PRE - FEASIBILITY REPORT

FOR

PROPOSED EXPANSION OF
ACTIVE PHARMACEUTICAL INGREDIENT (API)
MANUFACTURING UNIT

BY

52A, JAROD-SAMLAYA ROAD, GARDHIYA, P.O,
TALUKA SAVLI, DISTRICT VADODARA, GUJARAT

OF

M/S. KALINTIS HEALTHCARE PVT. LTD.

SUMMARY

M/s. Kalintis Healthcare Pvt. Ltd. is planning for the expansion of their existing API manufacturing unit by proposing new products at 52A, Jarod-Samlaya Road, Gardhiya, P.O, Taluka Savli, District Vadodara, Gujarat.

PROJECT COST

The total project cost for the proposed expansion project would be around Rs. 12 crores. Total capital cost of pollution control measures will be Rs. 0.80 crores & recurring cost per annum will be 0.25 crore.

DETAILS OF PRODUCTS

Details of existing and proposed products are given in following table.

LIST OF PRODUCTS

SR. NO	PRODUCT	PRODUCTION CAPACITY (KG/MONTH)		
		EXISTING	PROPOSED	TOTAL
1.	Activate Pharmaceutical Ingredients (API) in Pilot Plant	0	1000	1000
2.	Folic acid	0	1000	1000
3.	Frovatriptan	0	500	500
4.	Isosulfan blue	0	500	500
5.	Lorazepam	0	400	400
6.	Oxazepam	0	350	350
7.	S(+) Pregabalin	0	550	550
8.	Levetiracetam	0	550	550
9.	Teneligliptin hydro bromide hydrate	0	650	650
10.	Flupirtine Meleate	0	500	500
11.	3-Methoxyphenethylamine	500	0	500
12.	4-Methoxyphenethylamine	1000	0	1000
13.	3,4-Dimethoxyphenethylamine	1000	0	1000
14.	3,4-(Methylenedioxy) phenethylamine	200	0	200
15.	3-(Trifluromethyl) phenethylamine	50	0	50
16.	5-Methoxy-1 Indianone	300	0	300
17.	5,6-Dimethoxy-1-indianone	300	0	300
18.	1-[2-(Hydroxyethoxy) ethyl] piperaxine	1000	0	1000
19.	1-Piperazinecarboxaldehyde	500	0	500
20.	1-Phenylcyclopentanecarboxylic Acid	500	0	500
21.	Cyclopropymethylamine	200	0	200
22.	3-(Trifluoromethyl) acerophenone	200	0	200
23.	4-(2,4-Diflurobenzoyl) piperidine HCl	300	0	300
24.	1-Benzylpiperidine-4-methanol	200	0	200
25.	Cyclohexyl methyl ketone	200	0	200
BY-PRODUCT				
1.	Ammonium Chloride	118.4	0	118.4
2.	Sodium Bromide	868.3	0	868.3
3.	Methanol	152.1	0	152.1
4.	Carbon Dioxide	1120.6	0	1120.6
5.	Ammonium Sulphate	173.6	0	173.6
6.	Cuprous Bromide	152.5	0	152.5
7.	Magnesium Chloride	101.1	0	101.1
8.	Potassium Bromide	0	2300	2300
9.	Sodium Sulphate	0	3220	3220

REQUIREMENTS FOR THE PROJECT

LAND

No new land will be acquired for the proposed expansion project. The proposed expansion project will get established in existing premises by doing small modification and in available open space in existing premises. Existing premises of the company is around 11,059 m^2 from which around 3,650 m^2 (33%) land area will be utilized for the development of greenbelt.

WATER

Total water requirement for the proposed expansion project would be estimated as 78.25 KLD, which will be sourced from Ground water using bore well.

ELECTRICAL ENERGY

Total power requirement for the proposed expansion project will be around 250 KVA and will be sourced from MGVCL (Madhya Gujarat Vij Corporation Limited). During emergency purpose D. G. Set of 200 KVA will be utilized.

MANPOWER

For proposed expansion project total 100 (existing 50 and additional 50) personnel will be required.

SOURCES OF AIR POLLUTION AND CONTROL MEASURES

EMISSIONS FROM COMBUSTION OF FOSSIL FUELS FROM STATIONARY OR MOBILE SOURCES

SR. NO.	STACK ATTACHED TO	FUEL USED	STACK HEIGHT	POLLUTION CONTROL SYSTEM	FINAL CONCENTRATION
EXISTING					
1.	Baby Boiler* (500 Kg/Hr)	LDO/FO 0.04 KLD	9 meter	LDO/FO is used as fuel, adequate stack height is provided	SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
2.	Thermopack (4 Lac Kcal/hr)		9 meter		SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
PROPOSED					
1.	Steam Boiler (2000 Kg/Hr)	LDO/FO 120 Lit/Hr	30 meter	LDO/FO is used as fuel, adequate stack height is provided	SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
2.	D. G. Set (200 KVA)	HSD 60 Lit/hr	10 meter	Adequate stack height is provided	SPM ≤ 150 mg/nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm

Note: Baby Boiler (500 Kg/hr) will be replaced by Steam Boiler (2000 kg/hr)

PROCESS EMISSION

SR. NO.	STACK ATTACHED TO	FUEL USED	STACK HEIGHT	POLLUTION CONTROL SYSTEM	FINAL CONCENTRATION
EXISTING					
1.	*Glass Vessels	NA	10 meter	Water Scrubber with circulation tank pump	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20mg/Nm^3 HBr ≤ 30 mg/Nm^3 NH_3 ≤ 175 mg/Nm^3

SR. NO.	STACK ATTACHED TO	FUEL USED	STACK HEIGHT	POLLUTION CONTROL SYSTEM	FINAL CONCENTRATION
PROPOSED					
1.	Glass Vessels	NA	20 meter	Alkali Scrubber followed by Water Scrubber	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20 mg/Nm^3 HBr ≤ 30 mg/Nm^3
2.			20 meter	Acidic Scrubber followed by Water Scrubber	NH_3 ≤ 175mg/Nm^3
3.	Glass Vessels	NA	20 meter	Alkali Scrubber followed by Water Scrubber	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20 mg/Nm^3 HBr ≤ 30 mg/Nm^3
4.			20 meter	Acidic Scrubber followed by Water Scrubber	NH_3 ≤ 175 mg/Nm^3

* Note: Glass vessel in existing facility having a stack with water scrubber will be replaced by two separate stacks (Acidic and Alkali)

WASTE WATER GENERATION AND IT'S TREATMENT:

Total 38.25 KLD wastewater will be generated from the unit out of which 33.75 KLD industrial effluents will be generated from manufacturing process & washing, Cooling and boiler blow down, RO reject and will be given primary, secondary and tertiary treatment. Treated effluent will be sent to CETP operated by M/s. Enviro Infrastructure Co. Ltd. (EICL), Umaraya for further treatment and final disposal.

Domestic wastewater:

Total 4.5 KLD domestic wastewater will be disposed off through septic tank/soak pit system.

NOISE POLLUTION AND CONTROL MEASURES:

- From the proposed expansion manufacturing unit noise pollution will be generated which will be controlled by adopting different types of noise pollution control measures. Main sources of the noise pollution - machineries, electric motors, boiler, D. G. set and TFH, etc.

  Following noise control measures to be adopted in the proposed expansion manufacturing project,
- Encasement of noise generating equipment.
- Greenbelt will be developed all around the plant boundary to act as noise attenuator.
- In addition, personnel, working near high noise level generating sources, will be provided with ear muffs.
- Proper and suitable acoustic barrier will also be provided around, areas generating high noise.
- Effective preventive maintenance and vibration measurement of all rotating equipment will help in the improvement of plant life and also noise reduction.

SOLID WASTE GENERATION AND ITS DISPOSAL METHOD

The sources of solid wastes, generation and its management are as given in the following table.

SR. NO.	NAME OF THE WASTE	CAT NO.	EXISTING	PROPOSED	TOTAL	METHOD OF STORAGE AND DISPOSAL
1.	Used Oil	5.1	400 Lit/Year	400 Lit/Year	800 Lit/Year	Collection, storage and reuse as lubricants in the machineries within the premises only or send to authorized re-processors.
2.	Discarded Containers/Barrels/plastic	33.3	480 Nos./Year	350 Nos./Year	830 Nos./Year	Collection, storage and send to authorized recycler after decontamination.
3.	ETP Sludge	34.3	0.6 MT/year	49.4 MT/Year	50.0 MT/Year	Collection, storage and transport to TSDF site.
4.	Process Residue & Waste	28.1	1.2 MT/Year	35 MT/Year	36.2 MT/Year	Collection, Storage and send for incineration.
5.	Spent Solvent	28.5	--	500 MT/Year	500 MT/Year	Collection, Storage and send to re-processor.
6.	Spent Carbon/Hyflow	28.2	--	0.04 MT/Day	0.04 MT/Day	Collection, Storage and send for incineration.
7.	Off Specification Drugs	28.4	---	1.0 MT / Year	1.0 MT / Year	Collection, Storage and send for incineration.

GREEN BELT DEVELOPMENT

Company has proposed 33% of total land area for green belt development approx 3650 m^2 land area.

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CHAPTER-1

INTDOUCTION OF THE PROJECT

1.1 IDENTIFICATION OF PROJECT AND PROJECT PROPONENT

M/s. Kalintis Healthcare Pvt. Ltd. proposes to expanse its existing Active Pharmaceutical Ingredients (API) manufacturing unit with 1 MTPM of Pilot Plant. Unit is having CCA valid upto 30/11/2019.

M/s. Kalintis Healthcare Pvt. Ltd. is the company, took over the existing API unit of **M/s. Synth Services** located at 52A, Jarod-Samlaya Road, Gardhiya, P.O, Taluka Savli, District Vadodara, Gujarat.

1.2 PROMOTERS BACKGROUND

Details of project promoters are as below:

Mr. Rasik Madhabhai Gondalia, age about 60 years, B. Sc. in Pharmacy, founding Partner of Core Pharma LLC USA, served about 26 years in generic pharmaceutical industry in various departments such as manufacturing, packaging and quality assurance.

Mr. Anjnish Rasik Gondalia, age about 33 years, B. Sc. in Biotech and MBA from Rutgers University, USA. last two years engaged in pharma business development, One and half years of experience in Apicore Pharmaceuticals Pvt. Ltd. and one year of experience in Synth Services. Presently is the Vice President Operations in M/s. Leading Pharma, USA. Total number of years of experience is 5 years.

Mr. Pinak Rasik Gondalia, BS-Commerce from USA, and actively engaged in the administrative work of the company. He is handling administrative work in leading pharma as well as in the synth services. Total 2 years of experience.

Mr. Rameshbhai Muljibhai Thumar, age about 59 years, having total 32 years of experience in business and manufacturing activity. He is the founder of R. R. Infra projects Pvt Ltd and partner in TNG Precast Industries and Synth Services. He has good business development skills and actively involved in the day to day operations of the company.

1.3 BRIEF DESCRIPTION OF NATURE OF THE PROJECT

M/s. Kalintis Healthcare Pvt. Ltd. proposes to expanse its existing Active Pharmaceutical Ingredients (API) manufacturing unit at 52A, Jarod-Samlaya Road, Gardhiya, P.O, Taluka Savli, District Vadodara, Gujarat.

LIST OF PRODUCTS

SR. NO	PRODUCT	PRODUCTION CAPACITY (KG/MONTH)		
		EXISTING	PROPOSED	TOTAL
1.	Activated Pharmaceutical Ingredients (API) in Pilot Plant	0	1000	1000
2.	Folic acid	0	1000	1000
3.	Frovatriptan	0	500	500
4.	Isosulfan blue	0	500	500
5.	Lorazepam	0	400	400
6.	Oxazepam	0	350	350
7.	S(+) Pregabalin	0	550	550
8.	Levetiracetam	0	550	550
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12.	4-Methoxyphenethylamine	1000	0	1000
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8.	Potassium Bromide	0	2300	2300
9.	Sodium Sulphate	0	3220	3220

1.4 NEED FOR THE PROJECT AND ITS IMPORTANCE TO THE COUNTRY AND OR REGION.

The proposed expansion project will provide a potential & required growth opportunity for the Company. Moreover company has strong presence with leading pharma cos. locally as-well-as internationally; mainly in regulated market. The company & the products are well approved & registered with the leading regulatory authorities & the pharma customers' in local & international markets.

The Active Pharmaceutical Ingredient Industry is the organ by which active pharmaceutical ingredients are manufactured from raw materials through both chemical and physical means. Depending on the complexity of the molecule required, synthesis of APIs might need multi-step complex chemistry utilizing a range of processing technologies.

1.5 DEMANDS-SUPPLY GAP

The pharma / health industrial sector in the past many years has seen a consistent growth and also keeping in mind our strong presence in the local & global market. Hence we have identified the demand for the proposed products which are meant for very new medicines meant for fast growing therapeutic segments with pilot plant developed our own process patents we can take a lead & produce commercially in bulk for domestic market as well as with strong presence in export markets.

1.6 EMPLOYMENT GENERATION

For proposed expansion project total 100 (existing 50 and additional 50) personnel will be required.

PROJECT DESCRIPTION

2.1 TYPE OF PROJECT

M/s. Kalintis Healthcare Pvt. Ltd. is planning for the expansion of their existing plant by proposing new products at 52A, Jarod-Samlaya Road, Gardhiya, P.O, Taluka Savli, District Vadodara, Gujarat.

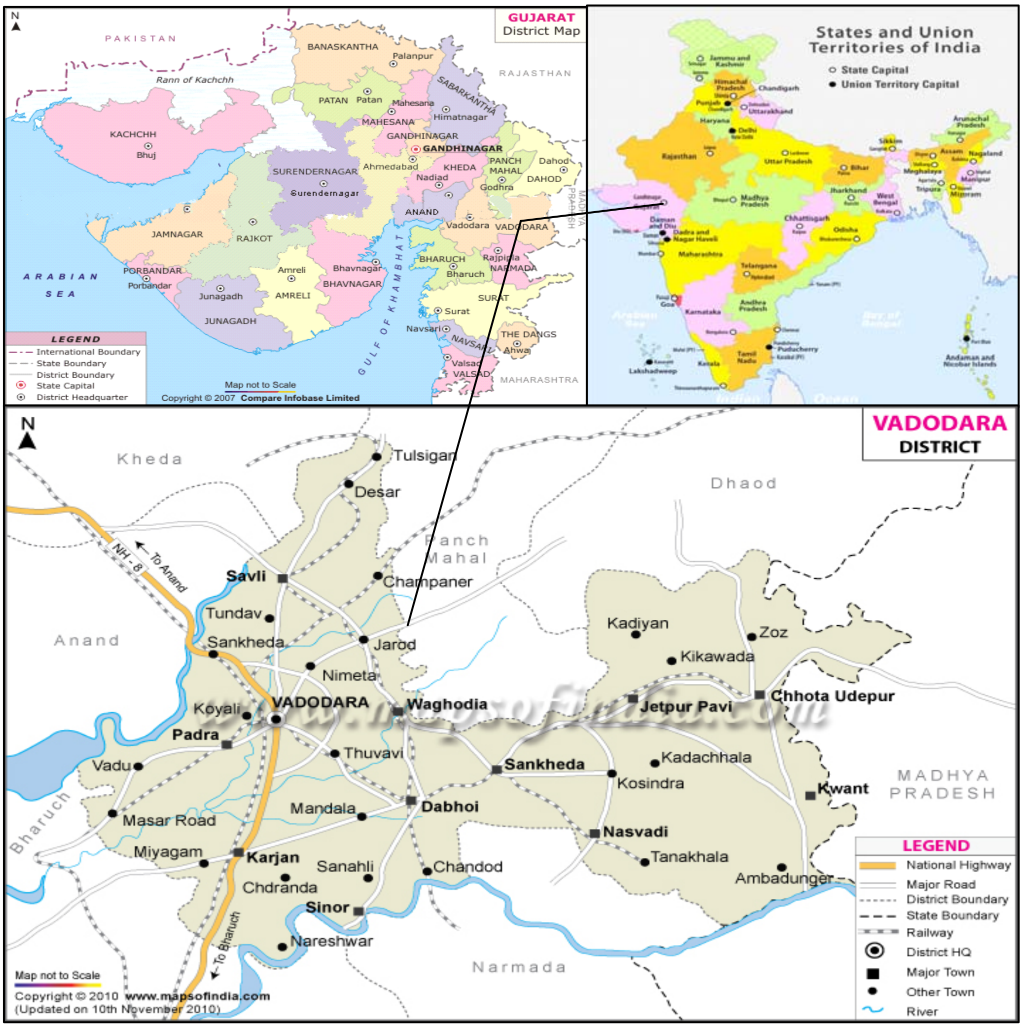
Industrial development in India has increased economic growth and improved living standards of people. These growths are achieved through industrialization, infrastructure development. The industrialization has played a major role in development of the country. This industrialization is also has many other benefits. Although the industrial development leads to rapid consumption of natural resources, fuel etc. in day to day operational activity. To control the pollutions from industrial activity, government has framed regulations which are governed by Ministry of Environment, Forests and Climate Change in India.

2.2 LOCATION

M/s. Kalintis Healthcare Pvt. Ltd. is planning to for the expansion of their existing unit by proposing new products at 52A, Jarod-Samlaya Road, Gardhiya, P.O, Taluka Savli, District Vadodara, Gujarat. Total plot area of the project is 11,059 m^2 from which around 3,650 m^2 (33% of total land area) will be required for the development of green belt. A map showing project site is given in following figure-1 & a detailed map of the project site & surrounding is showing in following figure.

Latitude - 22°27'.34.80" North
Longitude - 73°19'15.00" East

LOCATION MAP



2.3 SIZE OR MAGNITUDE OF OPERATION

M/s. Kalintis Healthcare Pvt. Ltd. is planning for expansion of their existing API manufacturing unit by addition of new products.

2.4 PROCESS DESCRIPTION

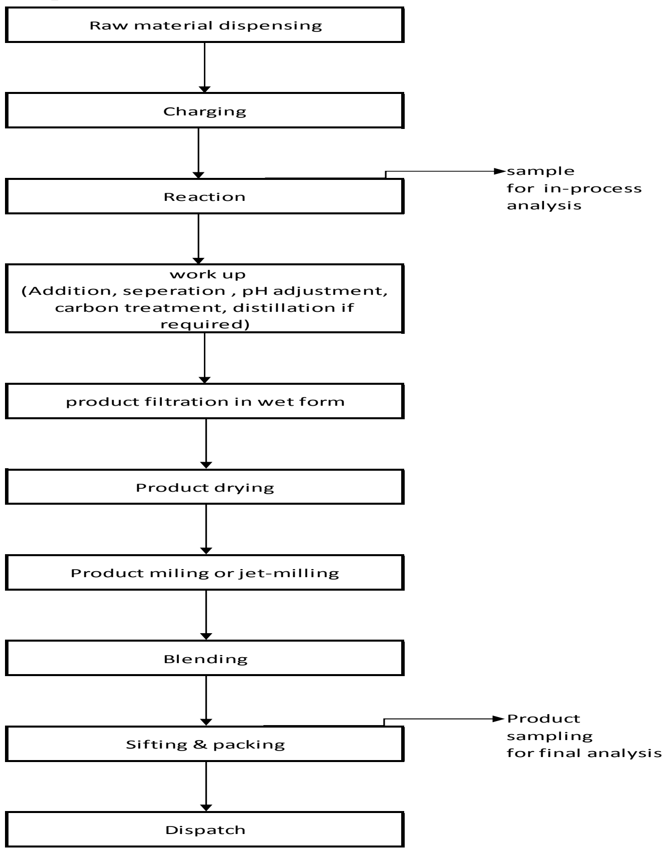
<u>MANUFACTURING PROCESSES</u>

1. <u>Typical Process details of API products in Pilot Plant</u>

<u>Description for manufacturing process of API product in Pilot Plant</u>

- Dispense the raw material from the store as per requirement.
- Charge the raw material in to the reactor. (Solid material shall be charged through manhole and liquid material shall be charged Nozzle using vacuum or charging pump)
- Stir the raw material mixture as per the process given.
- Sample shall be collected through sample point and shall be sent to QC for the analysis.
- After completion of reaction, further process shall be performed as per the given process.
- Then reaction mixture shall be filter through centrifuge or Nutsche or Pressure filter.
- During filtration, product shall be separated from the mixture as wet cake.
- Wet cake then shall be charged in to the tray dryer or Vacuum tray dryer.
- In drying operation product shall be dry as per the given process parameter. After drying dry product shall be obtained.
- This dry product shall be then milled using Multimill, Jet mill as per the requirement.
- After milling material shall be blended in blender.
- This blended material shall be sifted through sifter and packed in LDPE bag which is pecked in HDPE drums.
- Finally the sample of the product shall be sent to the Quality control Unit for the analysis of the product as per the specification.
- After analysis of the final product shall be dispatched to the market.

<u>Process flow diagram of API product in Pilot Plant</u>



2. Folic Acid

Stage - I

Ethyl cyanoacetate is reacted with guanidine HCl in presence of sodium methoxide to get 2,4-diamino-6-hydroxypyrimidine, which is reacted with sodium nitrite & acetic acid to get 2,4-diamino-6-hydroxy-5-nitrosopyrimidine. The latter is reacted with sodium dithionite to get 2,4,5-triamino-6-hydroxypyrimidine bisulfate.

Stage- II

4-Nitrobenzoic acid is reacted with thionyl chloride to get 4-nitrobenzoyl chloride, which is reacted with N-hydroxysuccinimide in presence of triethylamine base and later with L-glutamic acid to get N-(4-nitrobenzoyl)-L-glutamic acid, which is hydrogenated in methanol using nickel catalyst to get N-(4-aminobenzoyl)-L-glutamic acid.

Stage- III

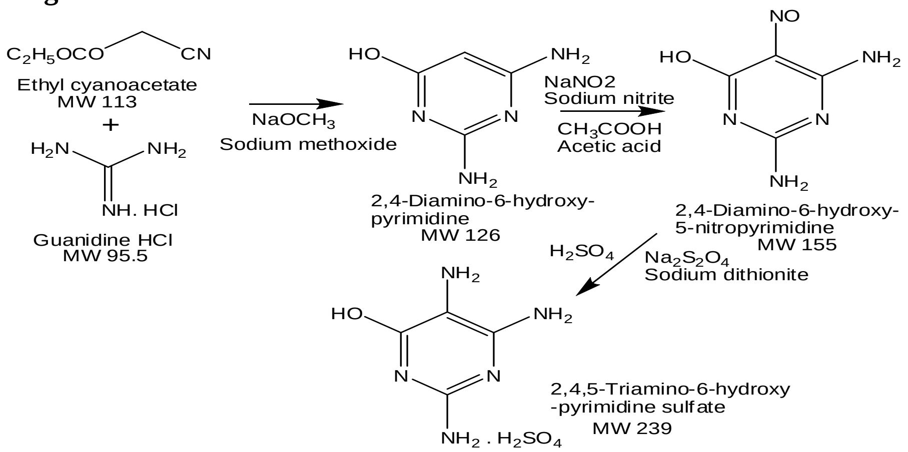
Acetone is chlorinated to get trichloroacetone.

Stage- IV

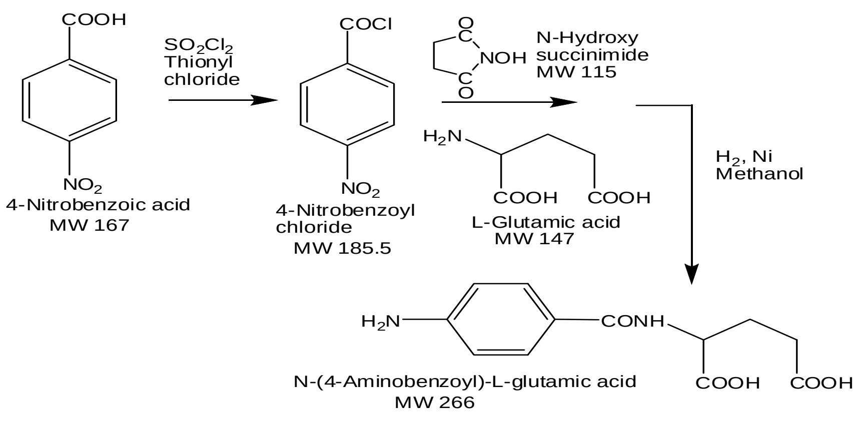
Intermediate 1 is reacted with intermediate 3 in presence of potassium carbonate to get 2-amino-4-hydroxy-6-(chloromethyl) pteridine, which is reacted with intermediate 2 in situ to get folic acid.

<u>Chemical Reaction</u>

Stage- I

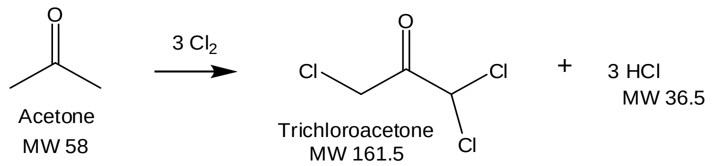


Stage- II

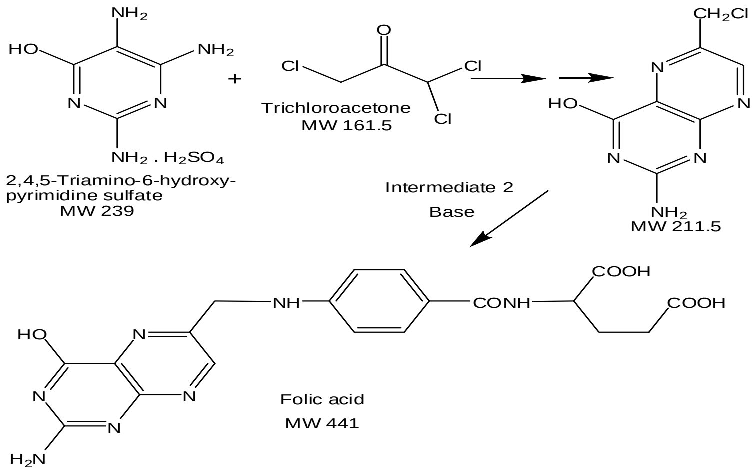


Stage- III

Intermediate 3:



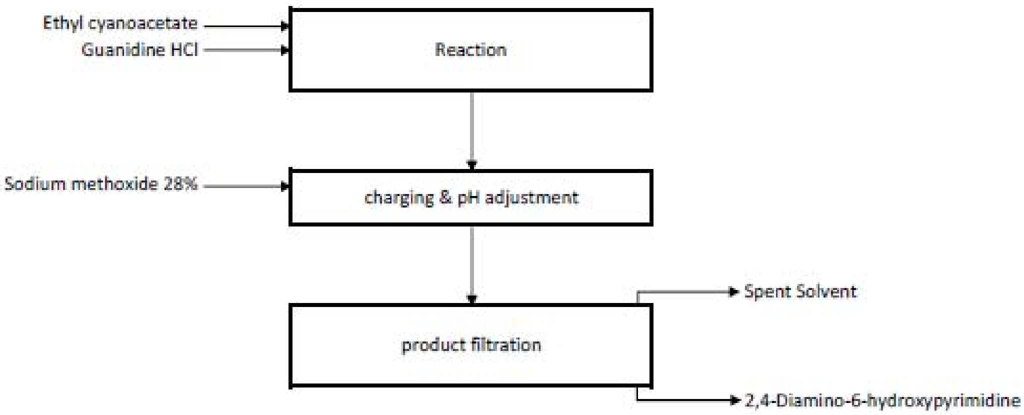
Stage- IV



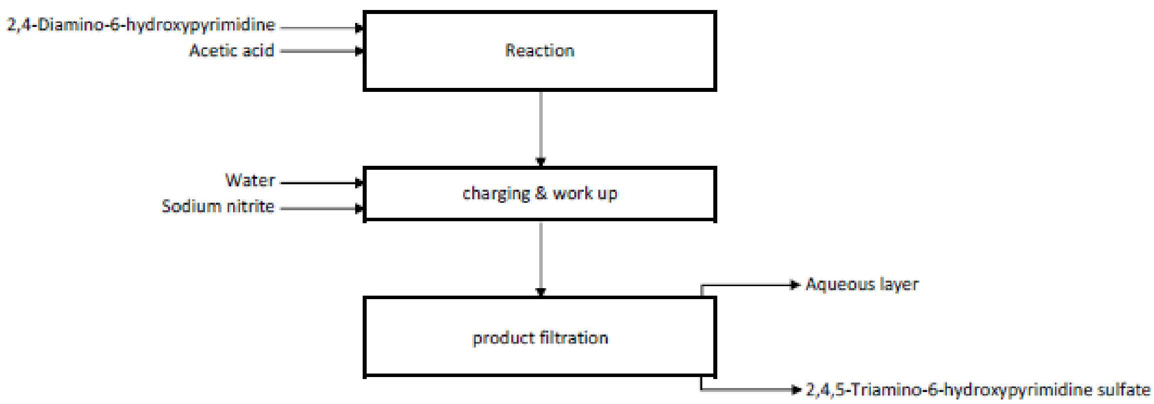
<u>Flow Diagram</u>

Stage-1

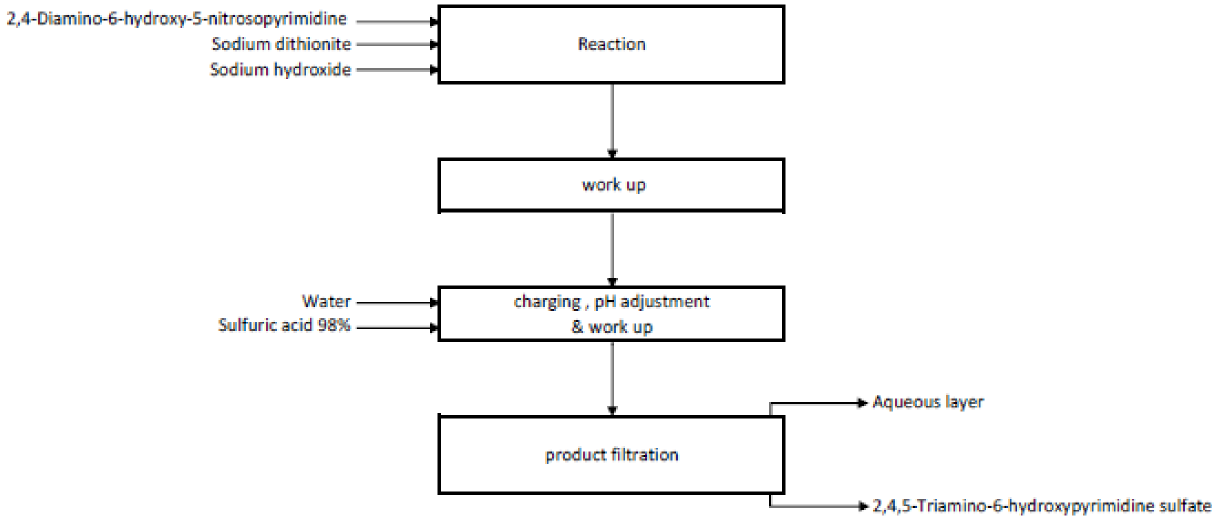
Step-1



Step-2

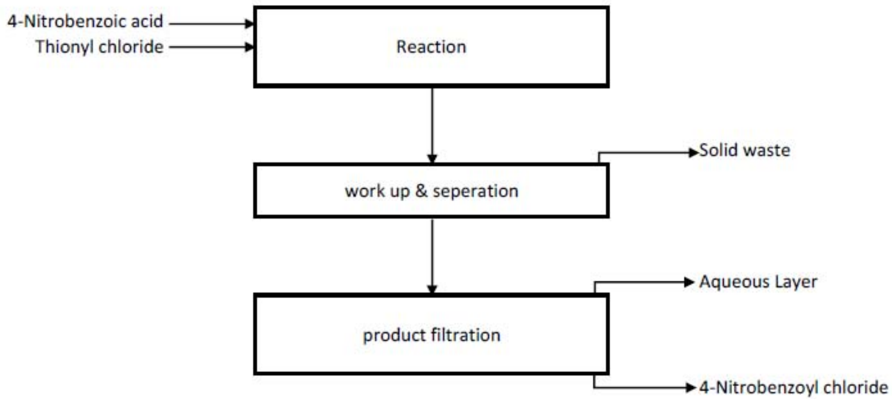


Step-3

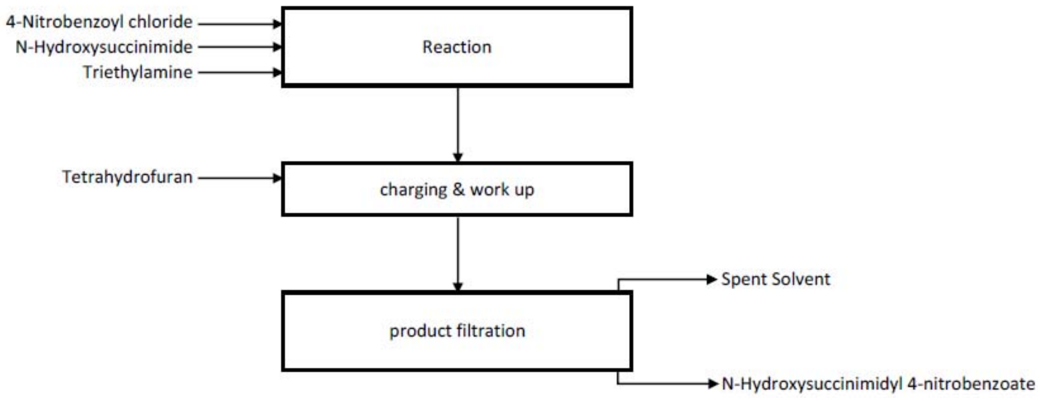


Stage-2

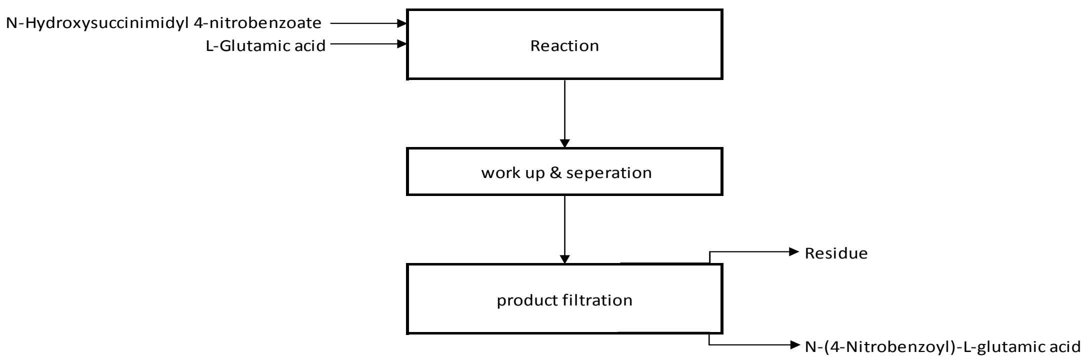
Step-1



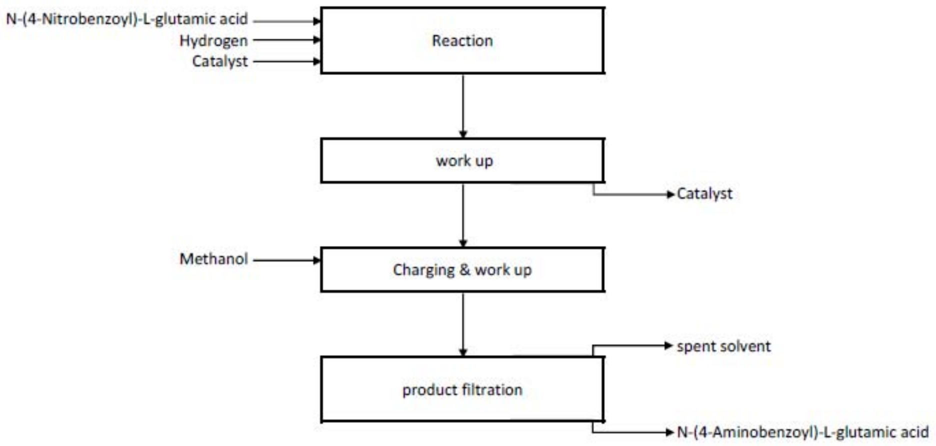
Step-2



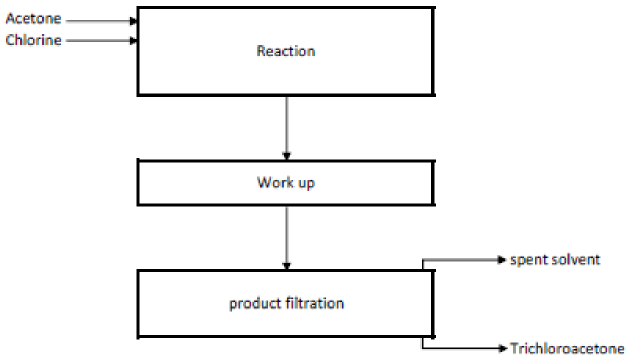
Step-3



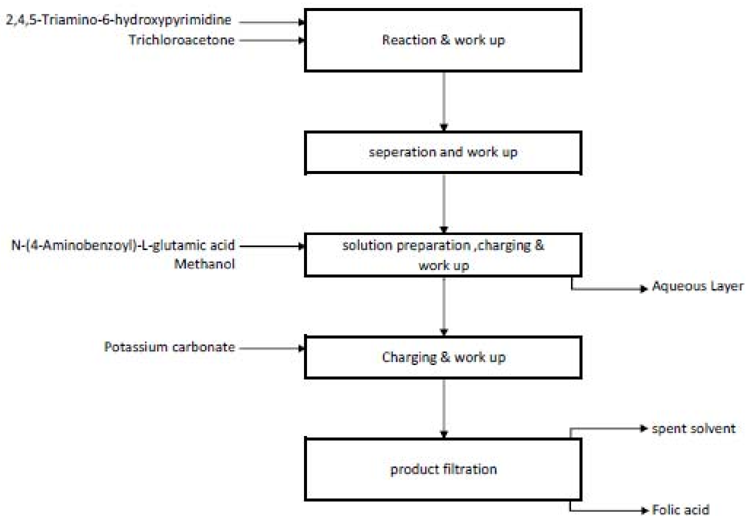
Step-4



Stage-3



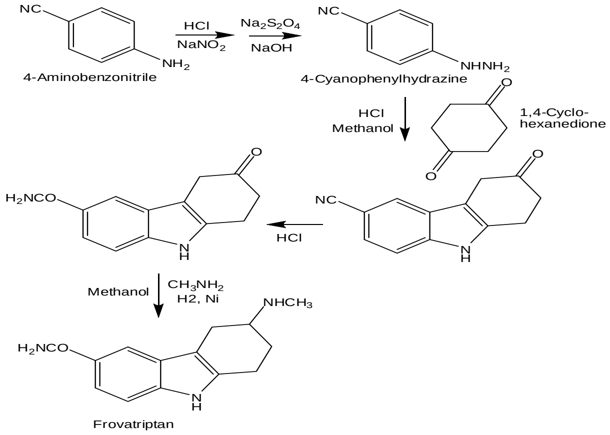
Stage-4



2. Frovatriptan

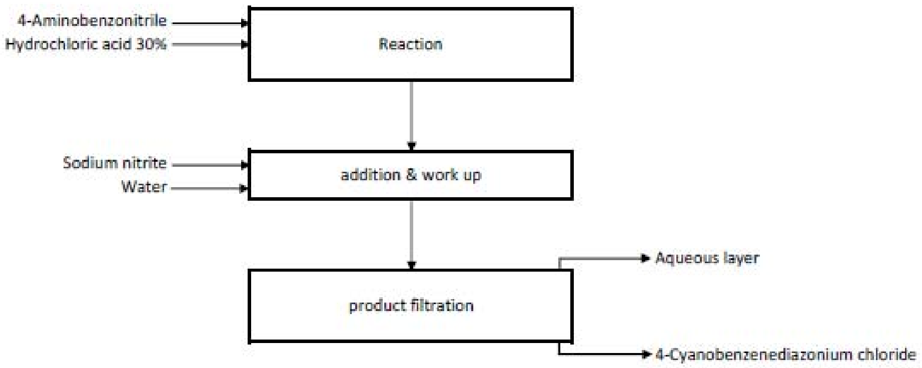
4-Aminobenzonitrile is dissolved in hydrochloric acid and treated with sodium nitrite solution at 0-5 deg C and subsequently with sodium dithionite and sodium hydroxide to get 4-cyanophenylhydrazine. This is reacted with 1,4-cyclohexanedione in presence of HCl in methanol to get the indole derivative, which is partly hydrolyzed in hydrochloric acid to get the amide. Reductive animation of this product using methylamine, hydrogen and Raney nickel catalyst yields racemic frovatriptan.

Chemical Reaction

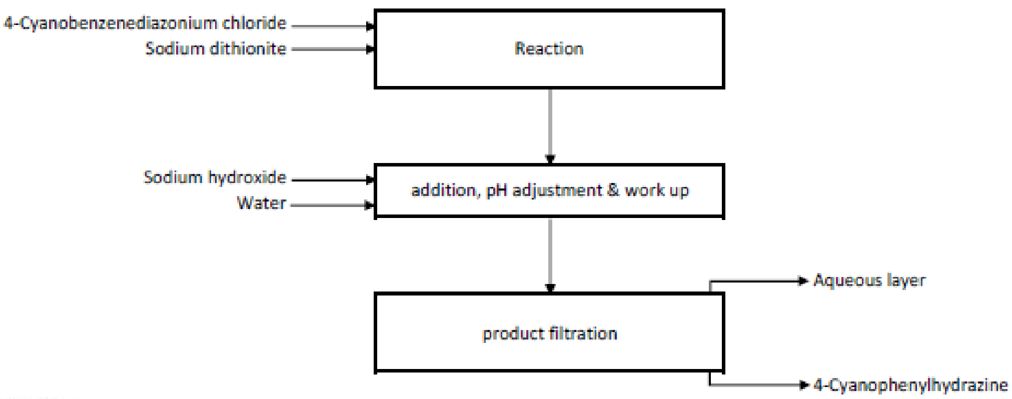


Flow Diagram

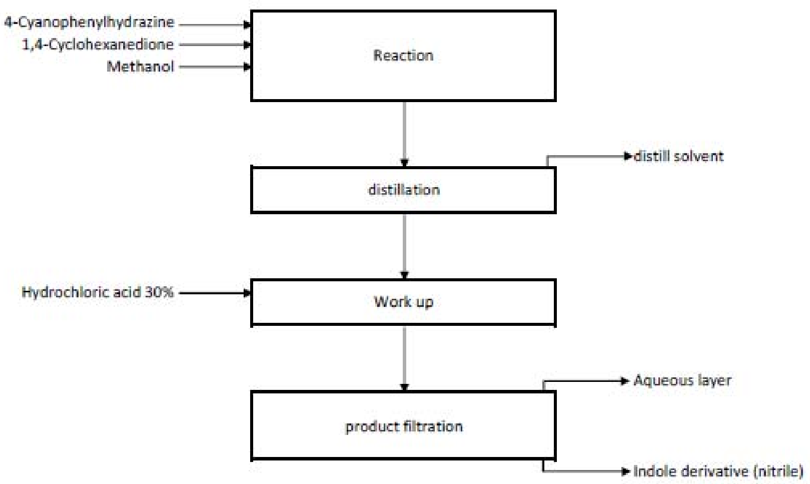
Stage-1



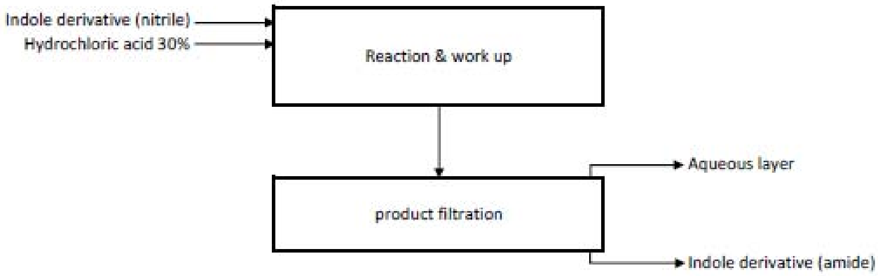
Stage-2



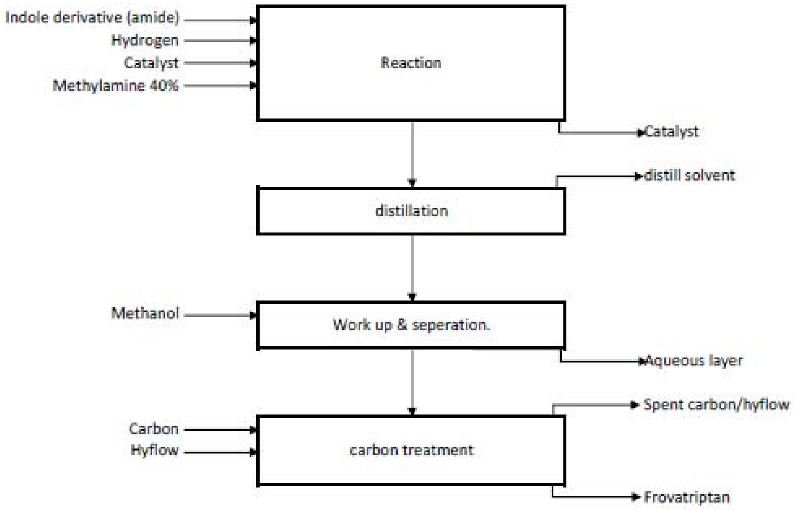
Stage-3



Stage-4



Stage-5

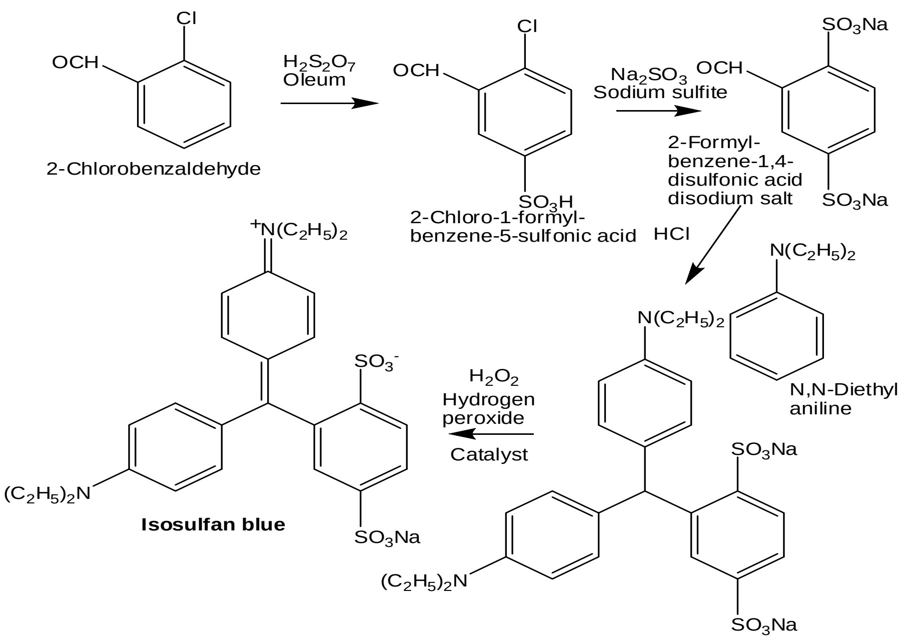


3. Isosulfan blue

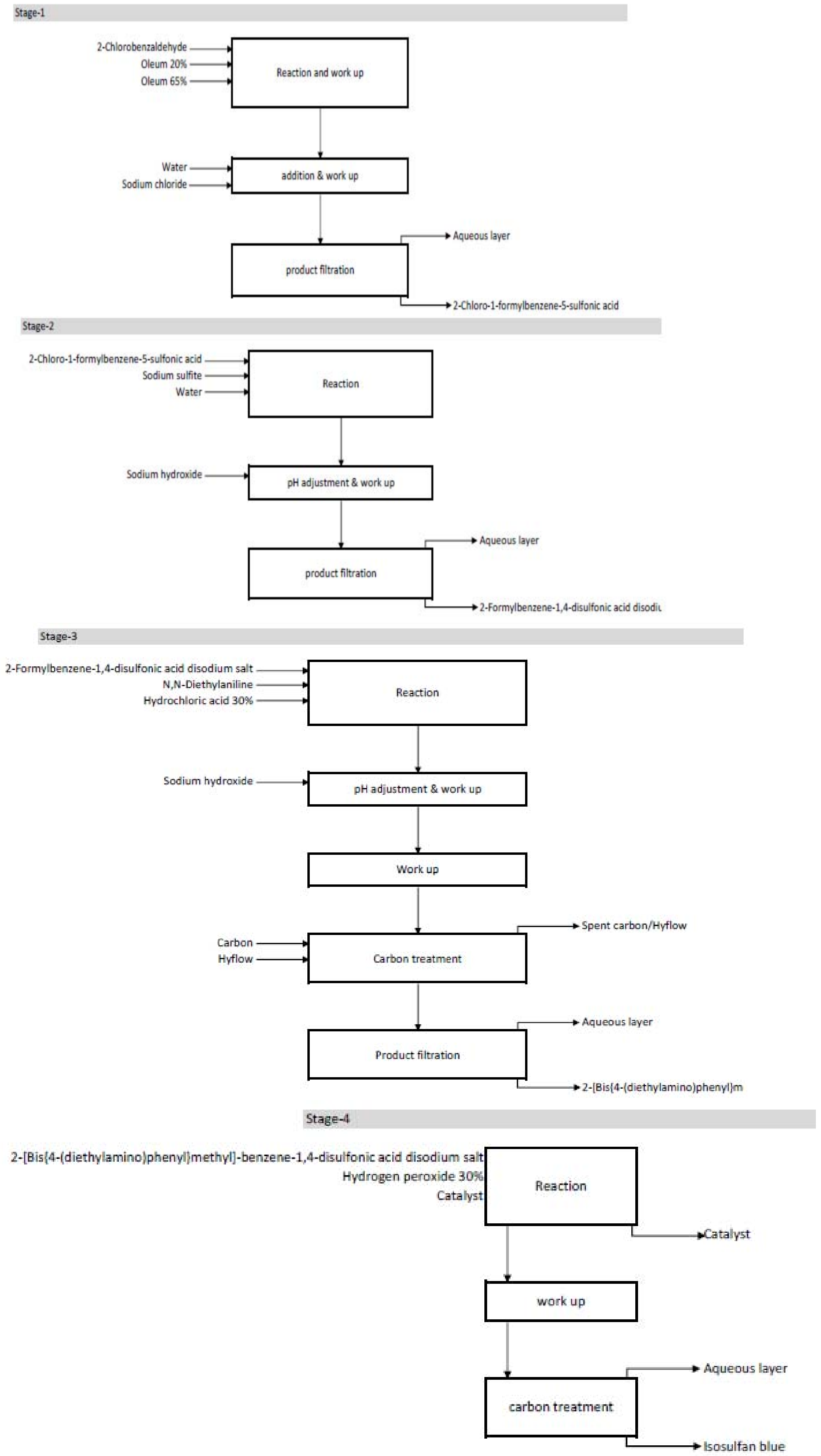
2-Chlorobenzaldehyde is sulfonated using oleum to get 2-chloro-1-formylbenzene-5-sulfonic acid, which is reacted with sodium sulfite to get 2-formylbenzene-1,4-disulfonic acid disodium salt. This is condensed with N,N-diethylaniline to get 2-[bis{4-(diethylamino)phenyl}methyl]benzene-1,4-disulfonic acid disodium salt, which is oxidized using hydrogen peroxide & catalyst to get isosulfan blue

Chemical Reaction

Stage- I



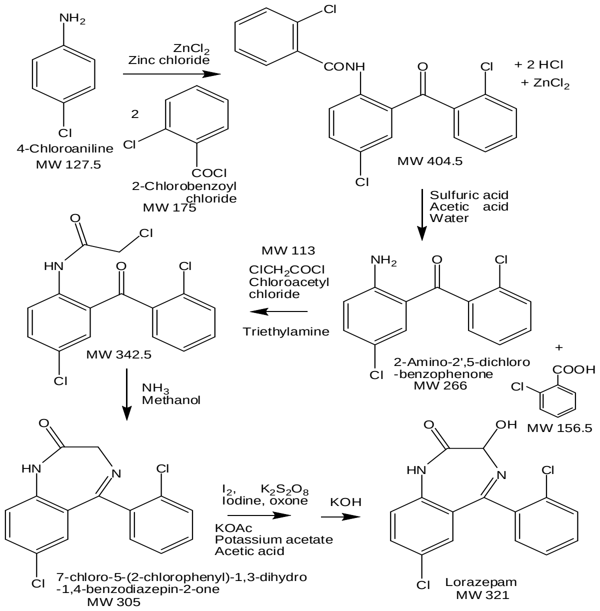
Flow Diagram



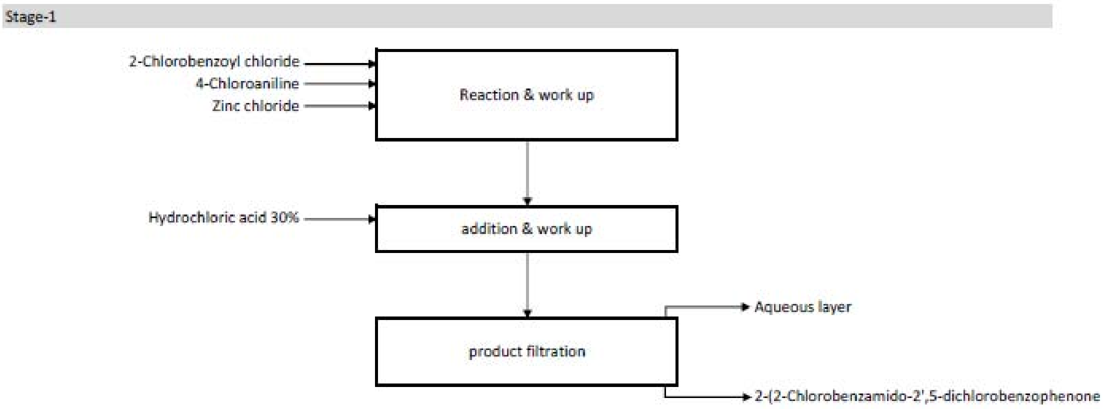
4. Lorazepam

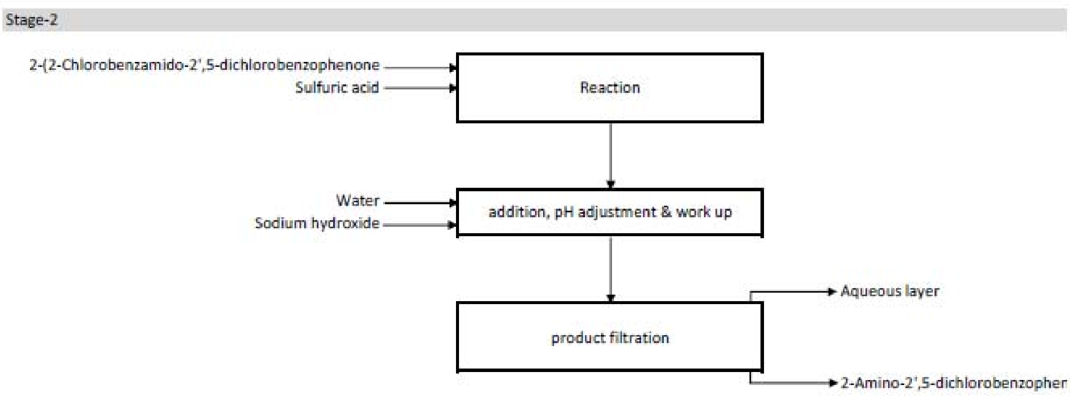
4-Chloroaniline and 2-chlorobenzoyl chloride are reacted in presence of zinc chloride and later sulfuric acid to get 2-amino-2',5-dichlorobenzophenone, which is acylated with chloroacetyl chloride in presence of base. Subsequent reaction with ammonia gives benzodiazepine derivative. Reaction with oxone & iodine in presence of potassium acetate gives 3-acetoxy derivative, which is saponified to get lorazepam.

Chemical Reaction

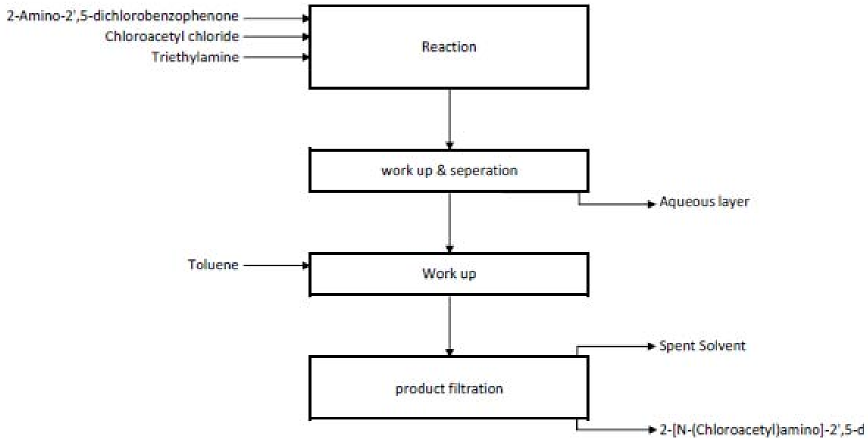


Flow diagram

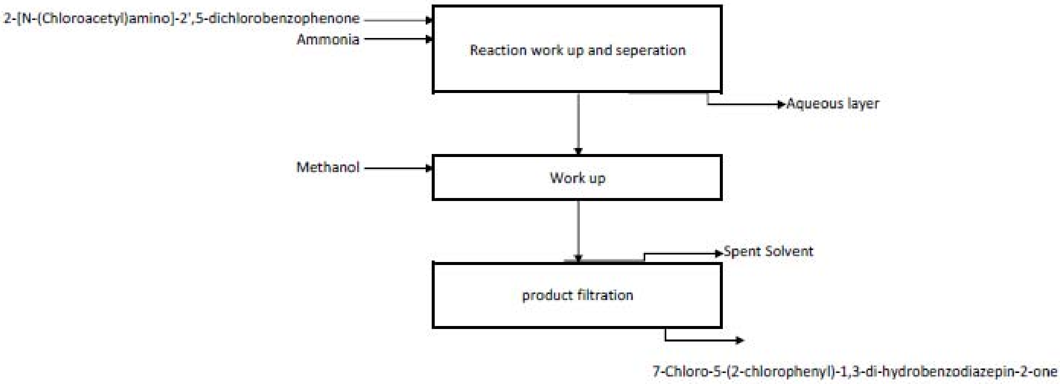




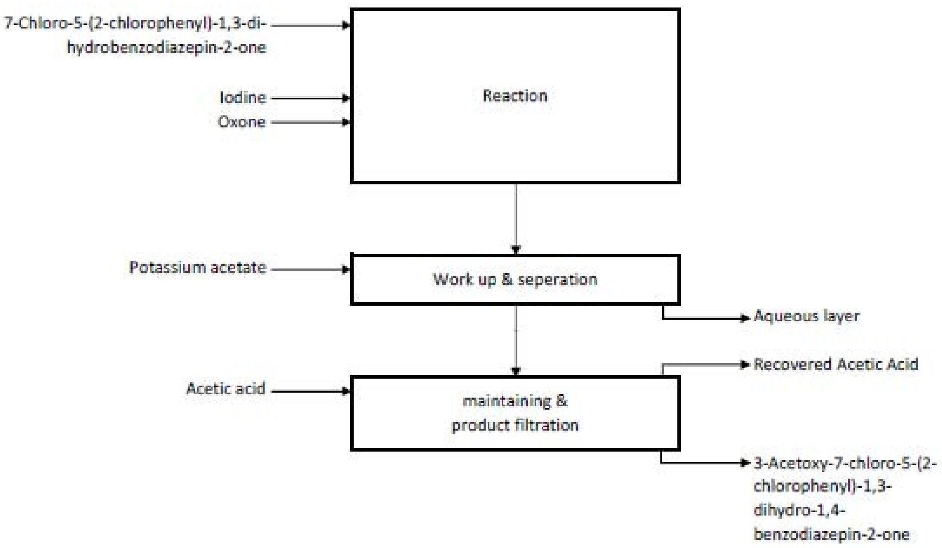
Stage-3



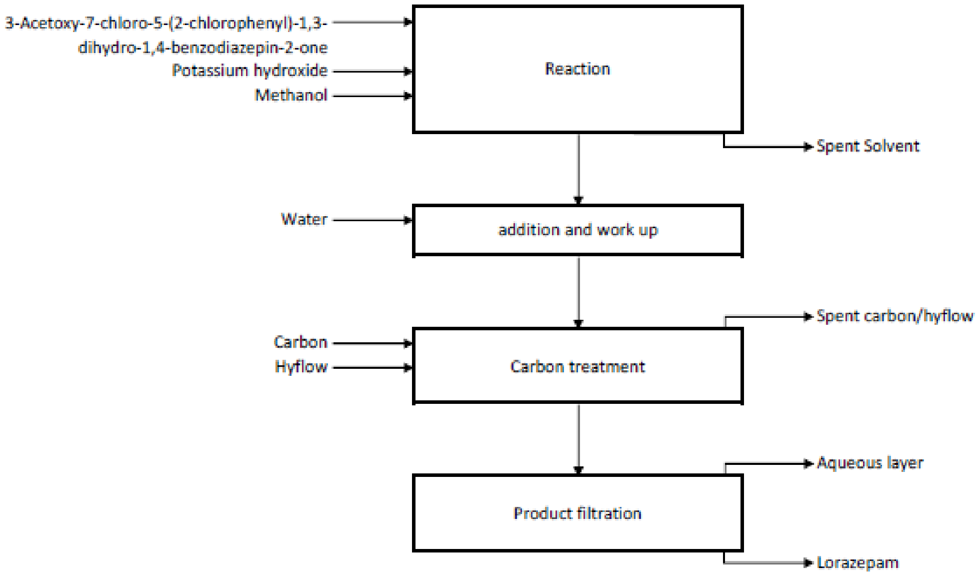
Stage-4



Stage-5



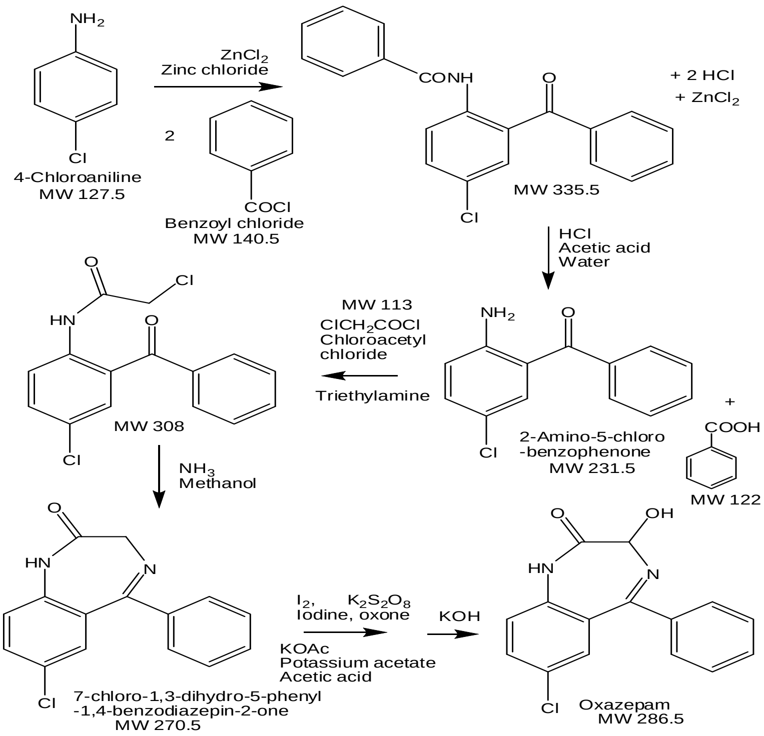
Stage-6



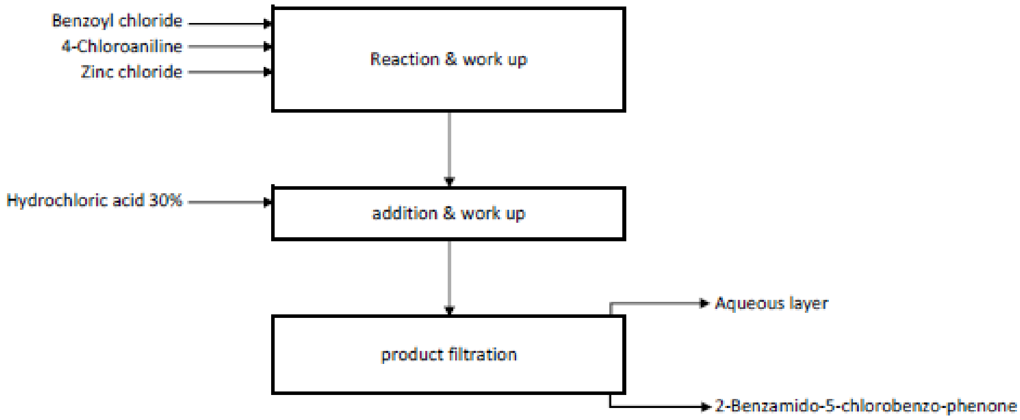
5. <u>Oxazepam</u>

4-Chloroaniline and benzoyl chloride are reacted in presence of zinc chloride and later sulfuric acid to get 2-amino-5-chlorobenzophenone, which is acylated with chloroacetyl chloride in presence of base. Subsequent reaction with ammonia gives benzodiazepine derivative. Reaction with oxone & iodine in presence of potassium acetate gives 3-acetoxy derivative, which is saponified to get oxazepam.

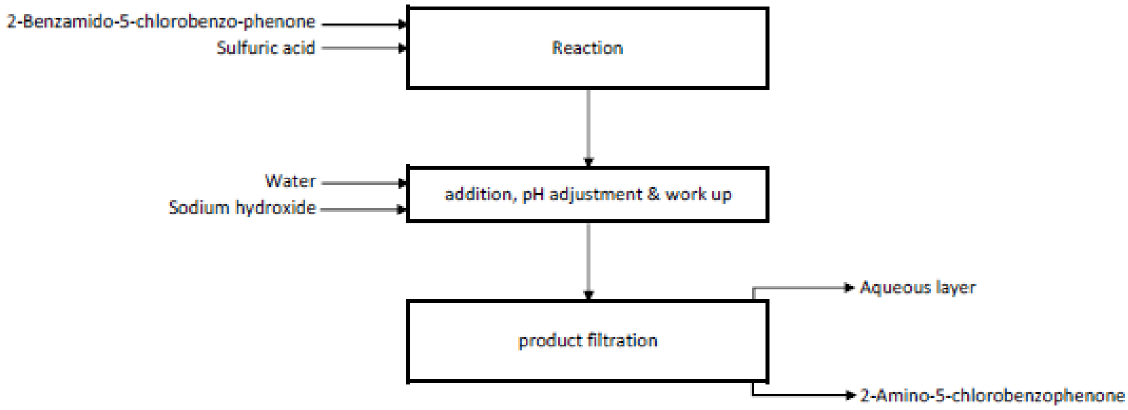
<u>Chemical Reaction</u>



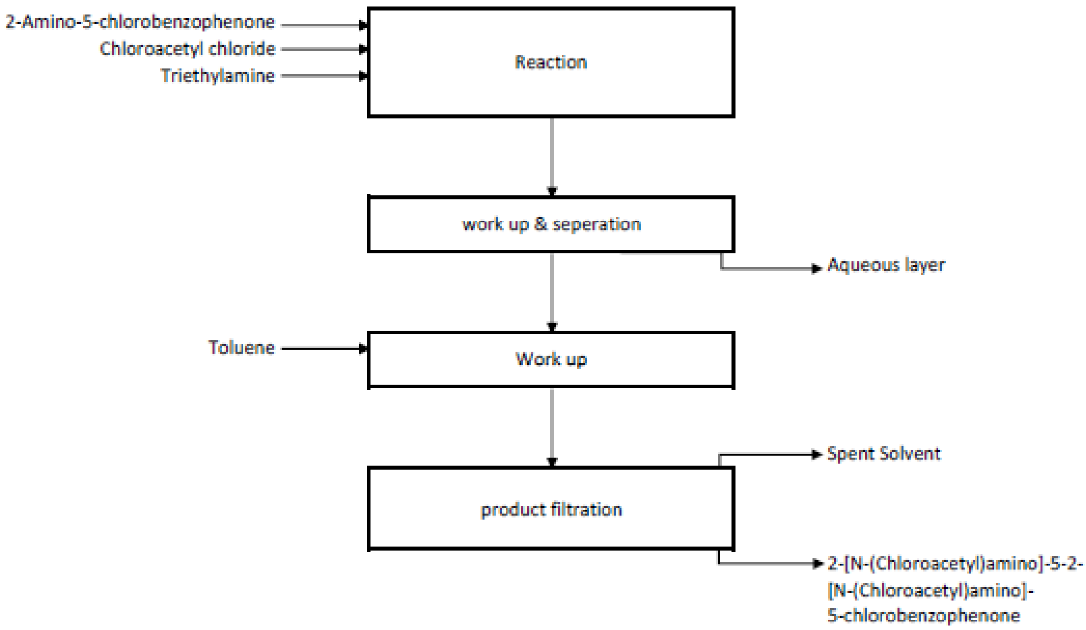
Stage-1



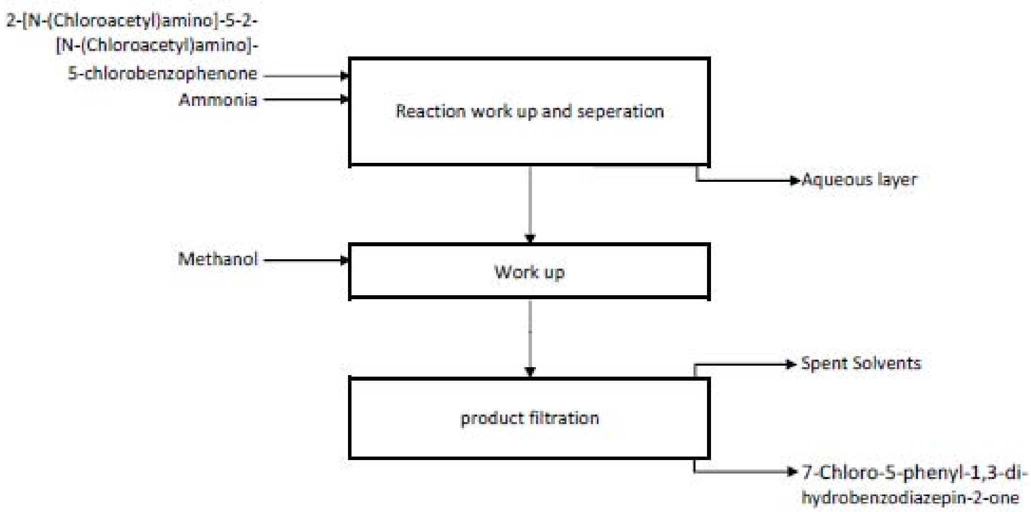
Stage-2



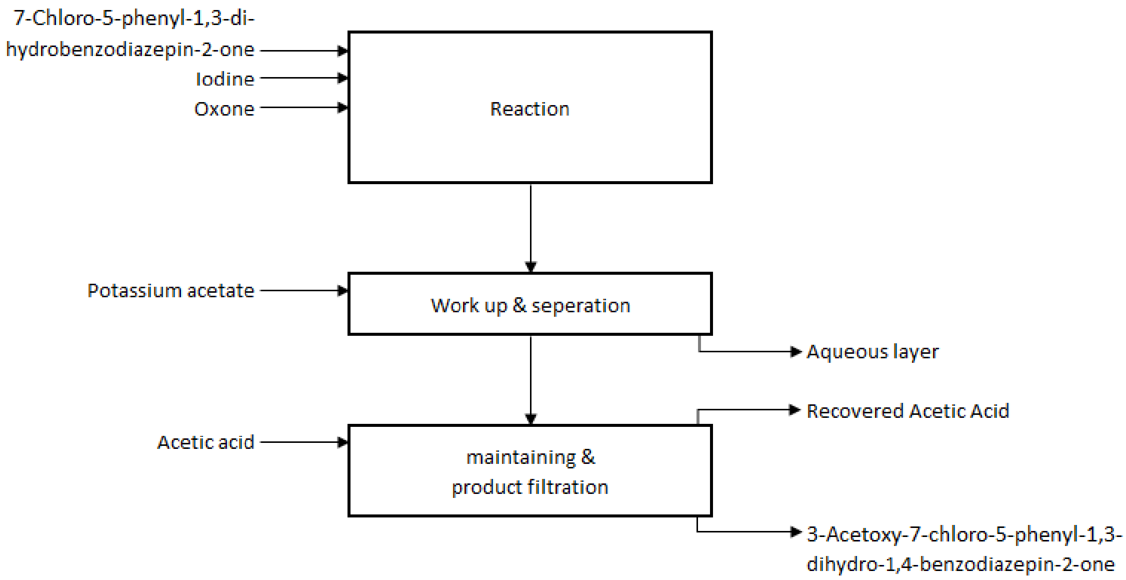
Stage-3



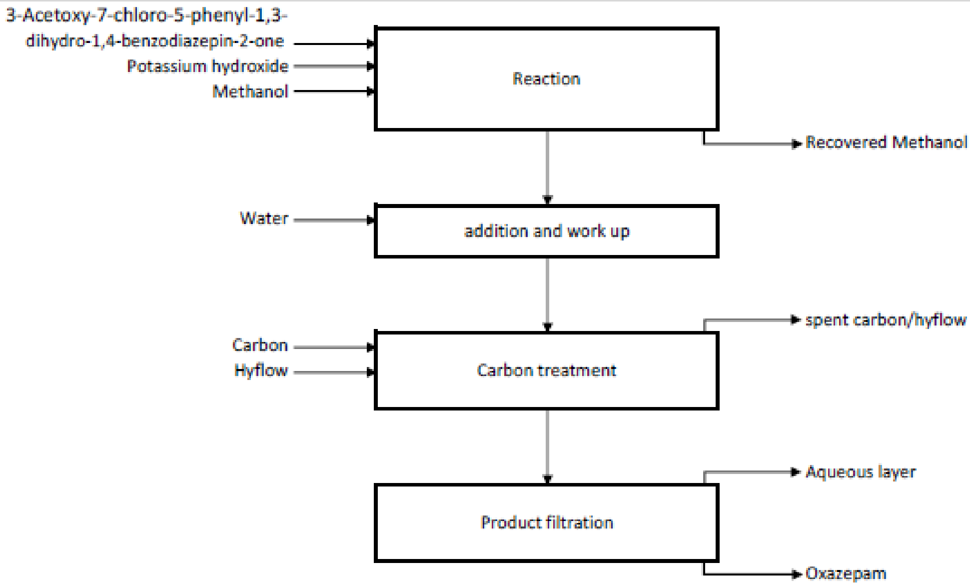
Stage-4



Stage-5



Stage-6



6. **Pregabalin**

Stage- I

CMH ((+)-3-(carbamoylmethyl)-5-methylhexanoic acid is treated with R-(+)-1 Methylbenzylamine in chloroform & methanol mixture to obtain R(+)-1-Methylbenzyl amine salt of R (-)-3 (Carbamoylmethyl)-5-methyl hexanoic acid (step-1) as solid whereas the unwanted salt of (S)-isomer remains in the solution which can be recovered in step-1A

Stage- II

R (+)-1-Methylbenzyl amine salt of R (-)-3 (Carbamoylmethyl)-5-methyl hexanoic acid (Step-1) is acidified with aqu.sulfuric acid in water to obtain R (-)-3 (Carbamoylmethyl)-5-methyl hexanoic acid) step-2 (R CMH). R-methylbenzylamine is recovered from filtrate in step-1 C

Stage III

R (-)-3-(Carbamoylmethyl)-5-methyl hexanoic acid (R-CMH) is reacting with NaOCl solution to undergo Hoffmann reaction to give Crude Pregabalin.

Stage- IV

Crude Pregabalin (Step-3 mass) is purified using aqueous isopropanol to afford S (+) PREGABALIN.

Stage-1a

S-CMH is isolated from step-1 filtrate and washings combined, by first recovering chloroform by distillation and the residual mass is treated with aqueous sulfuric acid in water to obtain a mix of S (+) -3 (Carbamoylmethyl) -5-methylhexanoic acid) S-CMH obtained is taken for racemiztion Step-1B and the R(+)-1-Methylbenzylamine goes in filtrate as sulphate salt and is processed further for recovery of R-MBA in step-1C.

Stage-1b

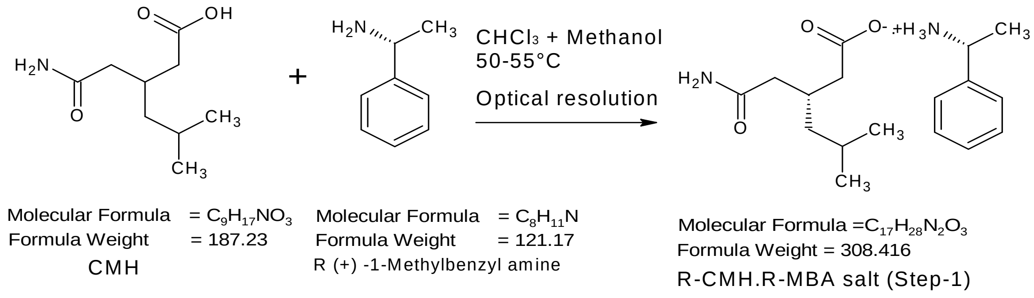
S-CMH is racemized by first heating at >1050C to undergo a dehydrative cyclization (Cyclocondensation) followed by hydrolysis with aqueous sodium hydroxide to give the racemic CMH ((+)-3-(carbamoyl-methyl)-5-methylhexanoic acid), which is purified in chloroform or other suitable solvent. This racemic CMH is recycled back to step-1.

Stage-1c

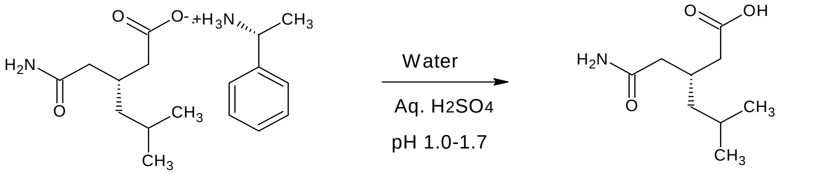
For recovery of R (+)-1-Methyl benzylamine, filtrate (ML) from step-2 (R-CMH) or the Step-1A (S-CMH) ML, is treated with sodium hydroxide followed by extraction with Chloroform & fractionation to give R(+)-1-Methyl benzylamine. This recovered R (+)-1-Methyl benzylamine is sufficiently pure to be recycled at resolution step-1.

Chemical Reaction

Stage- I



Stage- II



Molecular Formula = $C_{17}H_{28}N_3O_3$
Formula Weight = 308.416

R-CMH.R-MBA salt

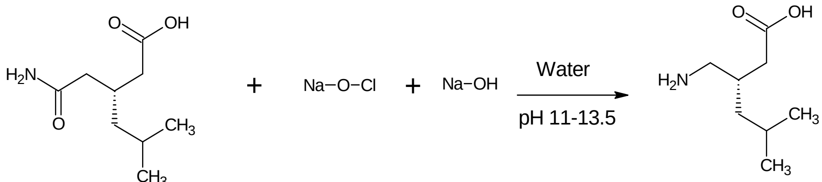
Step-1

Molecular Formula = $C_9H_{17}NO_3$
Formula Weight = 187.23

R-CMH

Step-2

Stage- III



Molecular Formula = $C_9H_{17}NO_3$
Formula Weight = 187.236

R(-)-3-(Carbamoylmethyl-5-methyl hexanoic acid

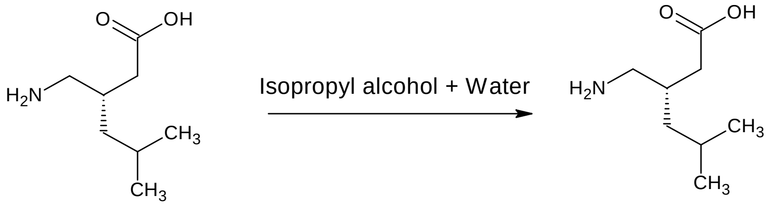
R-CMH

Molecular Formula = ClNaO
Formula Weight = 74.44
Sodium hypochlorite

Molecular Formula = $C_8H_{17}NO_2$
Formula Weight = 159.226
(3*S*)-3-(aminomethyl)-5-methylhexanoic acid

Crude pregabalin

Stage- IV



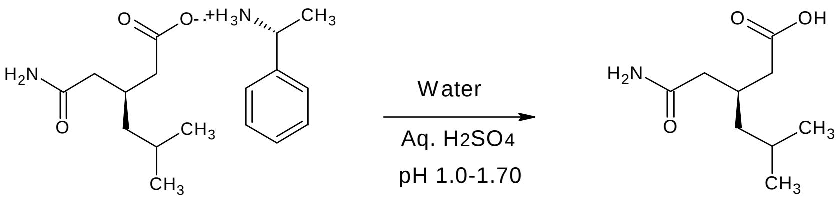
Molecular Formula = $C_8H_{17}NO_2$
Formula Weight = 159.226

Crude Pregabalin

Molecular Formula = $C_8H_{17}NO_2$
Formula Weight = 159.226

S(+) Pregabalin

Stage – 1a



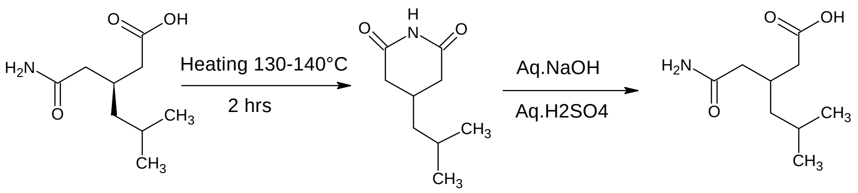
Molecular Formula =$C_{17}H_{28}N_3O_3$
Formula Weight = 308.40

S-CMH salt in ML

Molecular Formula = $C_9H_{17}NO_3$
Formula Weight = 187.23

S (+)-3-(Carbamoylmethyl-5-methyl hexanoic acid

Stage- 1b



Molecular Formula = $C_9H_{17}NO_3$
Formula Weight = 187.23

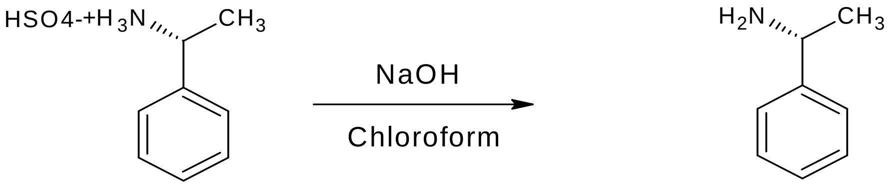
S-CMH

Molecular Formula = $C_9H_{15}NO_2$
Formula Weight = 169.22
4-isobutylpiperidine-2,6-dione

Molecular Formula = $C_9H_{17}NO_3$
Formula Weight = 187.23

RS-CMH

Stage-1c

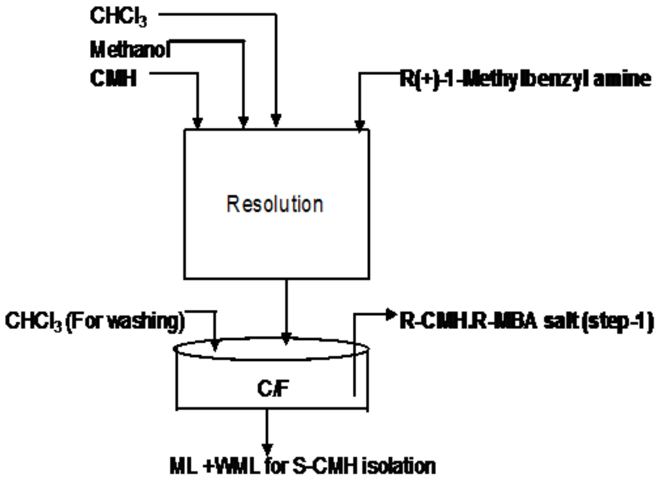


Molecular Formula = $C_8H_{11}N.H_2SO_4$
Formula Weight = 210.18
R (+) -1-Methylbenzyl amine sulphate salt in ML

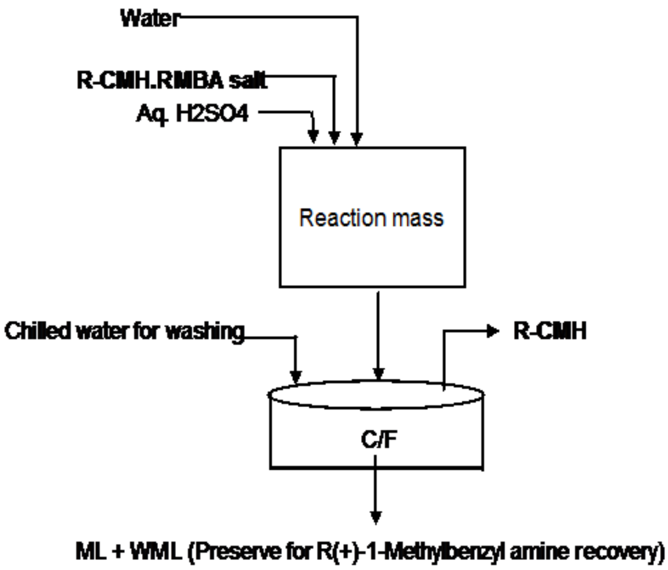
Molecular Formula = $C_8H_{11}N$
Formula Weight = 121.17
R (+) -1-Methylbenzyl amine

Flow Diagram

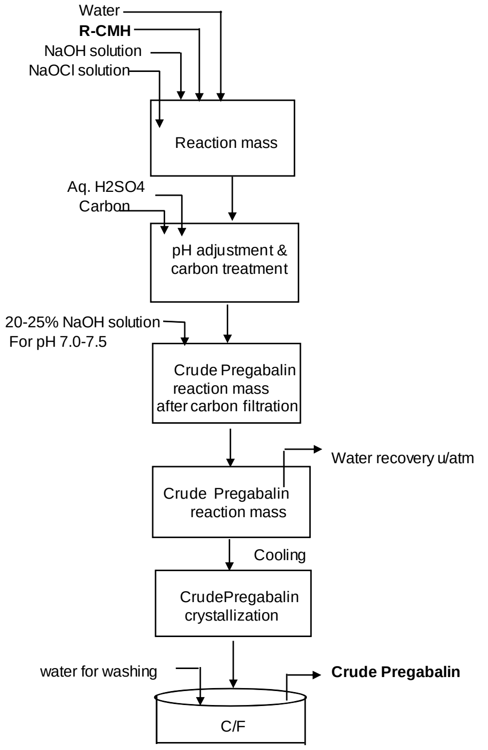
Step-1: Resolution (CMH to R-CMH.R-MBA salt)



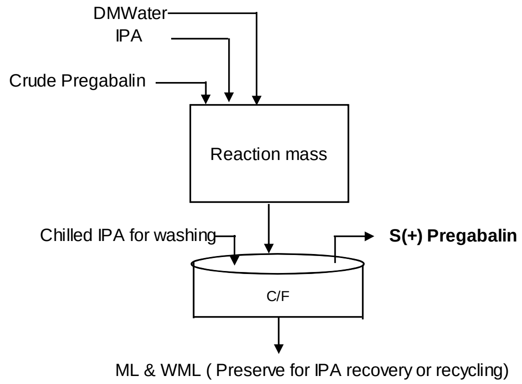
Step-2: Splitting (R-CMH.R-MBA salt to R-CMH)



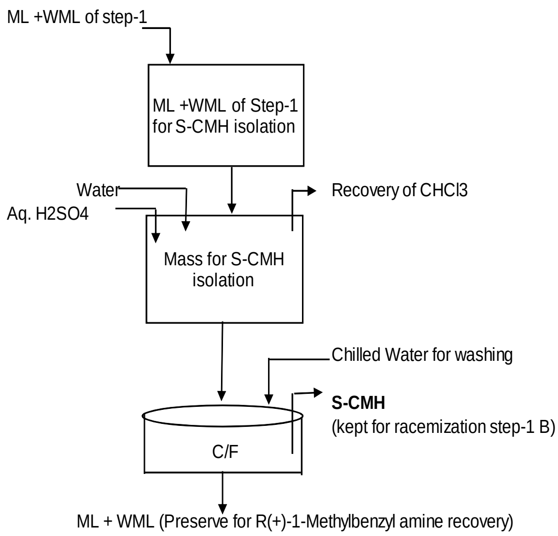
Step-3: Hofmann reaction (R-CMH to Crude Pregabalin)



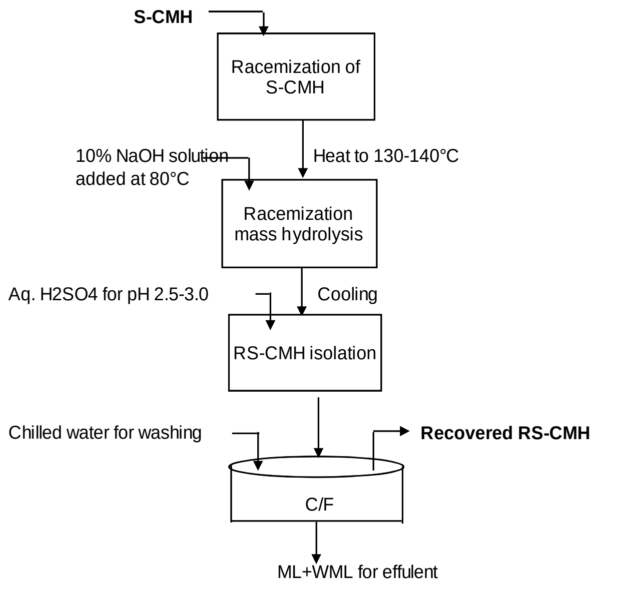
Step-4 : Purification (Crude Pregabalin to S(+) Pregabalin)



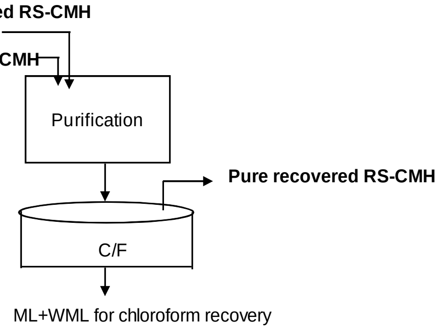
Step-1A: S-CMH isolation



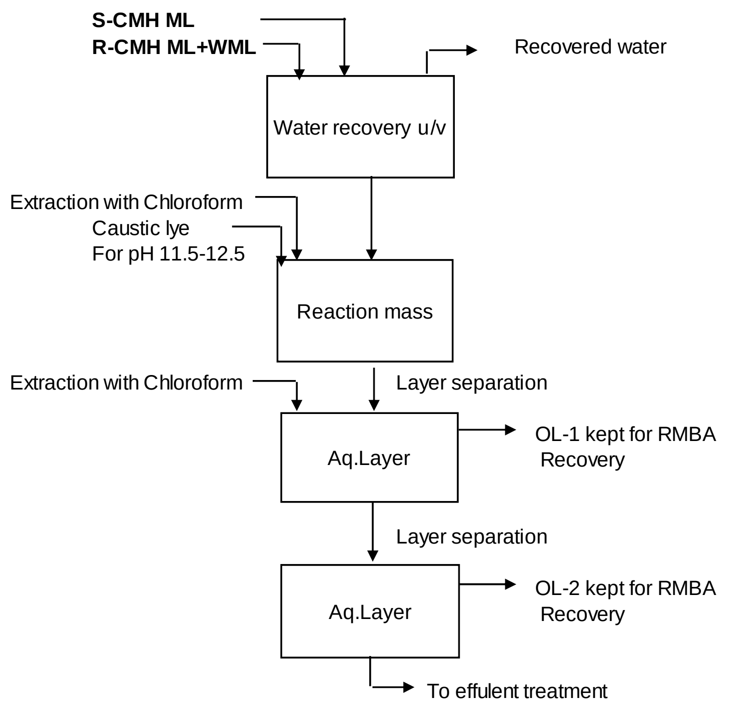
Step-1B: Racemization (S-CMH to Recovered RS-CMH)



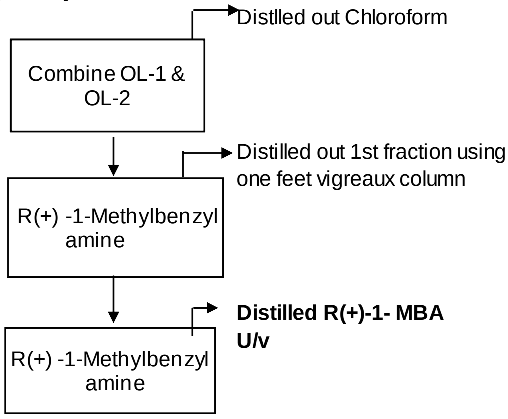
Purification of Recovered RS-CMH



Step-1C: Recovery of R-MBA



Fractionation of R(+)-1-Methylbenzyl amine



7. **<u>Levetiracetam</u>**

Stage- I

S-(+)-2-Aminobutyric acid is treated with thionyl chloride in methanol & recovery of methanol gives Methyl S (+)-2 Aminobutyrate hydrochloride.

Stage- II

Methyl S-(+) 2-Aminobutyrate hydrochloride is treated with ammonia solution in methanol & treated with Concentrate hydrochloric acid followed by isolation in Isopropyl alcohol gives S-Aminobutyramide hydrochloride.

Stage- III

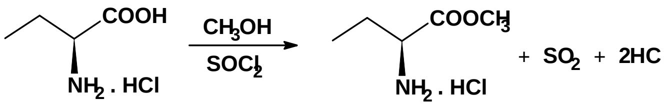
S-(+) 2-Aminobutyramide hydrochloride is treated with 4-Chlorobutyryl chloride in dichloromethane & potassium hydroxide, with presence of sodium sulphate, Tetra butyl ammonium bromide, followed by recovery of dichloromethane & isolation in ethyl acetate gives Crude Levetiracetam.

Stage- IV

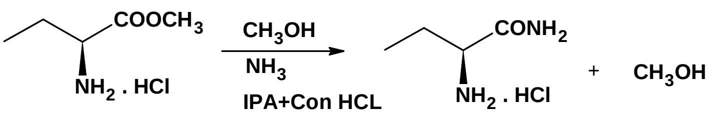
Levetiracetam is purified in Ethyl acetate & carbon treatment followed by crystallization gives Pure Levetiracetam

<u>Chemical Reaction</u>

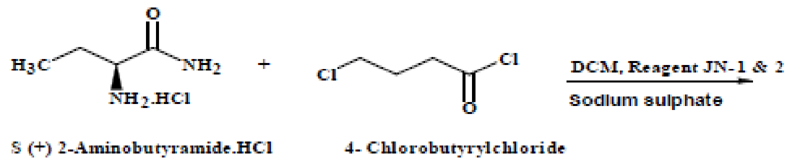
Stage- I

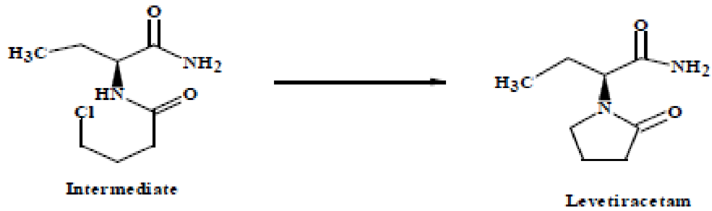


Stage- II

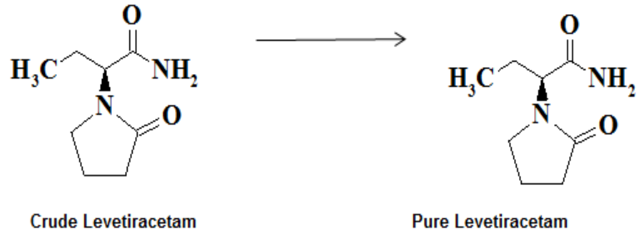


Stage- III





Stage-IV



8. <u>Teneligliptin hydrobromide hydrate</u>

Stage- I

1, 3-PTH and 3-MPPP are added in Tetrahydrofuran. Then it is treated with sodium triacetoxy borohydride in cooling. After the completion of reaction, Tetrahydrofuran distill out, Product is extracted in Dichloromethane, after layer separation, Dichloromethane layer distill out gives BOC-TNL isolated as a residual product.

Stage- II

Methane sulfonic acid is added in dichloromethane having BOC TNL and maintained specified temparature gives Teneligliptin which is extracted with dichloromethane at basic pH using sodium bicarbonate solution followed by sodium chloride washing. Dichloromethane then distilled out followed by adding Dysol. This solution is proceeding for next step.

Stage- III

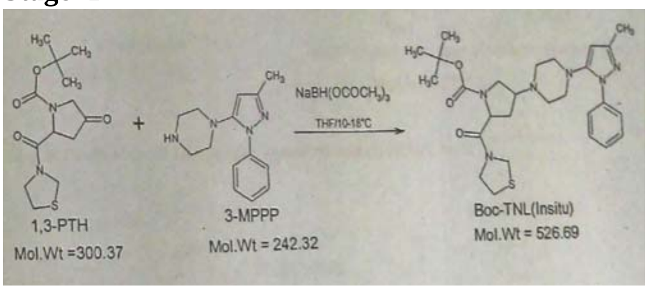
Teneligliptin in Dysol is treated with carbon followed by filtration & filtrate solution is further treated with 48% HBr solution, after cooling isolated mass filtration gives Teneligliptin hydrobromide hydrate (crude).

Stage- IV

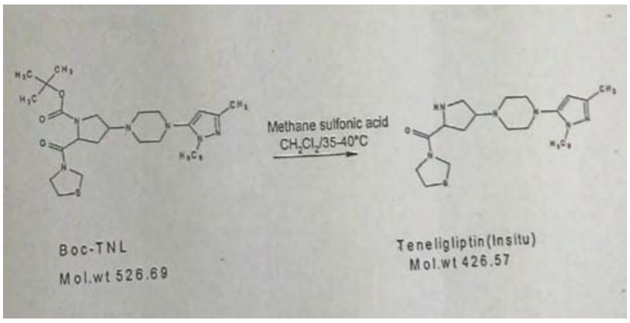
Teneligliptin hydrobromide hydrate is dissolved in methanol followed by isolation with acetone & crystallization gives Pure Teneligliptin hydrobromide hydrate.

<u>Chemical Reaction</u>

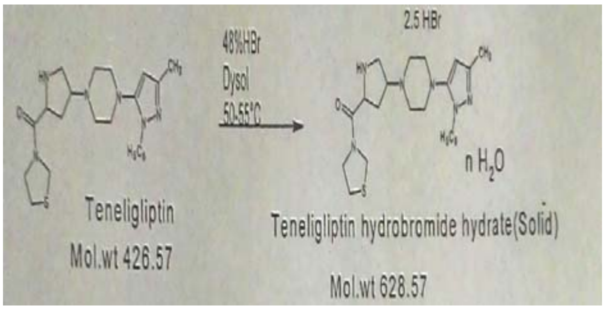
Stage- I



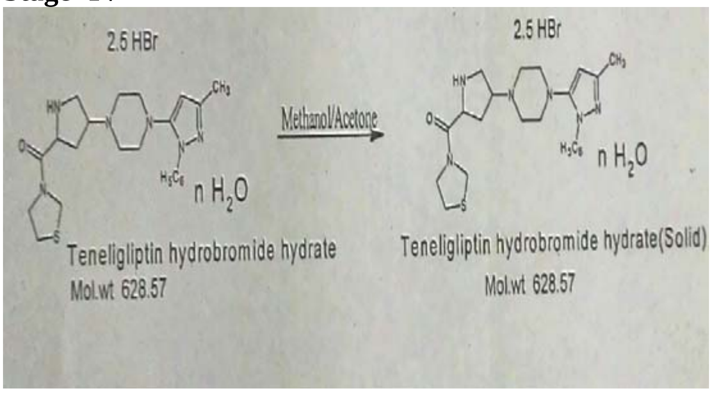
Stage- II



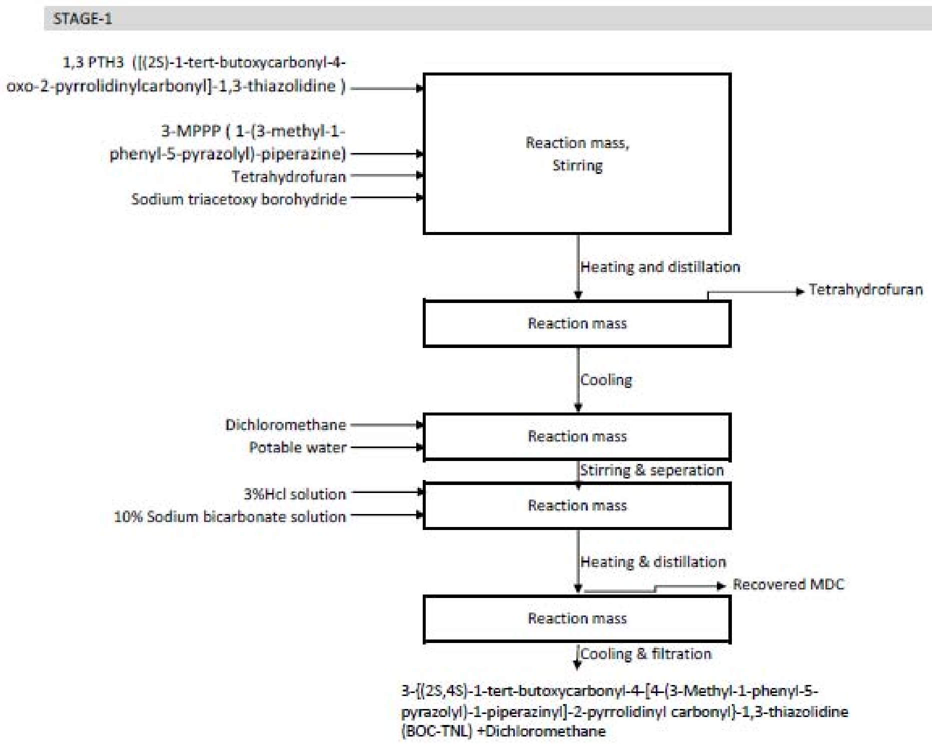
Stage- III



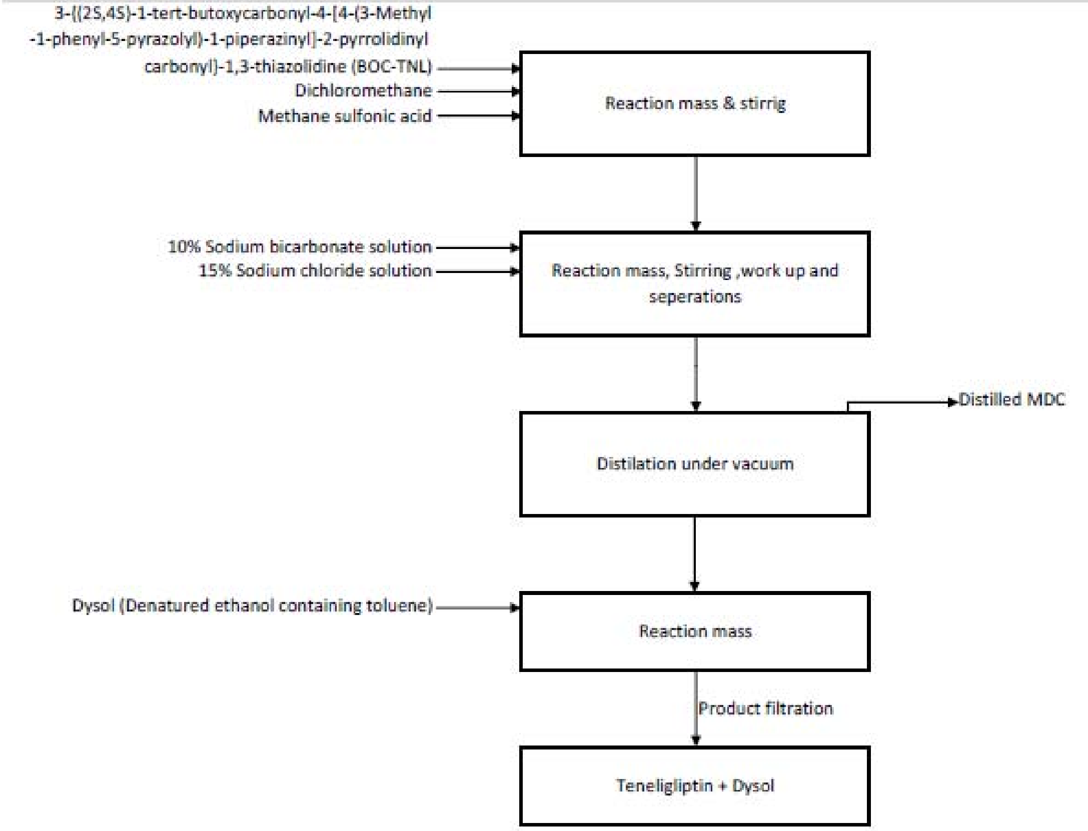
Stage- IV



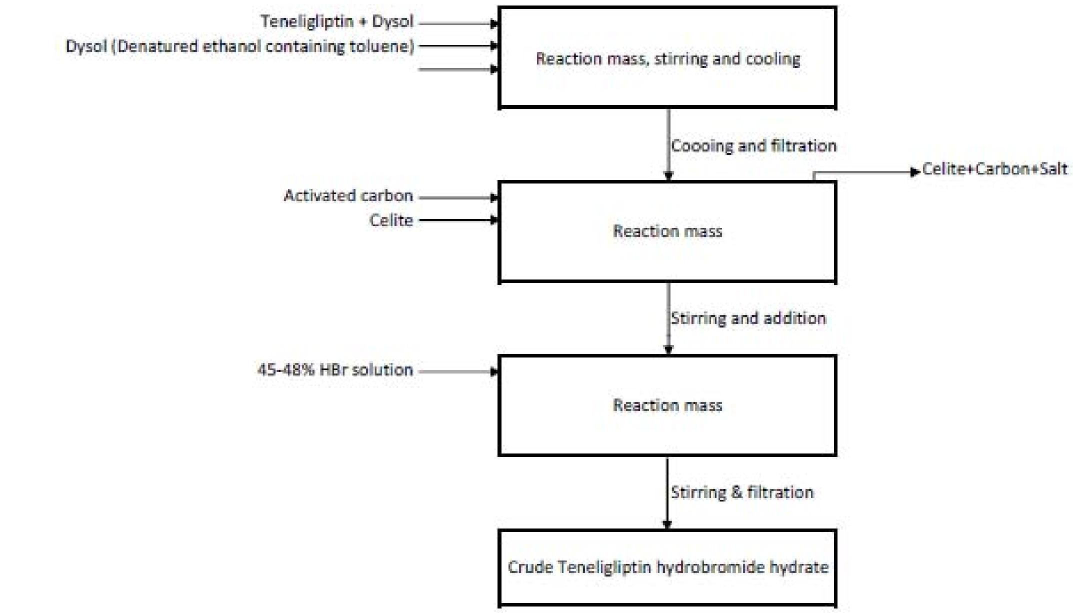
<u>Flow Diagram</u>



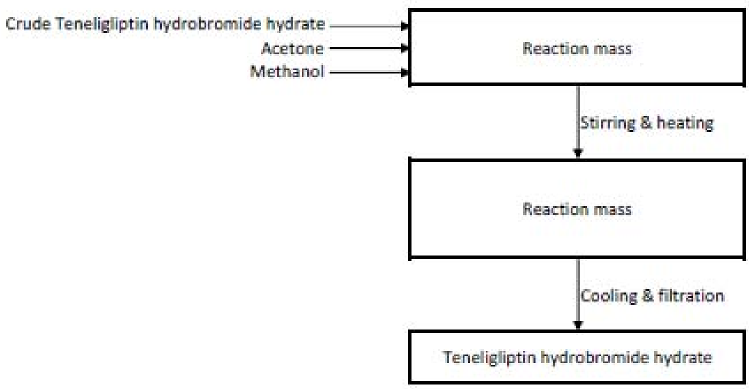
STAGE-2



STAGE-3



STAGE-4



9. Flupirtine Meleate

Stage-1

2-amino-6-chloro-3-nitropyridine is reacted with 4-fluorobenzylamine in Isopropyl alcohol and triethyl amine as base at specified temparature, after completion of reaction & addition of water gives 2-Amino-3-nitro-6-(4-flurobenzylamino) pyridine.

Stage-2

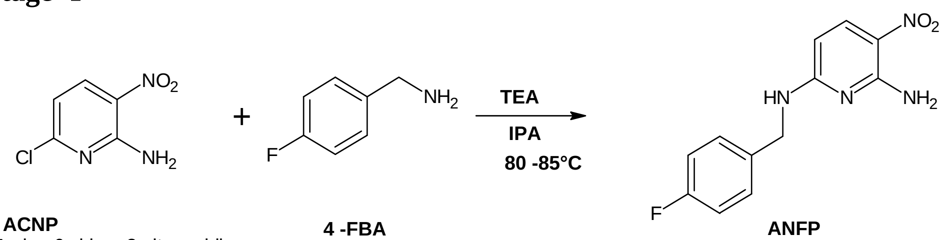
2-Amino-3-nitro-6-(4-flurobenzylamino) pyridine is reacted with Raney Nickel in presence of tetrabutyl ammonium bromide, Ethyl chloroformate,Hydrazine hydrate in toluene & isopropyl alcohol at specified temparature, after completion of reaction charge isopropyl alcohol & water, fileter the reaction mixture followed by cooling gives Flupirtine hydrochloride, which is treated with Meleic acid in water & isopropyl alcohol gives crude Flupirtine meleate.

Stage-3

Crude Flupirtine meleate is dissolvedin in methanol at specified temparature followed by isolation & crystalization under cooling gives Pure Flupirtine Meleate.

Chemical Reaction

Stage- I

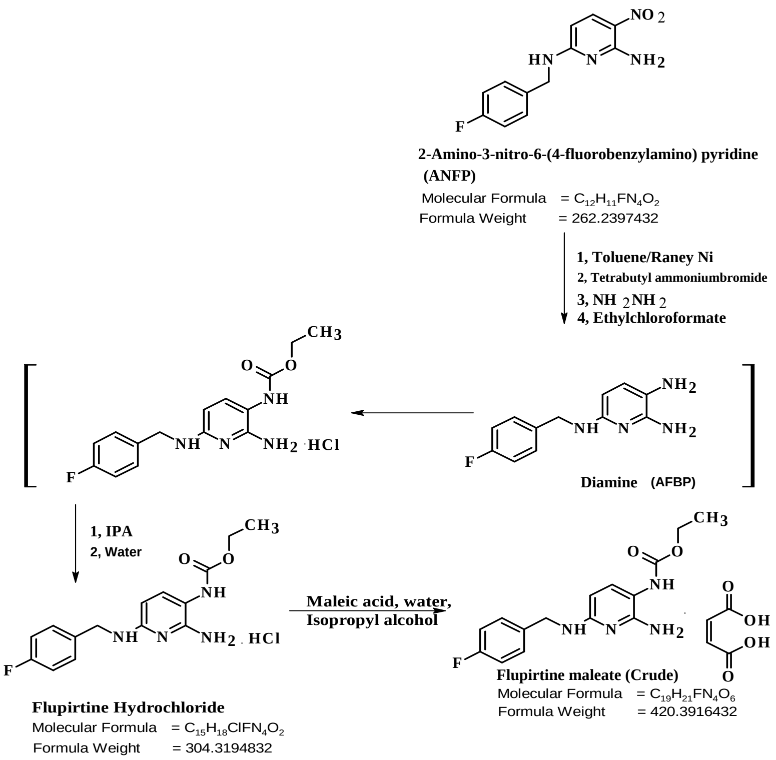


ACNP
2-Amino-6-chloro-3-nitropyridin
MF= $C_5H_4ClN_3O_2$
Formula Weight = 173.56

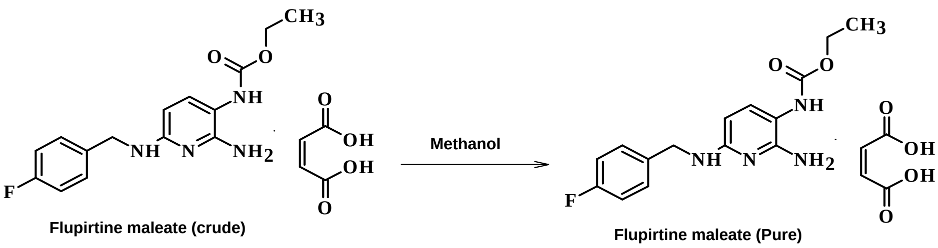
4 -FBA
4-Fluorobenzyl amine
MF = C_7H_8FN
Formula Weight = 125.14

ANFP
2-Amino-3-nitro-6-(4-fluorobenzylamino) pyridir
Molecular Formula = $C_{12}H_{11}FN_4O_2$
Formula Weight = 262.2397432

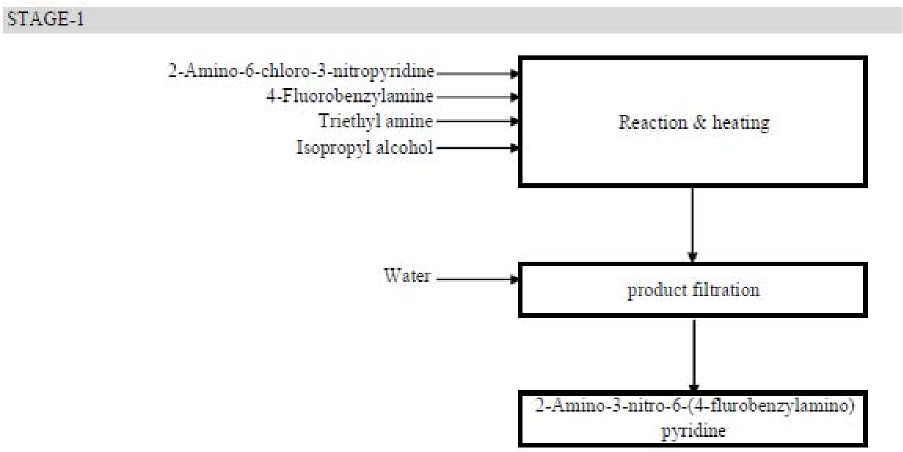
Stage-II

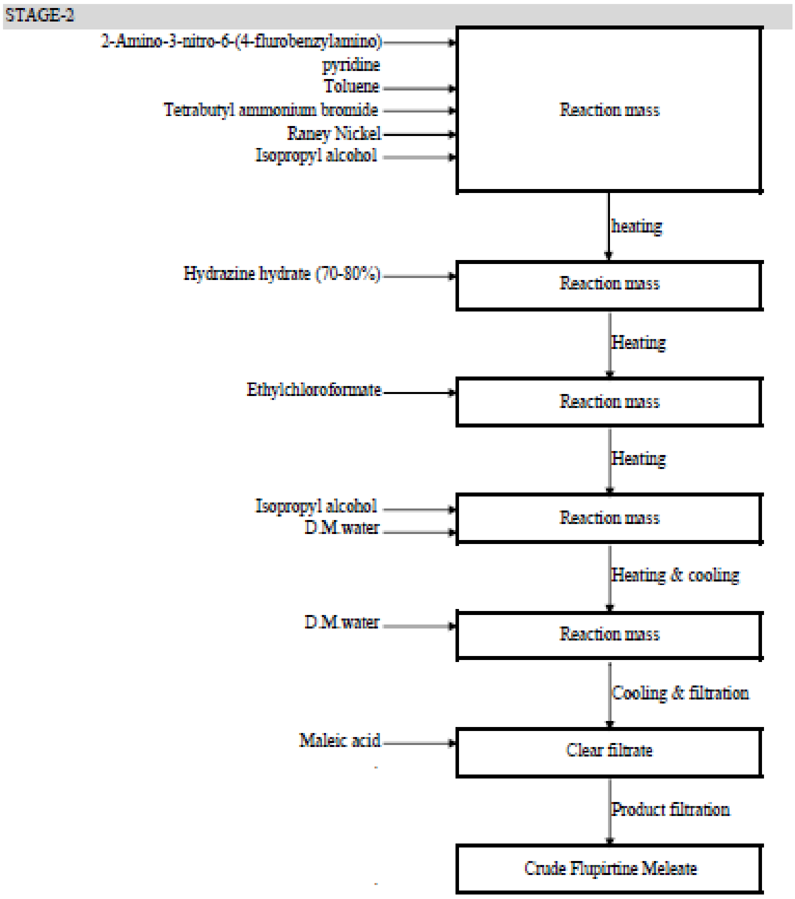


Stage- III



<u>Flow Diagram</u>

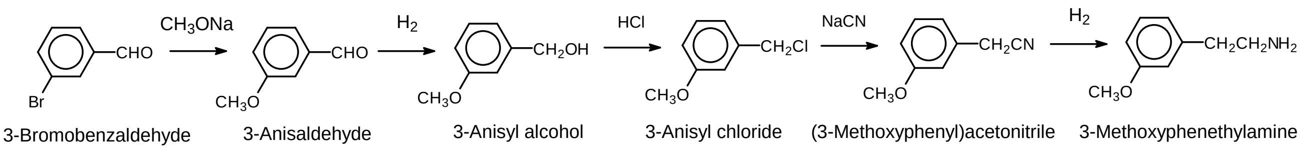




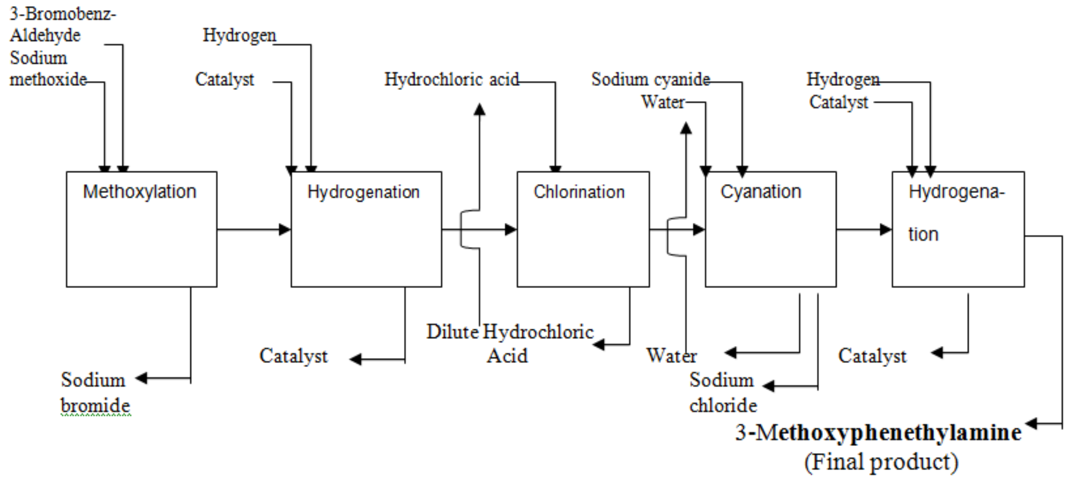
10. 3-Methoxyphenethylamine

3-Bromobenzaldehyde is reacted with sodium methoxide in solvent to get 3-anisaldehyde, which is hydrogenated to 3-anisyl alcohol and then reacted with hydrochloric acid to give 3-anisyl chloride. Further cyanation using sodium cyanide yields (3-methoxyphenyl) acetonitrile which is finally hydrogenated to get 3-methoxyphenethylamine.

Chemical Reaction



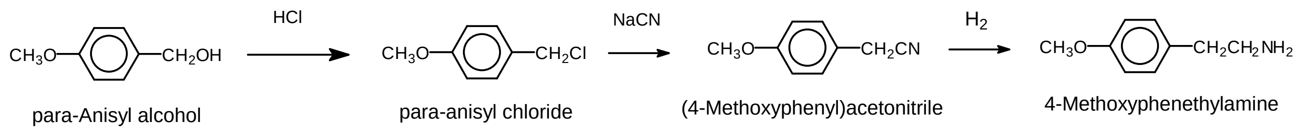
Flow diagram



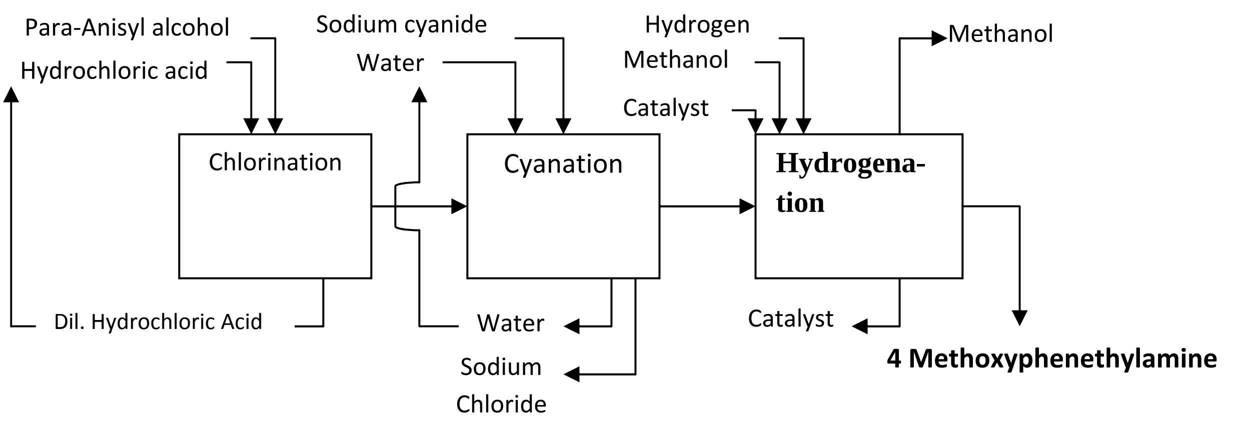
11. 4-Methoxyphenethylamine

para-Anisyl alcohol is reacted with hydrochloric acid and the resulting para-anisyl chloride is reacted with sodium cyanide to yield (4-methoxyphenyl)acetonitrile, which is hydrogenated in methanol medium to get 4-methoxyphenethylamine.

Chemical Reaction



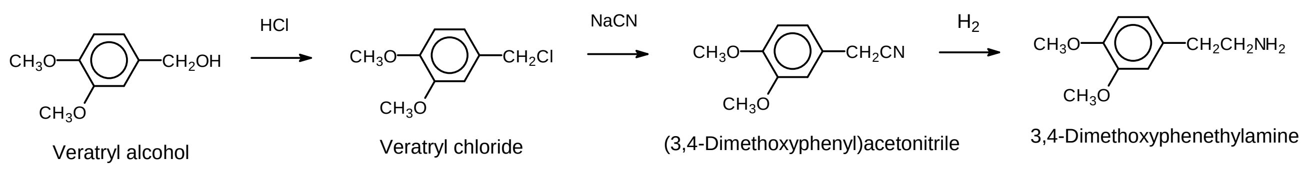
Flow diagram



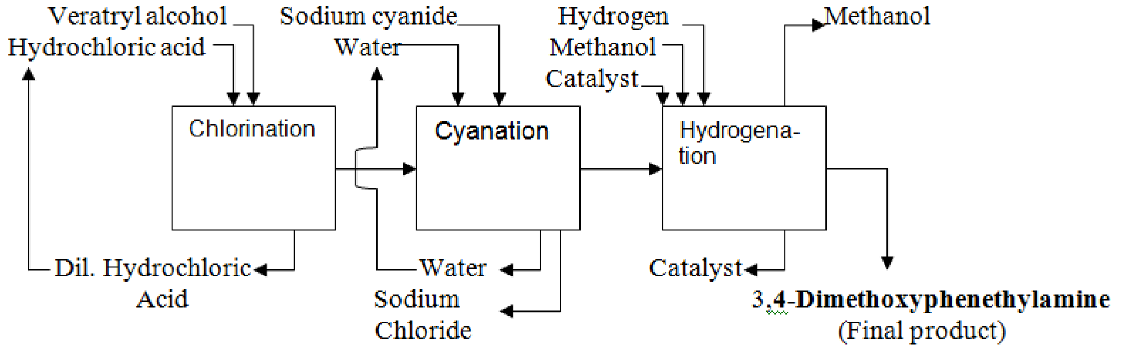
12. 3, 4-Dimethoxyphenethylamine

Veratryl alcohol is reacted with hydrochloric acid and the resulting veratryl chloride is reacted with sodium cyanide to yield (3,4-dimethoxyphenyl) acetonitrile, which is hydrogenated in methanol medium to get 3,4-dimethoxyphenethylamine.

Chemical Reaction



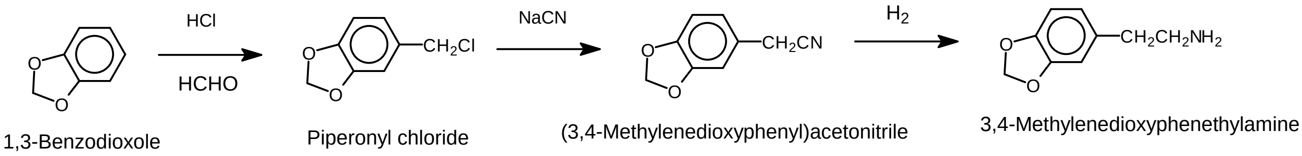
Flow Diagram



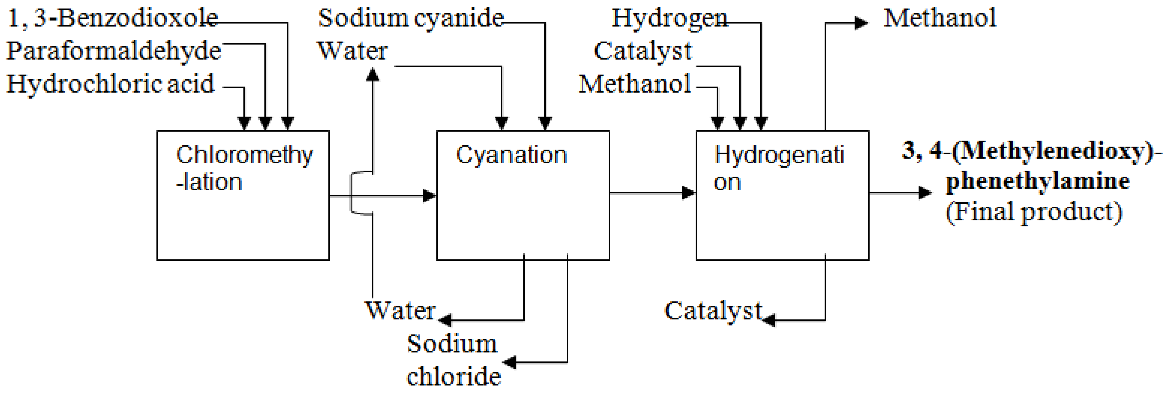
13. 3, 4-(Methylenedioxy) phenethylamine

1,3-Benzodioxole is chloromethylated using hydrochloric acid and paraformaldehyde to get piperonyl chloride which is reacted with sodium cyanide to yield (3,4 methylenedioxyphenyl)acetonitrile, hydrogenation of which gives 3,4-(methylenedioxy) phenethylamine.

Chemical Reaction



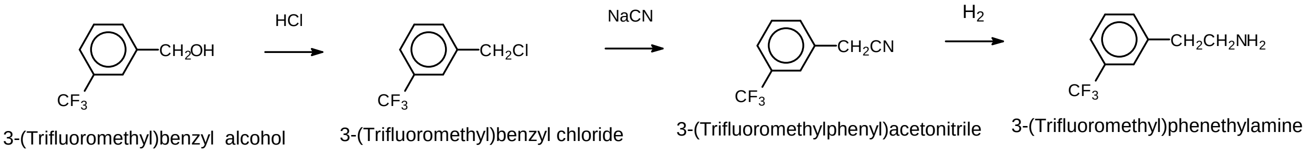
Flow diagram



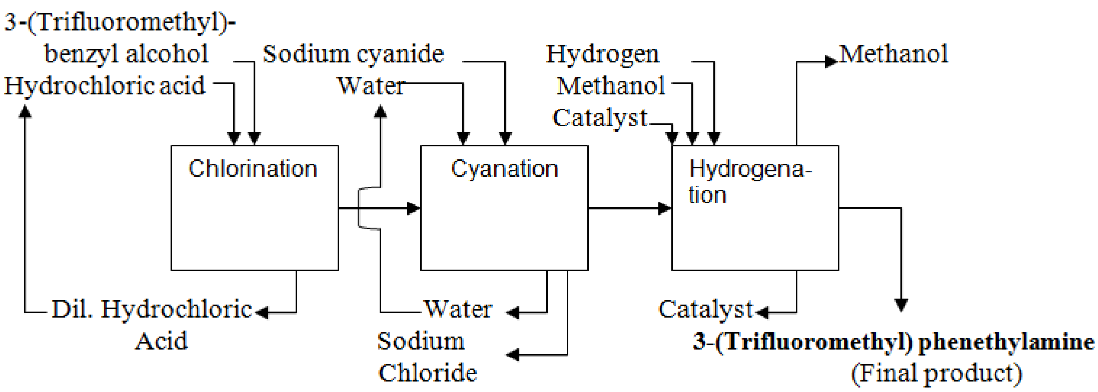
14. 3-(Trifluromethyl) phenethylamine

3-(Trifluoromethyl) benzyl alcohol is reacted with hydrochloric acid to get 3-(trifluoromethyl) benzyl chloride which is reacted with sodium cyanide to yield (3-trifluoromethylphenyl) acetonitrile. This product is further hydrogenated to get 3-(trifluoromethyl) phenethylamine.

Chemical Reaction



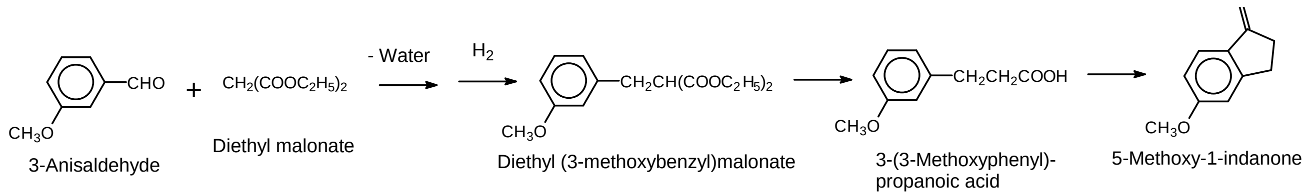
Flow Diagram



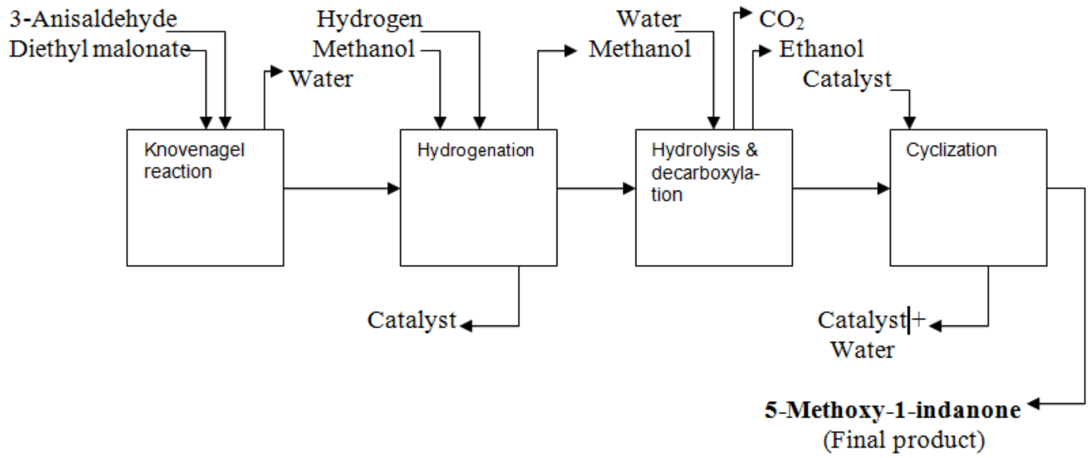
15. 5-Methoxy-1-indanone

3-Anisaldehyde is reacted with diethyl malonate and hydrogenated to get diethyl 3-methoxybenzylmalonate which is hydrolyzed & decarboxylated to get 3-(3-methoxyphenyl)-propanoic acid, which is cyclized in the presence of catalyst to get 5-methoxy-1-indanone.

Chemical Reaction



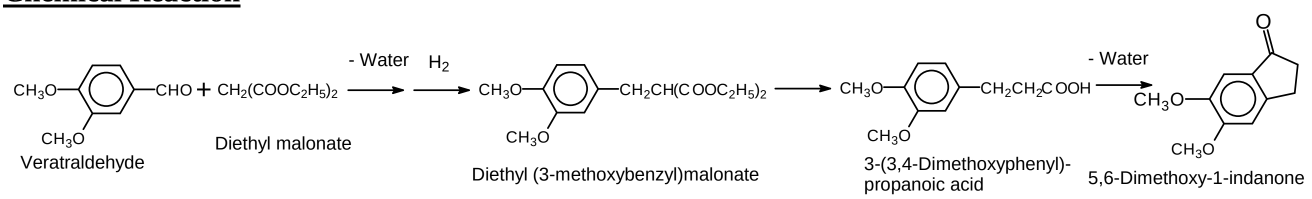
Flow Diagram



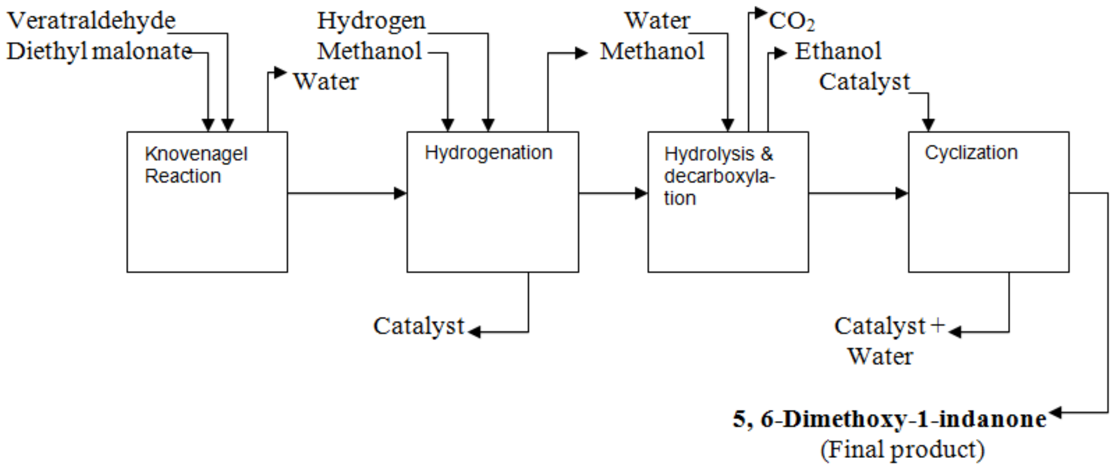
16. 5, 6-Dimethoxy-1-indanone

Veratraldehyde is reacted with diethyl malonate and hydrogenated to get diethyl 3,4-dimethoxybenzylmalonate which is hydrolyzed & decarboxylated to get 3-(3,4-dimethoxyphenyl)-propanoic acid, which is cyclized in the presence of catalyst to get 5,6-dimethoxy-1-indanone.

Chemical Reaction



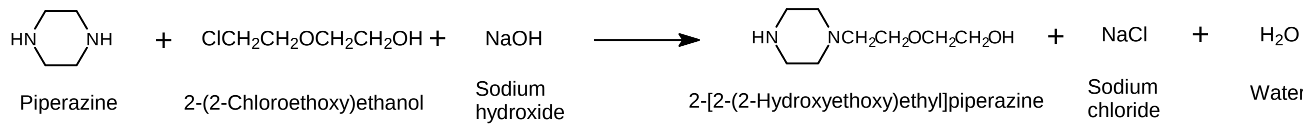
Flow Diagram



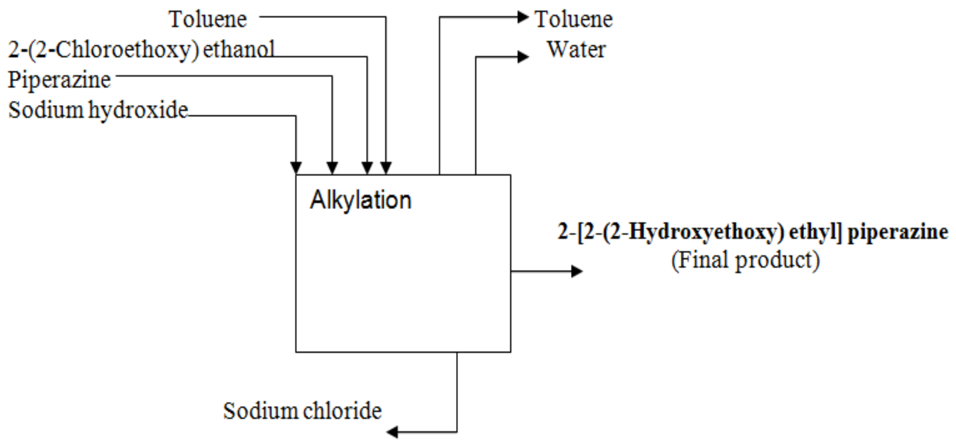
17. 1-[2-(2-Hydroxyethoxy) ethyl] piperazine

Piperazine is reacted with 2-(2-chloroethoxy)ethanol in the presence of sodium hydroxide & benzene, the product & unreacted piperazine separated from sodium chloride solid, and finally fractionally distilled to get benzene, unreacted piperazine and 2-[2-(2-hydroxyethoxy)ethyl]piperazine.

Chemical Reaction



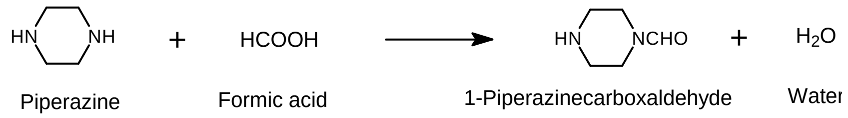
Flow Diagram



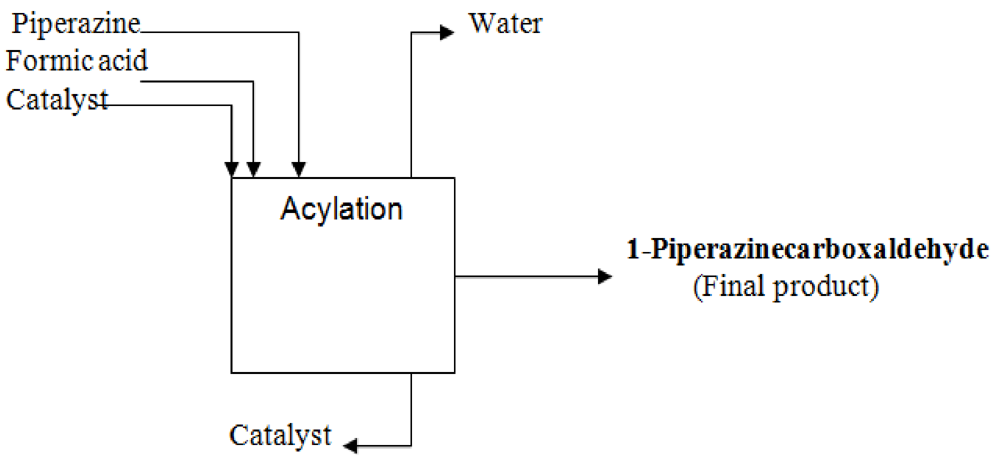
18. 1-Piperazinecarboxaldehyde

Piperazine is reacted with formic acid in the presence of catalyst to get 1-piperazinecarboxaldehyde.

Chemical Reaction



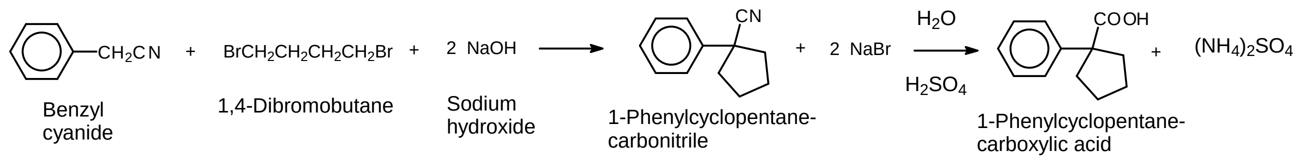
Flow Diagram



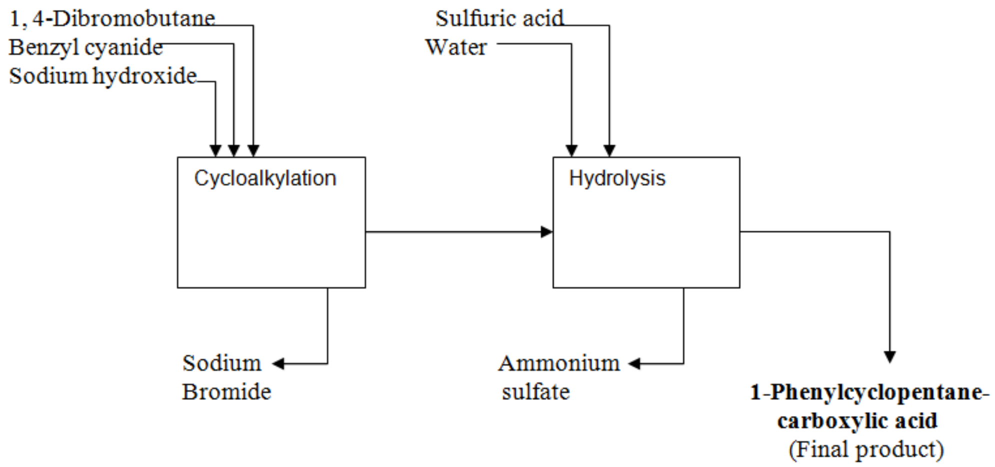
19. 1-Phenylcyclopentanecarboxylic acid

Benzyl cyanide is reacted with 1,4-dibromobutane in the presence of sodium hydroxide to get 1-phenylcyclopentanecarbonitrile which is hydrolyzed in the presence of sulfuric acid to get 1-phenylcyclopentanecarboxylic acid.

Chemical Reaction



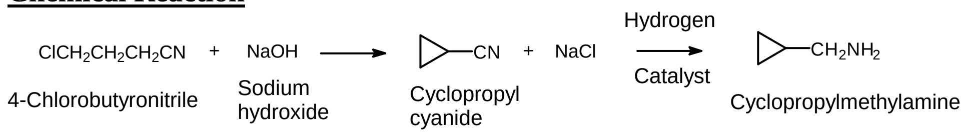
Flow Diagram



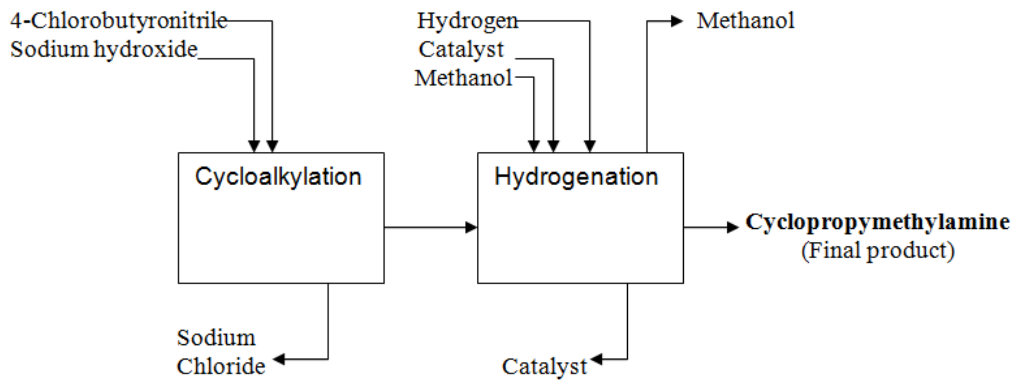
20. Cyclopropymethylamine

4-Chlorobutyronitrile is reacted with sodium hydroxide to get cyclopropyl cyanide which is hydrogenated to get Cyclopropymethylamine.

Chemical Reaction



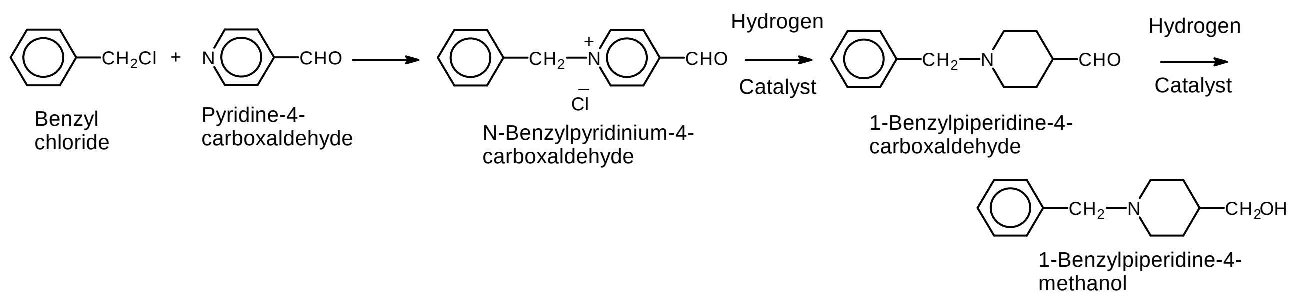
Flow diagram



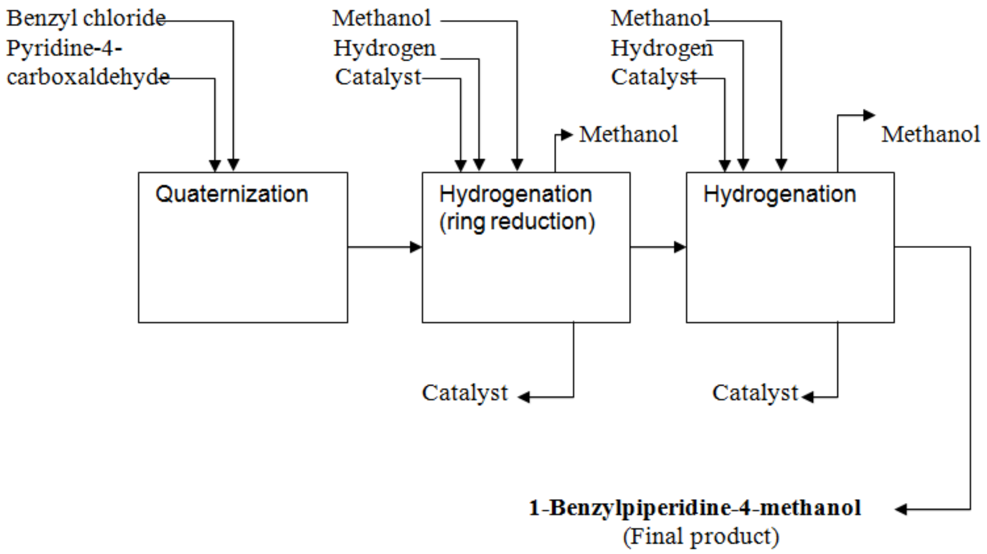
21. 1-Benzylpiperidine-4-methanol

Pyridine-4-carboxaldehyde is reacted with benzyl chloride and then hydrogenated & neutralized to get 1-benzylpiperidine-4-carboxaldehyde, which is again hydrogenated to get 1-benzylpiperidine-4-methanol.

Chemical Reaction



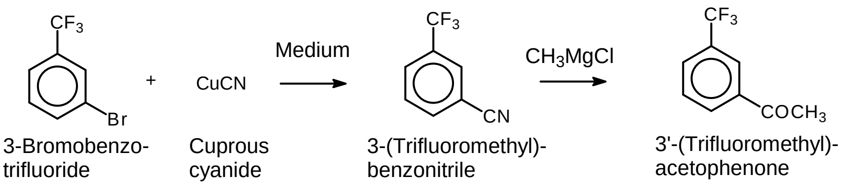
Flow Diagram



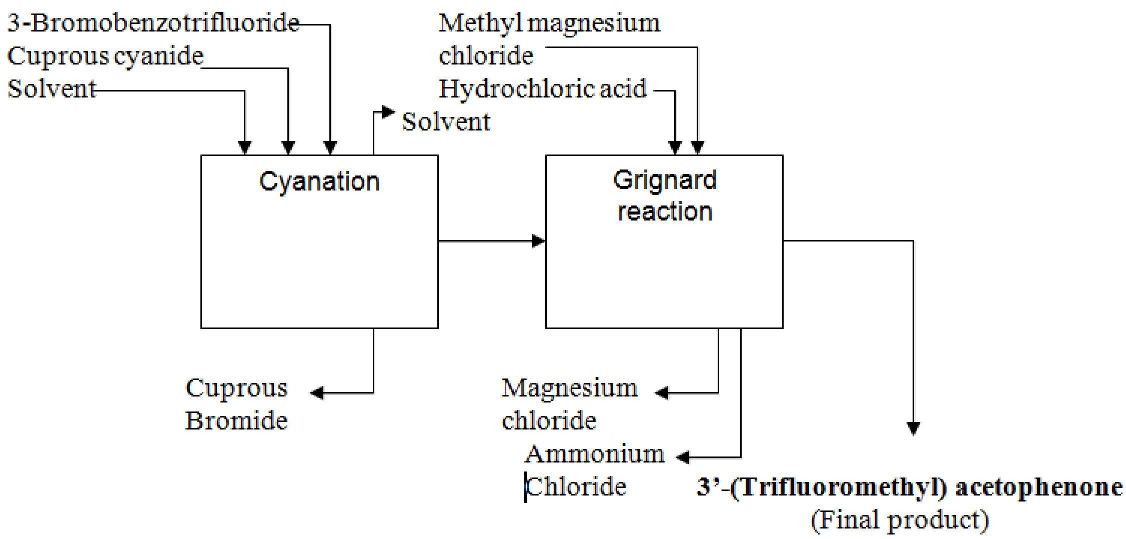
22. 3’-(Trifluoromethyl) acetophenone

3-Bromobenzotrifluoride is reacted with cuprous cyanide in solvent medium to get 3 (trifluoromethyl) benzonitrile, which is reacted with methyl magnesium chloride to get 3’-(trifluoromethyl) acetophenone.

Chemical Reaction



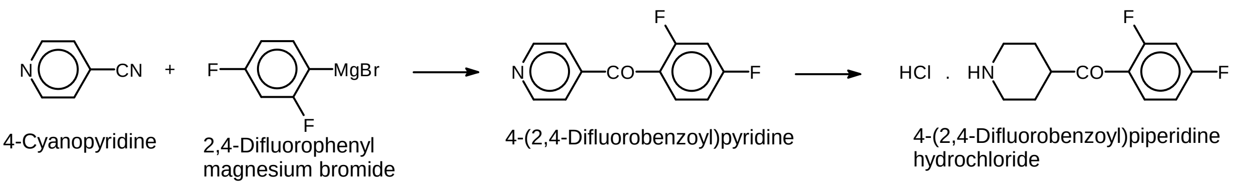
Flow Diagram



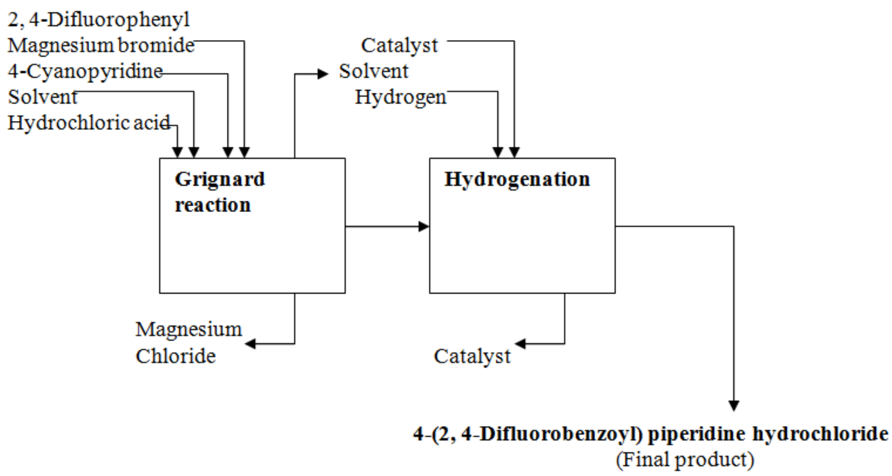
23. 4-(2, 4-Difluorobenzoyl) piperidine hydrochloride

4-Cyanopyridine is reacted with 2,4-difluorophenyl magnesium bromide to get 4-(2,4-difluorobenzoyl) pyridine which is hydrogenated to give 4-(2,4-difluorobenzoyl)piperidine, which is reacted with hydrochloric acid to get the hydrochloride salt.

Chemical Reaction



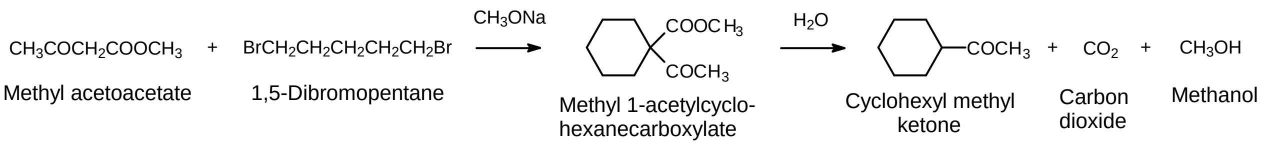
Flow Diagram



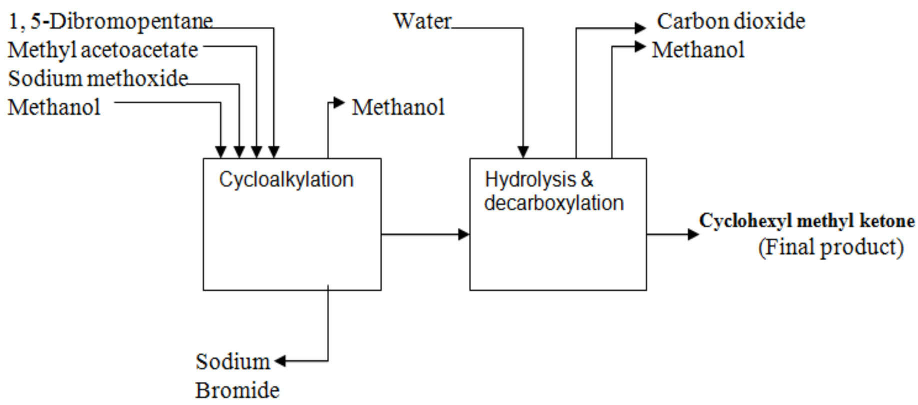
24. Cyclohexyl methyl ketone

1, 5-Dibromopentane is reacted with methyl acetoacetate in the presence of sodium methoxide in methanol solution and the resultant methyl 1-acetylcyclohexanecarboxylate is hydrolyzed & simultaneously decarboxylated to get cyclohexyl methyl ketone

Chemical Reaction



Flow Diagram



2.5 RAW MATERIALS REQUIREMENT WITH THEIR SOURCE AND TRANSPORATATION

Details of Raw material consumption and Mode of Transportation are given in following table.

LIST OF RAW MATERIALS

SR.NO	NAME OF RAW MATERIAL	MTPM	MODE OF TRANSPORT
EXISTING RAW MATERIALS			
1.	1-Bromo-3-chloropropane	750.0	By Road
2.	Pyrolidine	350.0	
3.	Toluene	200.0	
4.	Sodium carbonate	250.0	
5.	Para-Anisyl alcohol	913.90	
6.	Hydrochloric acid	660.11	
7.	Sodium cyanide	613.06	
8.	Hydrogen gas	111.94	
9.	Veratraldehyde	259.37	
10.	Diethyl melonate	545.99	
11.	Catalyst-A	630.0	
12.	Piperazine anhydrous	871.39	
13.	Formic acid	201.75	
14.	3-Anisaldehyde	251.60	
15.	2-(2-Chloroethoxy) ethanol	714.68	
16.	Sodium hydroxide	592.10	
17.	3-(Trifluoromethyl) benzyl alcohol	46.50	
18.	Veratryl alcohol	186.0	
19.	1,3-Benzodioxole	148.02	
20.	Paraformaldehyde	36.36	
21.	3-Bromobenzaldehyde	612.20	
22.	Sodium methoxide	349.80	
23.	Solvent-X	400.00	
24.	4-Cyanopyridine	119.30	
25.	2,4-Difluorophenyl magnesium bromide	249.00	
26.	Methyl acetoacetate	184.12	
27.	1,5-Dibromopentane	364.74	
28.	3-Bromobenzotrifluoride	239.25	
29.	Cuprous cyanide	95.25	
30.	Methyl magnesium chloride	79.35	
31.	4-Chlorobutyronitrile	291.54	
32.	Benzyl chloride	132.00	
33.	Pyridine-4-carboxaldehyde	111.65	
34.	Benzyl cyanide	307.89	
35.	1,4-Dibromobutane	567.88	
36.	Sulfuric Acid	128.94	
PROPOSED RAW MATERIALS			
37.	Cinnamic aldehyde	2.1	By Road
38.	30% HCl	1.8	
39.	Catalyst	0.5	
40.	Thionyl chloride	0.8	
41.	Sodium hydroxide	11.8	
42.	Carbon	0.4	

SR.NO	NAME OF RAW MATERIAL	MTPM	MODE OF TRANSPORT
43.	Hyflow	0.3	
44.	2,6-Di-tert-butylphenol	0.9	
45.	Dimethylamine 40%	0.5	
46.	Formaldehyde 37%	0.4	
47.	Methanol	90.5	
48.	Toluene	11.9	
49.	4-Fluorobenzaldehyde	1.1	
50.	Ammonia	2.1	
51.	Hydrogen	0.13	
52.	2-Aminophenol	0.6	
53.	2-Nitrophenol	0.3	
54.	Crotonaldehyde	0.5	
55.	Sulphuric acid 98%	6.1	
56.	Acetic acid	5.5	
57.	Methyl-2-BromoButyrate	3.9	
58.	Ammonia gas	6.7	
59.	Potassium carbonate	2.8	
60.	L(+) Tarteric acid	1.1	
61.	Isopropyl alcohol	20.8	
62.	1,5-Dibromopentane	5.1	
63.	Sodium cyanide	2.4	
64.	Barium hydroxide $8H_2O$	2.4	
65.	Carbon dioxide	0.3	
66.	Ethyl cyanoacetate	0.5	
67.	Guanidine HCl	0.4	
68.	Sodium methoxide 28%	0.8	
69.	Sodium nitrite	0.3	
70.	Sodium dithionite	0.4	
71.	4-Nitrobenzoic acid	0.8	
72.	Thionyl chloride	2.1	
73.	N-Hydroxysuccinimide	0.5	
74.	Triethylamine	1.2	
75.	Tetrahydrofuran	10.6	
76.	L-Glutamic acid	0.5	
77.	Acetone	0.2	
78.	Chlorine	0.9	
79.	4-Aminobenzonitrile	0.0	
80.	1,4-Cyclohexanedione	0.0	
81.	Methylamine 40%	0.0	
82.	2-Chlorobenzaldehyde	0.2	
83.	Oleum 20%	0.4	
84.	Oleum 65%	0.2	
85.	Sodium chloride	0.5	
86.	Sodium sulfite	0.2	
87.	N,N-Diethylaniline	0.7	
88.	Hydrogen peroxide 30%	0.1	
89.	2-Chlorobenzoyl chloride	1.2	
90.	4-Chloroaniline	0.4	

SR.NO	NAME OF RAW MATERIAL	MTPM	MODE OF TRANSPORT
91.	Zinc chloride	0.7	
92.	Chloroacetyl chloride	0.3	
93.	Iodine	0.3	
94.	Oxone	0.4	
95.	Potassium acetate	0.7	
96.	Potassium hydroxide	1.8	
97.	Benzoyl chloride	0.7	
98.	4-Chloroaniline	0.3	
99.	Zinc chloride	0.6	
100.	Chloroacetyl chloride	0.2	
101.	Racemic-3- (Carbamoylmethyl)-5-methyl hexanoic acid	2.7	
102.	R(+)-alpha phenyl ethyl amine	1.5	
103.	Chloroform	45.8	
104.	Aq.Sulphuric acid	3.7	
105.	Aq. Sodium hydroxide (~50%)	0.5	
106.	Activated carbon	0.2	
107.	Celite	0.3	
108.	Aq.Sodium hydroxide `(25%)	0.5	
109.	Con HCl	1.4	
110.	S-(+)-2-Aminobutyric acid	1.0	
111.	Dichloromethane	49.7	
112.	Sodium sulphate Anhydrous	1.0	
113.	Tetrabutyl ammonium bromide	0.1	
114.	4-Chlorobutyryl chloride	0.9	
115.	Ethyl acetate	5.3	
116.	1,3 PTH3 ([(2S)-1-tert-butoxycarbonyl-4-oxo-2-pyrrolidinylcarbonyl]-1,3-thiazolidine)	1.0	
117.	3-MPPP (1-(3-methyl-1-phenyl-5-pyrazolyl)-piperazine)	0.8	
118.	Sodium triacetoxy borohydride	2.2	
119.	3%HCl solution	0.2	
120.	10% Sodium bicarbonate solution	17.8	
121.	Methane sulfonic acid	1.2	
122.	15% Sodium chloride solution	10.7	
123.	Dysol (Denatured ethanol containing toluene)	12.0	
124.	45-48% HBr solution	1.2	
125.	Acetone	4.6	
126.	2-Amino-6-chloro-3-nitropyridine	0.5	
127.	4-Fluorobenzylamine	0.3	
128.	Raney Nickel	0.0	
129.	Hydrazine hydrate (70-80%)	0.6	
130.	Ethylchloroformate	0.3	
131	Maleic acid	0.4	

2.6 RESOURCE OPTIMIZATION / RECYCLING AND REUSE IN THE PROJECT

The materials are packed in drums and stored in a very organized way, segregated as Solid and Liquid area in warehouse. We have good practices in place like good house-keeping, good Manufacturing practices, best

Environment control, safety and health practices. By adoption of continuous improvement in technology and processes the desired reduction in process waste generation will be achieved. By proper and efficient handling of raw materials, wastages of raw materials will be reduced.

2.7 AVAILABILITY OF WATER ITS SOURCE, ENERGY / POWER REQUIREMENT AND SOURCE

WATER

Total water requirement for the proposed expansion project would be estimated as 78.25 KLD, which would be sourced from Ground water using borewell.

POWER

Total power requirement for the proposed expansion project will be 250 KVA. During emergency purpose D.G. Set of 200 KVA will be utilized. Power supply shall be full-filled by MGVCL (Madhya Gujarat Vij Corporation Limited).

2.7.1 WATER REQUIREMENT AND WASTE WATER GENERATION

Total wastewater i.e. 38.25 KLD will be generated from the proposed expansion project, from that 4.5 KLD sewage wastewater shall be generated from domestic uses which will be disposed off through septic tank/soak pit system, remaining 33.75 KLD industrial effluent will be given primary, secondary and tertiary treatment. Treated effluent will be sent to CETP operated by M/s. Enviro Infrastructure Co. Ltd. (EICL), Umaraya for further treatment and final disposal..

2.7.2 FUEL REQUIREMENT

HSD: 60 lit/hr will be used for D. G. Set for emergency purpose only,
LDO: Existing 0.04 KLD, Proposed 2.88 KLD will be used for Boiler and Thermic Fluid Heater (TFH) both fuels will be procured from nearest petrol pump.

2.7.3 AIR POLLUTION

EMISSIONS FROM COMBUSTION OF FOSSIL FUELS FROM STATIONARY OR MOBILE SOURCES

SR. NO.	STACK ATTACHED TO	FUEL USED	STACK HEIGHT	POLLUTION CONTROL SYSTEM	FINAL CONCENTRATION
EXISTING					
1.	Baby Boiler* (500 Kg/Hr)	LDO/FO 0.04 KLD	9 meter	LDO/FO is used as a fuel, adequate stack height is provided	SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
2.	Thermopack (4 Lac Kcal/hr)		9 meter		SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
PROPOSED					
1.	Steam Boiler (2000 Kg/Hr)	LDO/FO 120 Lit/Hr	30 meter	As LDO/FO is used as fuel, adequate stack height is provided	SPM ≤ 150 mg/Nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm
2.	D. G. Set (200 KVA)	HSD 60 Lit/hr	10 meter	As HSD is used as fuel, adequate stack height is provided	SPM ≤ 150 mg/nm^3 SO_2 ≤ 100 ppm NO_X ≤ 50 ppm

Note: Baby Boiler (500 Kg/hr) will be replaced by Steam Boiler (2000 kg/hr)

PROCESS EMISSION

SR. NO.	STACK ATTACHED TO	FUEL USED	STACK HEIGHT	POLLUTION CONTROL SYSTEM	FINAL CONCENTRATION
EXISTING					
1.	*Glass Vessels	NA	10 meter	Water Scrubber with circulation tank pump	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20mg/Nm^3 HBr ≤ 30 mg/Nm^3 NH_3 ≤ 175 mg/Nm^3
PROPOSED					
1.	Glass Vessels	NA	20 meter	Alkali Scrubber followed by Water Scrubber	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20 mg/Nm^3 HBr ≤ 30 mg/Nm^3
2.			20 meter	Acidic Scrubber followed by Water Scrubber	NH_3 ≤ 175mg/Nm^3
3.	Glass Vessels	NA	20 meter	Alkali Scrubber followed by Water Scrubber	SO_2 ≤ 100 ppm NO_X ≤ 50 ppm HCl ≤ 20 mg/Nm^3 HBr ≤ 30 mg/Nm^3
4.			20 meter	Acidic Scrubber followed by Water Scrubber	NH_3 ≤ 175 mg/Nm^3

* Note: Glass vessel in existing facility having a stack with water scrubber will be replaced by two separate stacks (Acidic and Alkali)

2.7.5 SOLID WASTE GENERATION AND ITS MANAGEMENT

The sources of solid wastes, generation and its management are as given in the following table.

SR. NO.	NAME OF THE WASTE	CAT NO.	EXISTING	PROPOSED	TOTAL	METHOD OF STORAGE AND DISPOSAL
1.	Used Oil	5.1	400 Lit/Year	400 Lit/Year	800 Lit/Year	Collection, storage and reuse as lubricants in the machineries within the premises only or send to authorized re-processors.
2.	Discarded Containers/Barrels/plastic	33.3	480 Nos./Year	350 Nos./Year	830 Nos./Year	Collection, storage and send to authorized recycler after decontamination.
3.	ETP Sludge	34.3	0.6 MT/year	49.4 MT/Year	50.0 MT/Year	Collection, storage and transport to TSDF site.
4.	Process Residue & Waste	28.1	1.2 MT/Year	35 MT/Year	36.2 MT/Year	Collection, Storage and send for incineration.

SR. NO.	NAME OF THE WASTE	CAT NO.	EXISTING	PROPOSED	TOTAL	METHOD OF STORAGE AND DISPOSAL
5.	Spent Solvent	28.5	--	500 MT/Year	500 MT/Year	Collection, Storage and send to re-processor.
6.	Spent Carbon/Hyflow	28.2	--	0.04 MT/Day	0.04 MT/Day	Collection, Storage and send for incineration.
7.	Off Specification Drugs	28.4	---	1.0 MT / Year	1.0 MT / Year	Collection, Storage and send for incineration.

CHAPTER-3

SITE ANALYSIS

3.1 CONNECTIVITY

3.1.1 RAIL

The nearest railway station is Samlaya Station, which is around 3.4 km in North West north direction from the project site.

3.1.2 ROAD

The site is well connected by road network to all the key places. The major highway passing near the project site is NH-8 which is around 20 km South West direction from the project site and SH-63 is adjacent to the project site in east direction.

3.1.3 AIR

The nearest airport from the project site is Vadodara Airport. The distance of airport from project site is around 17.8 km in South West direction.

3.1.4 COMMUNICATION

Proposed project site is within existing company premises which is already well connected with telephone, telefax etc. all the communications facilities are well developed in the area.

3.2 TOPOGRAPHY

Topography of the land is plane.

3.3 EXISTING LAND USE PATTERN

There is no Forest, National park; Wild life sanctuary within a radius of 10 km. Details of existing land use is given in the following table:

DETAILS OF EXISTING LAND USE

SR.NO.	PARTICULAR	NAME & ITS DISTANCE
1.	Nearest National Highway	NH-8 which is around 20 km south west direction
2.	Nearest city	Vadodara City is around 16 km in south west direction
3.	Nearest River	Vishwamitri at 20 km in north west direction
4.	Nearest Railway station	Samlaya Station at around 3.4 km in north west north direction.
5.	National park/Reserve Forest, Biosphere, etc.	None within 20 km

3.4 EXISTING SOCIAL STRUCTURE

Project site is located at a distance of around 16 km from Vadodara City. All the infrastructures are available within city like Schools, Hospitals & community facilities even nearby area of the project site is also developed.

CHAPTER – 4

PLANNING BRIEF

4.1 PLANNING CONCEPT

Type of industries:

The Active Pharmaceutical Ingredient industry is the organ by which active pharmaceutical ingredients are manufactured from raw materials through both chemical and physical means. Depending on the complexity of the molecule required, synthesis of APIs might need multi-step complex chemistry utilizing a range of processing technologies.

4.2 LAND USE PLANNING

The plant general Layout has been planned considering production facilities, auxiliary and ancillary facilities and plant utilities & services. The total plot area is 11,059 m^2. Land use shall be as build up area of buildings, storage facility, roads, greenbelt, open land etc., these kinds of facilities will be developed.

4.3 AMENTIES / FACILITIES

Adequate storage facility for chemicals, machinery spares and consumables shall be provided. A small mechanical and electrical/ instrument workshop facilities for repairs and maintenance shall be provided. Time and security offices shall be provided in the plant. To avoid fire hazard, internal fire hydrants system in all major plant unit will be provided.

CHAPTER – 5

PROPOSED INFRASTRUCTURE

5.1 INDUSTRIAL AREA

The company has already acquired land area of 11,059 m^2 in which company will expand their production capacity.

5.2 GREEN BELT

The main objective of the green belt is to provide a barrier between the source of pollution and the surrounding areas. The green belt helps to capture the fugitive emission and to attenuate the noise generated apart from improving the aesthetics. Development of green belt and other forms of greenery shall also prevent soil erosion and washing away of topsoil besides helping in stabilizing the functional ecosystem and further to make the climate more conducive and to restore water balance. The company will develop green belt area with Lawn, plants and flowers spread across about 33% of the total area i.e. 3650 m^2.

Green belt shall be developed at plant boundary, road side, around offices & buildings and Stretch of open land.

The selection of tree species suitable for plantation at the industry are governed by guiding factors as stated below:

- The trees should be tolerant to air pollutants present in the area
- The trees should be able to grow and thrive on soil of the area, be evergreen, inhabitant, having minimum of leaf fall.
- The trees should be tall in peripheral curtain plantation and with large and spreading canopy in primary and secondary attenuation zone.
- The trees should posses extensive foliar area to provide maximum impinging surface for continued efficient adsorption and absorption of pollutants.
- The trees should be fast growing and indigenous and should maintain ecological, land and hydrological balance of the region.
- It is also recommended to plant few trees, which are sensitive to air pollution, as air pollution indicator.
- It is also recommended to carry out extensive plantation within premises.

Keeping in view the climatic conditions, status of soils and vegetation types in and around the project area the species shall be selected for proposed green belt development.

5.3 SOCIAL INFRASTRUCTURE

Drinking water facility, Canteen, proper sanitation, etc. will be provided to the workers working in plant.

5.4 CONNECTIVITY

As discussed earlier, proposed location of the plant is already well connected with the network of road & rail. So there is no need to construct any new road or rail for the transportation.

5.5 WASTE WATER MANGAMENT

Total 38.25 KLD wastewater will be generated from the unit out of which 33.75 KLD industrial effluents will be generated from manufacturing process & washing, Cooling and boiler blow down, RO reject and will be given primary, secondary and tertiary treatment. Treated effluent will be sent to CETP operated by M/s. Enviro Infrastructure Co. Ltd. (EICL), Umaraya for further treatment and final disposal.

5.7 INDUSTRIAL SOLID WASTE MANAGEMENT

From the proposed expansion project activity there shall be mainly Spent/Used Oil, ETP Sludge, Process Residue & Waste, Spent Solvent, Spent Carbon/Hyflow, Off Specification Drugs and Discarded containers.

CHAPTER – 6

REHABILITATION AND RESETTLEMENT (R & R) PLAN

The project is located on private land, which is already acquired and there is no habitat. So the project proposal does not involve any Rehabilitation & Resettlement.

PROJECT SCHEDULE & COST ESTIMATES

7.1 TIME SCHEDULE FOR THE PROJECT

The implementation of the project will involve major activities like preparation of specification / drawings, issue of tenders, receipt of quotations, scrutiny of tenders, placing of orders, civil & structural construction, delivery & erection of equipment, test trial runs of various items of equipment and commissioning of the plant & equipment and completion of the project will take about 6 months after the necessary clearances are available, and the funding for the project has been tied up.

7.2 ESTIMATED PROJECT COST

The total project cost for the proposed expansion project would be around Rs. 12 crores. Total capital cost of pollution control measures will be Rs. 0.80 crores & recurring cost per annum will be 0.25 crore.

7.3 BUDGETORY PROVISIONS FOR EMP

Adequate budgetary provisions have been made by the management for execution of environmental management plans. The details of capital and recurring (per annum) budget earmarked for pollution control / monitoring equipment; operation and maintenance of pollution control facilities, for greenbelt development and maintenance.

COST OF ENVIRONMENTAL PROTECTION MEASURES

SR. NO.	PARTICULATES	RS. IN LACS
1.	Capital Expenditure	80
2.	Recurring expenditure on environmental management cell and on pollution control systems per annum.	25

CHAPTER – 8

ANALYSIS OF PROPOSAL

8.1 FINANCIAL AND SOCIAL BENEFITS

The total cost of the proposed expansion project is estimated at about Rs. 12 crores for the installation of plants & machinery along with required auxiliary and balancing facilities for the production.

For the coming of this project surrounding area will get developed due to this project and through the Corporate Social Responsibility (CSR) activities, socio-economic status of the region will also get developed.