene-4-sulfonic acid, 2-thiophen-2-yl ethyl ester.

Stage-III

Charge Stage-IC and Stage-II into a reactor followed by Dipotassoum hydrogen phosphate and Tetrabutyl ammonium bromide. Heat the mass and maintain. After completion of the reaction, Cool the mass and dilute with water. Separate the organic layer and wash with water. Charge Isopropyl alcohol and cool. Adjust the pH of the organic layer with Hydrogen chloride gas and maintain. Centrifuge the mass and wash with toluene. Dry the mass to produce (+)-N-(2-(2-Thionyl) ethyl)-2-chlorophenyl glycine methyl ester hydrochloride.

FLOW CHART – Stage-IC



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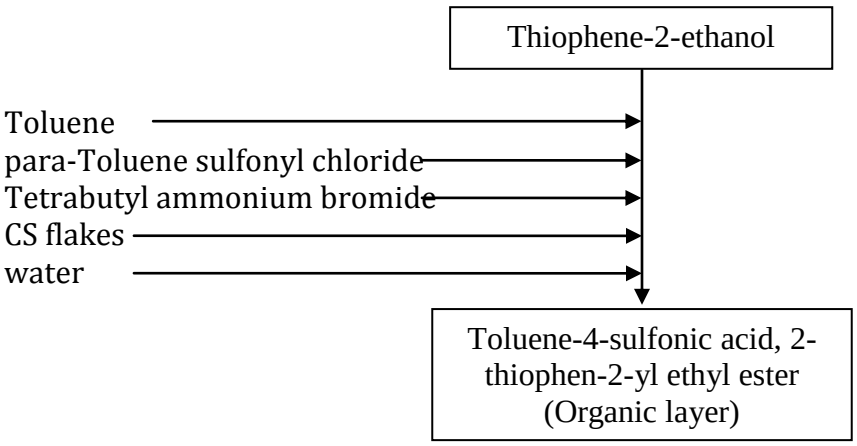
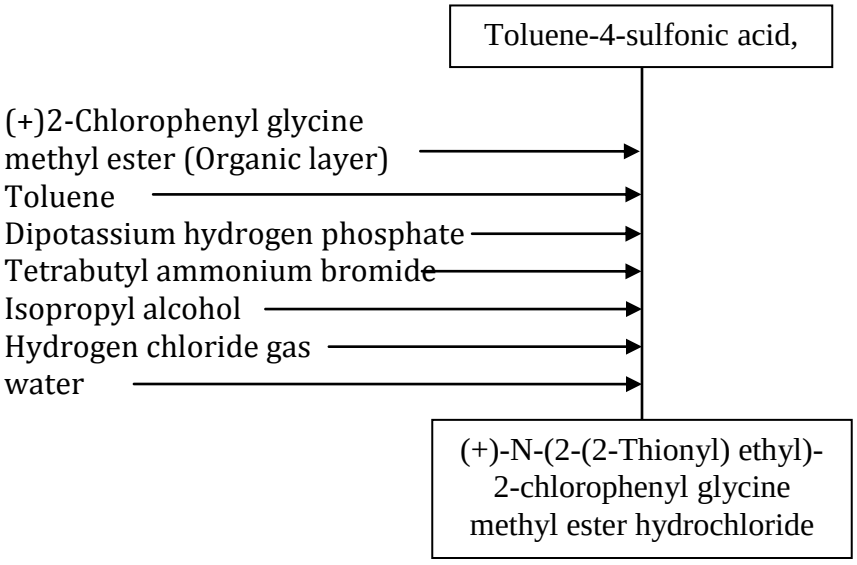
FLOW CHART – Stage-II



FLOW CHART – Stage-III



REACTION SCHEME – Stage-IC

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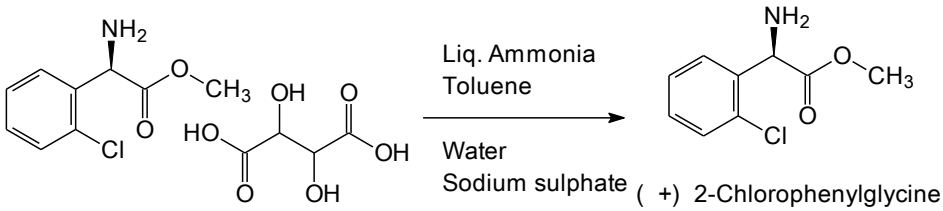


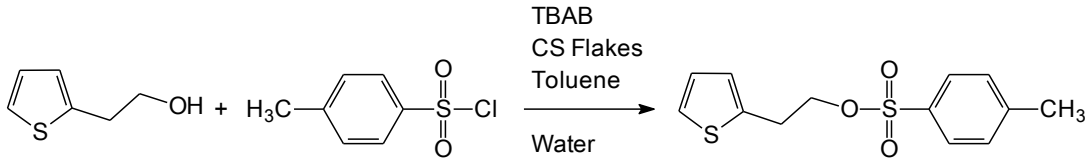
2-Chlorophenylglycine methyl ester tartarate

$C_{13}H_{16}Cl\,NO_8$ (379.72)

(+) 2-Chlorophenylglycine methyl ester

$C_9H_{10}Cl\,NO_2$ (199.63)

REACTION SCHEME – Stage-II



Thiophene-2-ethanol

C_6H_8OS (128.19)

para-Toluenesulfonyl chloride

$C_7H_7ClO_2S$ (190.65)

Toluene-4sulfonic acid, 2-thiophen-2-yl ethyl ester

$C_{13}H_{14}O_3S_2$ (282.37)

REACTION SCHEME – Stage-III

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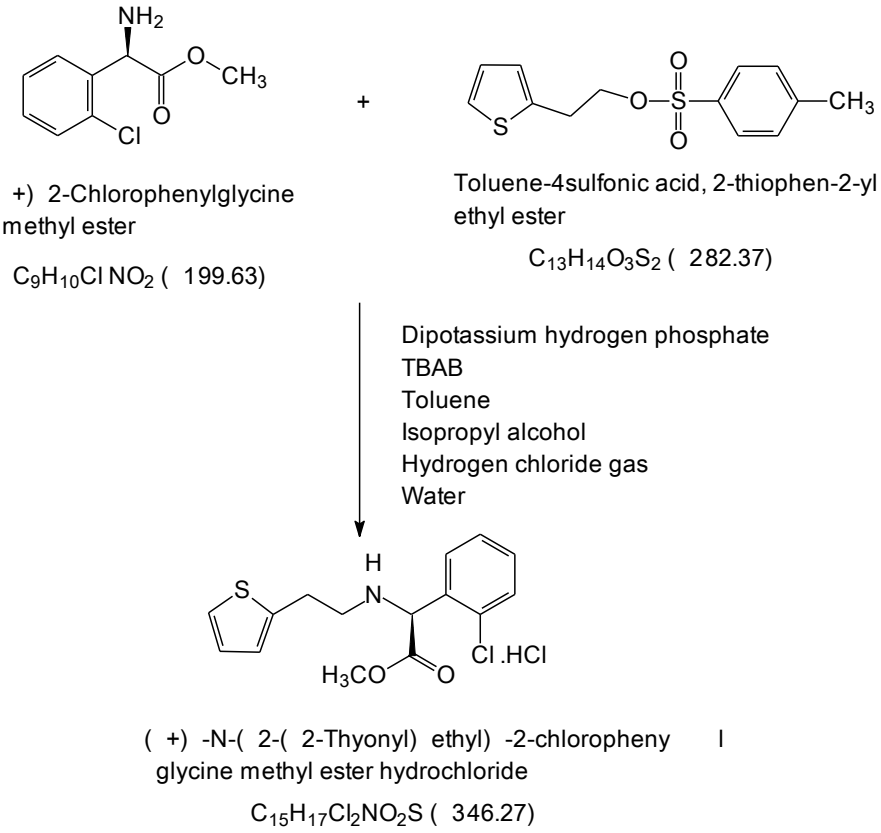

(+) 2-Chlorophenylglycine methyl ester

$C_9H_{10}Cl\,NO_2$ (199.63)

Toluene-4sulfonic acid, 2-thiophen-2-yl ethyl ester

$C_{13}H_{14}O_3S_2$ (282.37)

(+) -N-(2-(2-Thyonyl) ethyl) -2-chlorophenyl glycine methyl ester hydrochloride

$C_{15}H_{17}Cl_2NO_2S$ (346.27)

Clopidogrel Bisulphate Intermediate- II: (+)-N-(2-(2-Thionyl) ethyl)-2-chlorophenyl glycine methyl ester hydrochloride

Stage-IC

INPUT		OUTPUT	
Stage-IB	370	Stage-1C (Organic layer)	780
Liquor ammonia	265		
Toluene	385	Aq. Effluent	475
Sodium sulphate	10	Spent sodium sulphate	20
Water	260	Solvent loss	15
	1290		1290

Stage-II

INPUT		OUTPUT	

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Thiophen-2-ethanol	115	Stage-II (Organic layer)	700
para-Toluene sulfonyl chloride	185		
Tetra butyl ammonium bromide	10	Aq. Effluent	600
Caustic soda flakes	90		
Toluene	520		
Water	400	Solvent loss	20
	1320		1320

Stage-III

INPUT		OUTPUT	
Stage-IC	780	Stage-IV	175
Stage-III	700	Solv. Rec (Toluene)	1520
Dipotassium hydrogen phosphate	260		
Tetra butyl ammonium bromide	10	Aq. Effluent	2890
Toluene	690		
Isopropul alcohol	180		
Hydrogen chloride gas	15	Residue	35
Water	2125	Solvent loss	140
	4760		4760

Water usage	**Quantity**
Stage-IC	260
Stage-II	400
Stage-III	2125
Total	**2785**

Raw Material	**Quantity**	**CC**
Caustic soda flakes	90.0	0.51
Dipotassium hydrogen phosphate	260.0	1.49
Hydrogen chloride gas	15.0	0.09
Intermediate-I	370.0	2.11
Isopropul alcohol	180.0	1.03
Liquor ammonia	265.0	1.51
para-Toluene sulfonyl chloride	185.0	1.06
Sodium sulphate	10.0	0.06
Tetra butyl ammonium bromide	20.0	0.11

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Thiophen-2-ethanol	115.0	0.66
Toluene	75.0	0.43
Intermediate-II	175.0	1.00

Waste water	Kg	pH	TDS	BOD	COD	Chloride	Sulphate	Disposal
Stage-IC	475.0	7.5	300.0	800.0	1500.0	100.0	100.0	
Stage-II	600.0	8.5	300.0	500.0	800.0	0.0	0.0	
Stage-III	2890.0	6.5	800.0	1000.0	1200.0	500.0	0.0	
Total	**3965.0**	**6.9**	**664.4**	**900.4**	**1175.4**	**376.4**	**12.0**	**FE**

Solid waste	Residue	Spent CB	Spent SS	Spent HF
Stage-IC	0.0	0.0	20.0	0.0
Stage-II	0.0	0.0	0.0	0.0
Stage-III	35.0	0.0	0.0	0.0
Total	35.0	0.0	20.0	0.0
Disposal	**TSDF**	**TSDF**	**TSDF**	**TSDF**

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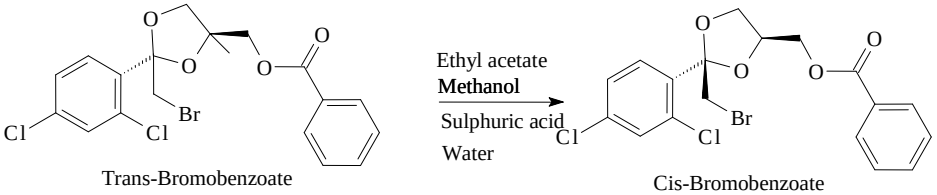
11. RECOVERED CIS-BROMOBENZOATE

Stage-I:

Charge TBB (Trans-Bromo benzoate) mass and Methanol in a stainless steel reactor. Filter the material and charge ethyl acetate. Add Sulphuric acid slowly into the reactor maintaining the temperature at 0 – 5°C. Maintain the mass at same temperature. After completion of the reaction, Charge ethyl acetate and water. Stir the mass and settle. Separate the organic layer and distill off methanol and ethyl acetate completely, cool the mass and centrifuge. Dry the material to produce Cis-bromo benzoate.



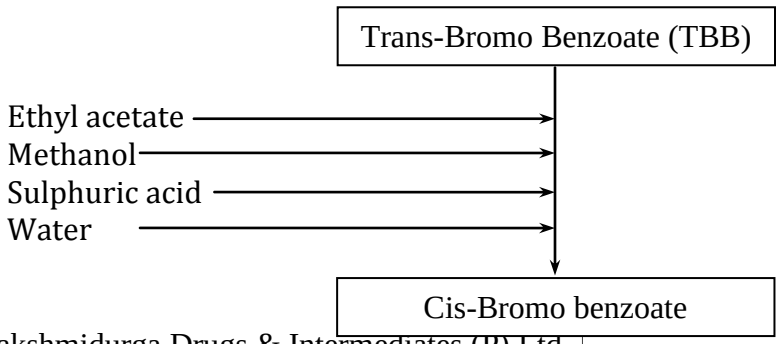
Trans-Bromobenzoate
$C_{18}H_{15}O_4BrCl_2$ (446.12)

Cis-Bromobenzoate
$C_{18}H_{15}O_4BrCl_2$ (446.12)

Raw Material:

Raw Materials	Quantity	CC
Trans-Bromo benzoate (TBB)	500.0	3.85
Methanol	40.0	0.31
Ethyl acetate	60.0	0.46
Sulphuric acid	50.0	0.38
Output - CBB	130.0	1.00

FLOW CHART OF CIS-BROMO BENZOATE:



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Material Balance:

Stage-I			
Input	**Quantity**	**Output**	**Quantity**
Trans-Bromo Benzoate	500	Cis-Bromo benzoate	130
Methanol	500		
Ethyl acetate	1200	Methanol + Ethyl acetate (Rec)	1600
Sulphuric acid	50	Aqueous effluent	900
Water	500	Residue	150
		Solvent loss	100
Total	**2750**	**Total**	**2750**

Water Usage	**Quantity**
Stage-I	500.0
Total	**500.0**

Aqueous Effluent	**Kg**	**pH**	**TDS**	**BOD**	**COD**	**Chloride**	**Sulphate**	**Disposal**
Stage-I	900.0	6.5	2900	1000	3000	100	200	
Total	900.0	6.5	2900	1000	3000	100	200	**FE**

Solid waste	**Residue**	**Spent CB**	**Spent SS**	**Spent HF**
Stage-I	150	0	0	0
Total	**150**	0	0	0

vi. Raw material required along with estimated quantity likely source marketing area of final product/s, mode of transport of raw material and finished product

Details are provided in the previous item

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

After the reaction is complete the solvents are recovered in a distillation unit. The distillation unit is Stainless Steel or Glass Lined Reactor. The residue from the distillation unit is collected in a container and sent to incinerator. The recovered solvents are collected in drums, labeled and analyzed. Then they are reused (recycled) for the process, mostly for the same product

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viii. Availability of water its source, energy/power requirement and source should be given

Source of water is from bore well and estimated as 29 KLD. Power requirement of the project is 165KVA from GESCOM.

ix. Quantity of wastes to be generated (liquid & solid) and scheme for their management/disposal

Trade waste water

The main sources of effluents are:

1. Process.
2. Floor wash
3. Boiler blow down
4. Cooling tower blow down

Volume of Process waste water & Boiler blow down.

The volume of wastewater generated from process, per batch of Drug manufacture is furnished below. Volume of wastewater generated from each Drug proposed to be manufactured

Treatment of Process waste water: MEE = 20 KLD

Treatment of Other wastewater

The wastewater generated from Boiler blow down, cooling tower blow down will be drained to equalization cum neutralization tank followed by setting unit, and the treated clear effluents will be used for the greenbelt development and coal ash quenching.

Solvent residue

Sources of solid waste in the plant are (i) Solvent residue (ii) Process residue (iii) Forced evaporation salts and (iv) Coal ash.

Solid waste disposal

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- The solid from the bottom of the neutralization tank will have a selling potentiality. In such case, this solid will be sold to the parties who have a license form handling the same, other it will be sent to Haz disposal yard established by Govt.
- The coal ash will be given to the brick manufactures by which we can be sure of safe disposal system.

Treatment & Disposal of Sewage as per IS: [Septic tank Dispersal system]

The domestic effluents will be treated in septic tank & disposed through dispersion trenches. No effluent will be discharged outside of the plant premises.

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

Attached site plan

4. SITE ANALYSIS

(i) Connectivity:

Project site is well connected by an asphalted road which is located at a distance of about 4.4 Km from Humnabad and near state highway NH-218 just 0.2km away from the Factory entrance.

(ii) Land Form, Land use and Land ownership:

Land is owned by M/s Lakshmidurga Drugs & Intermediates Private Limited of project proponent. This land has been allotted by KIADB in the Industrial area. The present land use is industrial.

(iii) Topography (along with map):

The project site is located at the Northeast side from the Humnabad town with the distance of 4.4 km. The elevation in the project site is 662 meter above mean sea level. An area covering 10 km radius, with project site as centre, is considered as the Study area.

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(iv) 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 the HFL of the river), CRZ, In case of notified industrial area, a copy of the gazette:

It is bounded by Gulbarga district to the Southern portion, Andra Pradesh State towards Eastern side, Maharashtra state to the North and Western portion.

The project site is in the notified industrial area. There are no reserved forests, national parks, wild life sanctuary and CRZ regions within 10 km radius. There are no eco-sensitive locations within 10Km from the site.

(v) Existing Infrastructure:

M/s R. Lakshmidurga Drugs & Intermediates Private Limited has the necessary concrete structures for the production. Only few types of equipment have to be installed.

PLANT LAYOUT

A copy of the Plant Layout is enclosed herewith. This details the entire plot area, position of all the building structures within the plot

LAND

The Plant facilities are spread over 16,188 Sqmt KIADB of leveled land which is completely fortified and protected on all four sides by boundary walls.

BUILDINGS

Total built up area is divided into various sections like Production plant, Engineering, Quality Control/ and Administration, Canteen, toilets, There is adequate space & provision for present operations and future growth. Additional space is available for future storage requirements.

PLANT AND MACHINERY & UTILITIES

The plant facilities are spread over 16,188 Sqmt of leveled freehold land in developed KIADB Industrial Area at Bidar. The Plant facilities have been designed and set up with the objective

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to carry out almost all critical chemical reactions and processes.

(vi) Soil Classification:

Geology: The entire district forms a part of the Deccan Plateau and is made up mostly of solidified lava. The northern part of the district is characterized by expanses of level and treeless surface punctuated here and there by flat and undulating hillocks, black soils and basaltic rocks. The southern half of the district is a high plateau about 715 m above mean sea level and is well drained. The average elevation of the district is between 580 to 610 m above mean sea level. Alluvial deposit is normally found along the banks of the Manjra river and its main tributaries.

The district is entirely covered by the Deccan trap flows of the tertiary period. The Deccan trap is composed of horizontal flows of basaltic lava. They generally form flat-topped hillocks and terrace-like features. The physical characteristics of individual flows show considerable variations. Some flows are hard and massive while others are weathered, soft and friable. This character has resulted in terraced landscape, suddenly ending in escarpments. The traps are seen generally 618 m above mean sea level. These are jointed and show the characteristics of spherical weathering leaving massive hard cores. Columnar jointing is predominantly developed in these rocks, besides horizontal joints, which impart to the rocks bedded appearance. The top layers of the Deccan trap in parts of Bidar and Humnabad Taluk are altered to reddish vesicular laterite, forming and extensive undulating plateau.

The minerals found in the area are Bauxite, Kaolin and Red ochre. A deposit of highly siliceous bauxite clay has been located about three kilometers south of Basavakalyan. Similar deposits are noticed near Alwal and Kamthana Villages of Bidar Taluk. A large deposit of Kaolin is located near Kamthana village. Red ochre deposits are found near Sirsi and Aurad Village.

Soils: Two types of soils founds in the district are Lateritic red soil and black cotton soil. Aurad and Bhalki taluks have mainly black cotton soil. Bidar and Humnabad taluks have mainly lateritic red soil. Basavakalyan Taluk has both types of soils.

(vii) Climatic data from secondary sources:

The study area is characterized by general dryness except during the monsoon season. During summer the climate is hot. Rains during June to September are rare and occasionally heavy. Summer season observed during March to May, there is study increase in the temperature, with the maximum temperature of the year occurring in April and May.

The southwest monsoon season lasts from June to September, during which period humidity is high. October and November constitutes the Post monsoon season, when humidity decreases in this period to the minimum and the evening air begins to be chilly. Heavy fogs gather soon after sunset and continue towards the morning. For some time after sunrise, this reason is shrouded in thick mist.

The winter season lasts from December to February, Where the night temperature is at its minimum. The sky is generally clear or slightly cloudy.

(viii) Social Infrastructure available

As the proposed project brings employment generation, both skilled and unskilled, it is obvious to assume that, all the economic activities in the project area would induce considerable improvement in the socio-economic levels of people.

The impact of human settlement is expected to be positive, as apart from some people being directly employed, many others will get indirect employment.

5. PLANNING BRIEF

i. Planning concept (type of industries, facilities, transportation etc) Town and Country Planning/Development authority Classification:

Industrial area.

ii. Population Projection:

Not applicable.

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

Total land area = 16,188 Sqmt

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Build up area = 2,800 Sqmt
Landscape area = 8,388 Sqmt
Road area = 4,000 Sqmt
Vacant area = 1,000 Sqmt

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

As the entire infrastructure needed for modification is already available there is no demand of any further Infrastructure.

v. Amenities/Facilities:

All the facilities exist already. In the existing facility proposed products will be produced

6. PROPOSED INFRASTRUCTURE

i. **Industrial Area**: The proposed project is coming in KIADB Industrial area.
ii. **Residential Area**: NA.
iii. **Greenbelt:** 8,388 Sqmt.
iv. **Social Infrastructure:** Necessary support infrastructure will be provided for the project.
v. **Connectivity:** Project site is well connected by an asphalted road which is located at a distance of about 4.4 Km from Humnabad and near state highway NH-218 just 0.2km away from the Factory entrance.
vi. **Drinking Water Management:** Separate drinking water will be provided.
vii. **Sewerage system:** The wastewater generated from Boiler blow down, cooling tower blow down will be drained to equalization cum neutralization tank followed by setting unit, and the treated clear effluents will be used for the greenbelt development and coal ash quenching.
viii. **Industrial waste management:**

a. Air Environment:

i. Sources:

- Boilers

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- D.G. sets

ii. Mitigative measures:

1. Process emission will be connected to scrubber with a stack attached.
2. The vapours are been collected through exhaust system consisting of hood, duct and vacuum fan and then vented out.
3. Stack of 5mAGL are provided to D.G. sets.
4. Boilers are connected with dust collector
5. Plantation of green trees around the factory building and premises to control the intensity of noise to the surrounding area.
6. Use of PPE's

b. Noise Environment:

i. Sources:

- Generators
- Reactors
- Compressors
- Fans

ii. Mitigative measures:

1. Acoustic barriers or shields to the machineries.
2. Vibration free foundations for machineries
3. Acoustical walls and roofs to the building where such machineries are installed.
4. Segregation of machineries having high noise level in isolated buildings.
5. Sound control measures to steam vents.
6. Proper maintenance of machineries especially oiling and greasing of bearing and gears etc.
7. Avoiding vibration of machineries with proper design of machineries such as speed, balancing etc.
8. Use of personnel protective such as earmuff and ear fug for persons working in such locations.

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9. Plantation of green trees around the factory building and premises to control the intensity of noise to the surrounding area.
10. Use of PPE's

c. Water Environment:

i. Sources:

- Process water
- Cooling tower blow down
- Floor wash
- Boiler blow down

ii. Mitigative measures:

1. Effluents from the plant is been stored and neutralized in a collection tank and then sent to Forced Evaporation System
2. Rain water harvesting plan has been executed effectively & a storage reservoir of adequate capacity is provided to hold rainwater.
3. Domestic water will be treated in Septic tank followed by soak pit.
4. Recycle of process water including steam condensate and reuse of treated wastewater in the plant
5. Control of water taps, washings, leakages from pump glands and flanged joints.
6. Floor cleaning with water will be replaced with dry cleaning.

d. Solid & Hazardous waste:

i. Sources:

- Used oil
- Spent carbon
- Inorganic salts
- Polythene bags
- Used fiber drums

ii. Mitigative measures:

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1. Used oil shall be collected in leak proof containers & disposed to Central Pollution Control Board / Karnataka State Pollution Control Board registered authorized recyclers.
2. The solid from the bottom of the neutralization tank will have a selling potentiality. In such case, this solid will be sold to the parties who have a license form handling the same, other it will be sent to Haz disposal yard established by Govt.
3. The coal ash will be given to the brick manufactures by which we can be sure of safe disposal system.

ix. **Solid waste management:** Oil soaked cotton wastes, discarded containers, etc are the solid wastes generated and it will be stored in secured manner & handed over to the Karnataka State Pollution Control Board authorized recyclers.

x. **Power Requirements and Supply and Source**: The total power requirement of the proposed plant is about 165KVA, which is being met from GESCOM. DG sets of about 165 KVA-1 no are available to meet the emergency power requirement.

7. REHABILITATION & RESETTLEMENT (R & R) PLAN

Rehabilitation and Resettlement is not applicable.

8. PROJECT SCHEDULE AND COST ESTIMATE

i. Likely date of start of construction and likely date of completion (Time schedule for the project to be given)

Not applicable as the plant is already exists and there is no additional infrastructure enhancement in the proposed expansion.

ii. Estimated project cost along with analysis in terms of economic viability of the project.

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There is not much additional project cost as it is an existing unit. The gross value of existing infrastructure is Rs. 10 Crores. The infrastructure needed for the proposed expansion is already in place except the additional equipments.

9. ANALYSIS OF PROPOSAL

i. Financial and social benefits with special emphasis on the benefit to the local people including tribal population, if any, in the area

The proposal will bring employment opportunities. It will also bring trade opportunities to the country.

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