PREFEASIBILITY REPORT

FOR

MODIFICATION & EXPANSION- MANUFACTURING OF BULK DRUGS & INTERMEDIATES FACILITY

AT

SURVEY NO. 8 & 16, PLOT NO. 183,

KIADB KOLHAR INDUSTRIAL AREA,

BIDAR TALUK & DISTRICT, KARNATAKA

PROMOTER:

M/S. STEREO DRUGS PRIVATE LIMITED

BIDAR

For Stereo Drugs Pvt. Ltd.

Managing Director

1. EXECUTIVE SUMMARY

M/s. **Stereo Drugs Private Limited** is situated in **Kolhar Industrial area, Kolhar** in **Bidar** district of **Karnataka State**. It is a progressive company engaged in the Manufacturing of API's & Intermediates and is professionally managed by people who have vast experience in the field of bulk drugs. The company is promoted by technically qualified and professionally experienced technocrats who crave for innovation and value addition. We recognize that our ability to excel in our core competences depends on the skill, knowledge, creativity and hard work of our employees. A high standard of ethics, integrity and responsibility towards our customers remains our top priority. The company's competitiveness is displayed not only in cost-effectiveness and fast time frames but also in dependability, quality and respect for intellectual property rights and strict procedural norms ensuring clients and associates absolute confidentiality. We have a well established and highly motivated R&D team working relentlessly to develop new molecules and to improve the quality and process of the existing products. Manufacturing with effective quality management is of paramount importance to our success. Our manufacturing sites are regularly evaluated internally and inspected by regulatory authorities to ensure that finished product have the identity, strength, quality and purity they are required to have. Our line of products is vast and varied. With a strong emphasis on innovative and efficient process development our products conform to the highest standards of quality that we have set for ourselves. Apart from our core competence in standard unit operations, process innovation and development to achieve higher yields, we see ourselves as our customers long term and faithful partners, motivated by the understanding that the customers success is our success.

The company as established in the year 2008, at Hyderabad, Telengana State, India, "Stereo Drugs Private Limited" provides a wide range of Pharmaceutical Drugs and Drug Intermediates. They have come with the objective of delivering innovative organic as well as biotransformation solutions. The major clients include Lupin Ltd, Actavis, Glenmark Ltd, Dr Reddys and MSN Labs, Emcure.

For Stereo Drugs Pvt. Ltd.

Managing Director

With the assistance of qualified professionals including those who have already worked in the renowned pharmaceutical companies in India as well as abroad, they are able to provide quality chemicals. The company in a short span of time has expanded its operations to offer total turnkey solutions to the various Indian pharmaceutical industries. Organization offers both standard as well as custom made APIs & intermediates to its clients. Owing to our quality chemicals, large installation capacity, cost effective supply and customized packaging, they have secured a remarkable position in this domain in short time.

The main objective of M/s. Stereo Drugs private Limited is to modify its manufacturing unit by producing products such as 2-Acetyl Thiophene, Darunavir, Ritonavir, Linezolid etc. The company is presently manufacturing the consented products of cellulose powder & Methyl Cellulose Crystalline powder at Bidar, Karnataka State. The Company has manufactured only 2 or 3 APIs as there is no demand for other drugs. As a common problem for the bulk drug manufacturing companies, and the inconsistency in the market, the company is unable to sustain in the market. The Industry has got permission only for the above drugs, is unable to manufacture any other product, even though the orders are in hand for other latest products. In these circumstances the company decided to change the products mix within the limits and rules prescribed by the pollution control Board for survival. The company can manufacture the proposed API's and Bulk drugs with the existing infrastructure facilities without any major alterations.

Quality Policy:

Stereo Drugs Private Limited manufacturing products of high quality and creates an environment where each employee contributes to all aspects of our business processes. The company recognizes that quality is not just another goal, but an essential strategy for growth. Towards this objective of quality we advocate continuous improvement in all our activities by fostering teamwork, innovation, providing good working environment and effective training to our employees to make them more competent and quality conscious.

Quality Assurance:

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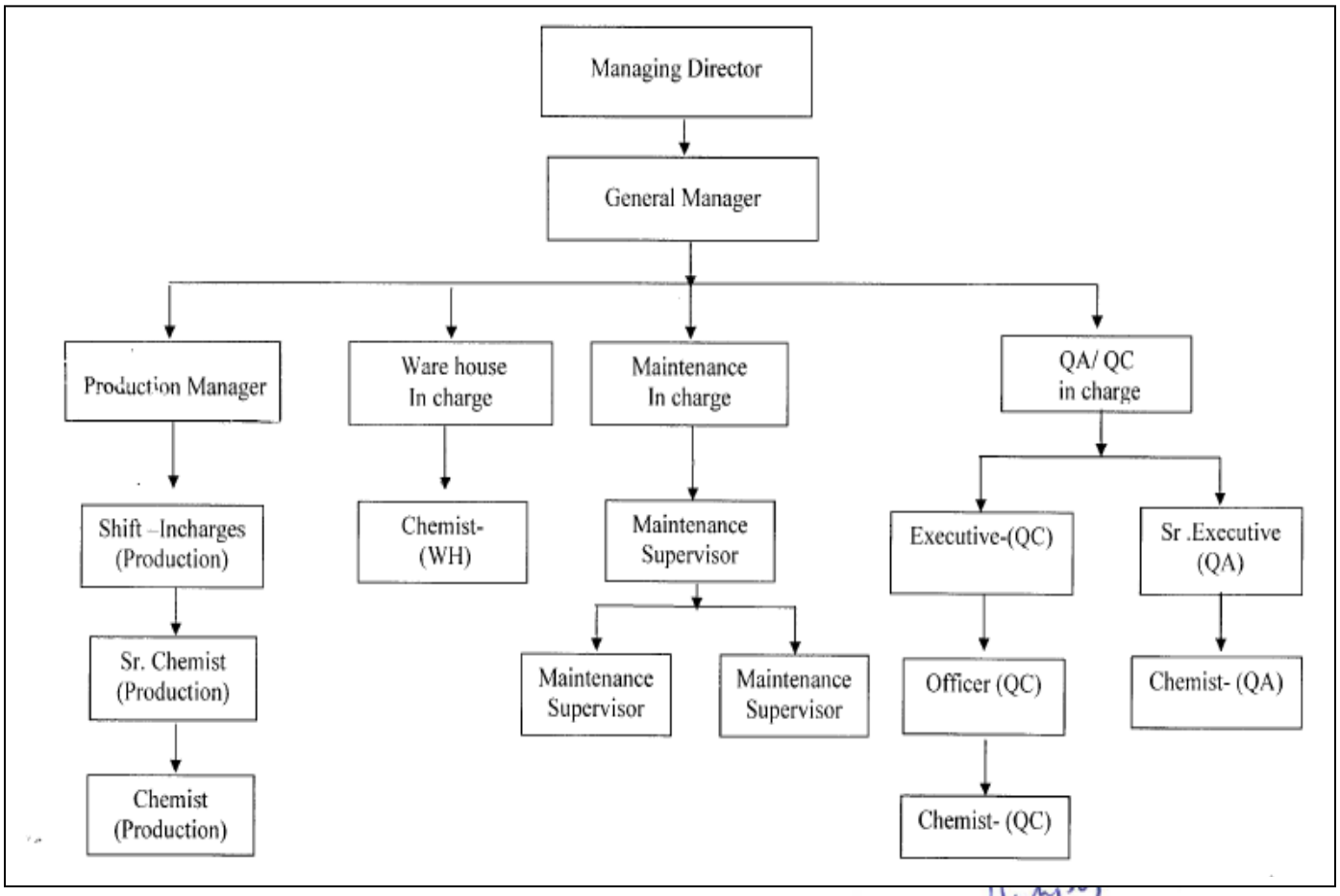
The company's quality focus encompasses all areas of the manufacturing operations-from procurement of raw materials to best possible manufacturing technology, from on time delivery of the customer's requirements to promotional help pushing its product to become the market brand thus ensuring a rapid penetration in the domestic markets-nationwide.

Key personnel details

S.No.	Name of the Employee	Qualification	Designation	Experience
01	Mr. K.Suryanarayana	M.Pharmacy (P.hd.,)	CEO & Managing Director	25 Years
02	Mr. Nagendra Prasad	B.E Chemical Engineering	Production Manager	23 Years
03	Mr. D.Nagendra Babu	M.Sc., M.Phil	Manager-QA & QC	14 Years
04	Mr. A.V. Ram Babu	DME	Manager-Engg & Maintenance	12 Years
05	Mr. Ambresh Cholker	M.Sc. Biotechnology	Asst., Manager- QA	05 Years

Organization Chart:



Managing Director

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 in product of drug manufacturing & intermediates in the premises; existing product will be stopped and addition of new drug products for API is proposed to manufacturing of products. The modification of Bulk drugs manufacturing industry is located at survey No. 8 & 16, Plot No. 183, KIADB Kolhar Industrial Area, Bidar Taluk & 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.
M/s. Stereo Drugs Private Limited is positioned to become one of leading Pharmaceuticals and Specialty Chemicals Manufacturing and Exporting 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 and exports. 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

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countries. According to the Department of Pharmaceuticals, the sector employs 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.

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.

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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 both locally and in European Market. 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 2-Acetyl Thiophene, Darunavir etc., by discontinue 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 quality APIs but also in bringing down the prices of wide range of APIs, which are being imported in large quantities.

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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 Stereo Drugs Private Limited 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 plans to export its products to outside the countries. The company has a long list of satisfied regular customers across the globe.

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.

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

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The total strength of the M/s Stereo Drugs Private Limited plant facilities is 40 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 modify its production capacity in the existing unit at Survey No 8 & 16, Plot No. 183, KIADB Kolhar Industrial Area, Bidar Taluk & District, Karnataka.

All the required concrete structures for the manufacture of the proposed change 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

17°54'27.21"N
77°27'21.46"E

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Managing Director

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 co-ordinates (Latitude & Longitude)	**Direction**	**Latitude**	**Longitude**
		North	17° 54' 28.2" N	77° 27' 21.8" E
		South	17° 54' 27.1" N	77° 27' 20.9" E
		East	17° 54' 25.3" N	77° 27' 23.7" E
		West	17° 54' 26.4" N	77° 27' 23.9" E
2	Temperature	Max. - 42ºC, Min. -28ºC		
3	Present land-use	KIADB land (Industrial area)		
4	Average rainfall	885 mm per year		
5	Nearest Highway	SH- 105 (Bidar-Humnabad road) – 0.9 Km (N)		
6	Nearest Railway station	Bidar railway station – 6.4 Km (E)		
7	Nearest Airport	Rajiv Gandhi International Airport, Shamshabad – 119 Km (SE)		
8	Nearest Water body	Papnash river - 4.5 Km (NE) Janwada kere – 9.3 Km (N) Karanja Riservoir – 15 Km (W)		
9	Nearest Village	Kolhar -1.8 Km (N)		
10	Nearest Town/City	Bidar city – 6.9 Km (E)		
11	Reserved/ protected Forests	Honnikere Reserved forest – 2.9 Km (N) Chitta Reserved forest – 3.3 Km (SE) Kamthana Reserved forest – 4.9 Km (N) Kaplapur protected forest – 5.8 Km (NW)		
12	Seismic Zone	Seismic zone-II as per IS-1893 (Part-1) - 2002		
13	Defence Installations	Bidar Air Force – 250m (E)		
14	Interstate boundary	Karnataka – Andhra Pradesh – 14.4 Km (E) Karnataka – Maharashtra– 38 Km (N)		

iv. Size or magnitude of operation

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M/s. Stereo Drugs Private Limited, is presently planning to modify the manufacturing of chemical product and its capacity at proposed unit at survey No. 8 & 16, plot No. 183, Kolhar Industrial Area, Bidar Taluk & District.

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The details of the manufacturing chemical drug products are given in Table 2.4.1 & Table 2.4.2.

TABLE 3.4.1: LIST OF EXISTING PRODUCTS

Sl.No.	Products	Capacity (TPM)
1	Cellulose powder & Methyl Cellulose Crystalline powder	**30**

Existing products production stopped and will not produce in future

TABLE 3.4.2: LIST OF PROPOSED PRODUCTS

Sl. No	Name of the product	TPM
1.	2-Acetyl Thiophene	1.0
2.	(S)-Methyl-2-(3-((2-isopropylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanoate	2.0
3.	(S)-3-(3-Fluoro-4-morpholinophenyl)-5-(hydroxymethyl) oxazolidin-2-one	1.0
4.	Darunavir	1.0
5.	Desvenlafaxine Succinate Monohydrate	1.0
6.	Dapoxetine Hydrochloride	0.5
7.	Ketorolac Tromethamine	1.0
8.	Sitagliptin Phosphate Monohydrate	0.5
9.	Pregabalin	1.0
	Total	**9.0**

Any two products at a time will be produced from the above listed products.

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 the existing product

Methyl Cellulose:

Description:

Stage-1: Cellulose powder reacts with chloromethane in Ethyl acetate media to get Methyl Cellulosed by centrifuging.

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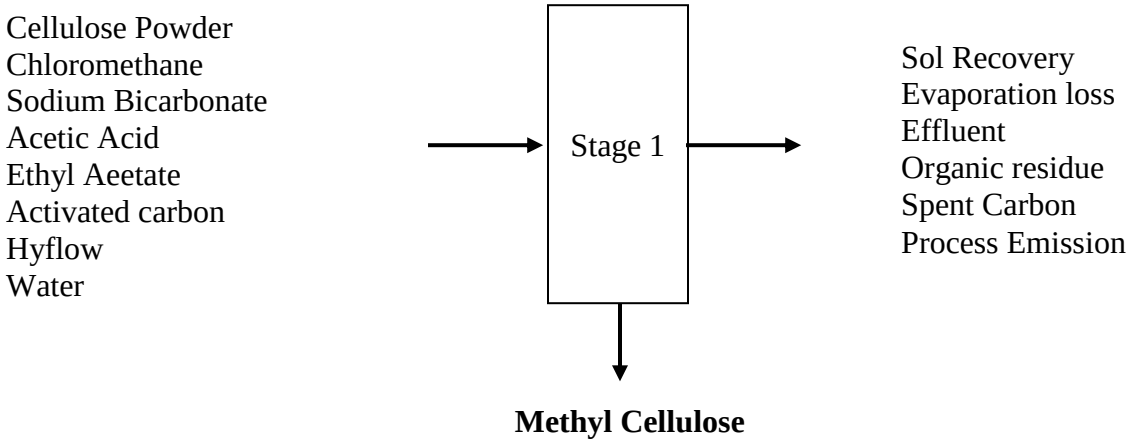
Flow chart:



Mole Balance:

Input	No. of moles	Mol.Wt.
Cellulose powder	1	324
Chloromethane	6	303
Sodium Carbonate	3	318
Total input		**945**

Output	No. of moles	Mol.Wt.
Methyl cellulose	1	408
Sodium chloride	6	351
Water	3	54
Carbon Dioxide	3	132
Total output		**945**

Material Balance:

Input	kg		Output	kg
Cellulose powder	1060		**Product**	
Chloromethane	1160		Methyl Cellulose	1000
Sodium Bicarbonate	1350		**Recovery**	
Acetic acid	350		Ethyl Aeetate	9858
Ethyl Aeetate	10600		Ethyl Aeetate Loss	530
Activated Carbon	50		**Aqueous**	
Hyflow	75		Effluent (Sodium Chloride 1303.22, Sodium Acetate 261.95, Methanol 106.9, Acetic acid 158.33, gen.water 205.42, Water 6963.69)	8999.51
Water	7000		**Organic Residue**	

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			Un-reacted Organic Impurities (Organic Impurities 334.81, Ethyl Acetate 212)	546.81
			Spent Carbon	
			Spent Carbon (Carbon 50, Hyflow 75)	125
			Process Emissions	
			Process Emissions (Hydrogen Chloride 25.3, Carbon Dioxide 560.38)	585.68
Total Input	**21645**		**Total Output**	**21645**

Description of the proposed products

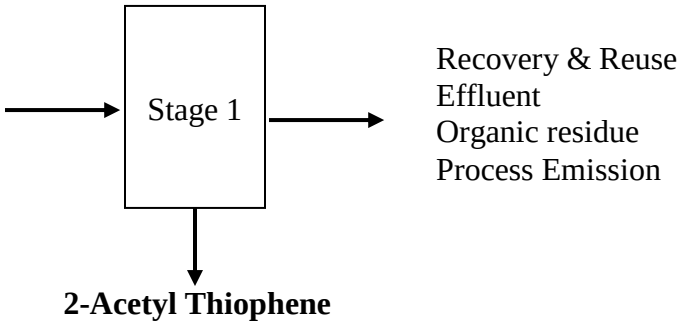
1. 2-ACETYL THIOPHENE:

Description:

Stage-1: Thiophene is undergoes Acetylation with Acetic anhydride to get 2-Acetyl Thiophene as final product.

Flow chart:

Thiophene
Acetic Anhydride
Phosphoric acid
Sodium carbonate
Water



Route of synthesis of product:

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Mole Balance:

Input	No. of moles	Mol.Wt.
Thiophene	1	84
Acetic Anhydride	1	102
Total input		**186**

Output	No. of moles	Mol.Wt.
2-Acetyl Thiophene	1	126
Acetic acid	1	60
Total output		**186**

Material Balance:

Input	kg
Thiophene	184
Acetic Anhydride	132
Phosphoric acid	11
Sodium Carbonate	20
Water	450
Total Input	**797**

Output	kg
Product	
2-Acetyl Thiophene	100
Recovery	
Thiophene	92
Acetic acid	75
Aqueous	
Effluent (Trisodium Phosphate 18.41, Sodium Acetate 3.33, Acetic acid 12.14, gen.water 3.4, Water 446.42)	483.7
Organic Residue	
Un-reacted Organic Impurities (Organic Impurities)	38
Process Emissions	
Process Emissions (Carbon Dioxide)	8.3
Total Output	**797**

2. (*S*)-METHYL-2-(3-((2-ISOPROPYLTHIAZOL-4-YL)METHYL)-3-METHYLUREIDO)-3-METHYLBUTANOATE

Description:

Stage-1: L-Valline methylester Hydrochloride is treated with Phenyl chloroformate in presence of Sodium Carbonate base in Toulene solvent media to get Stage-1 compound.

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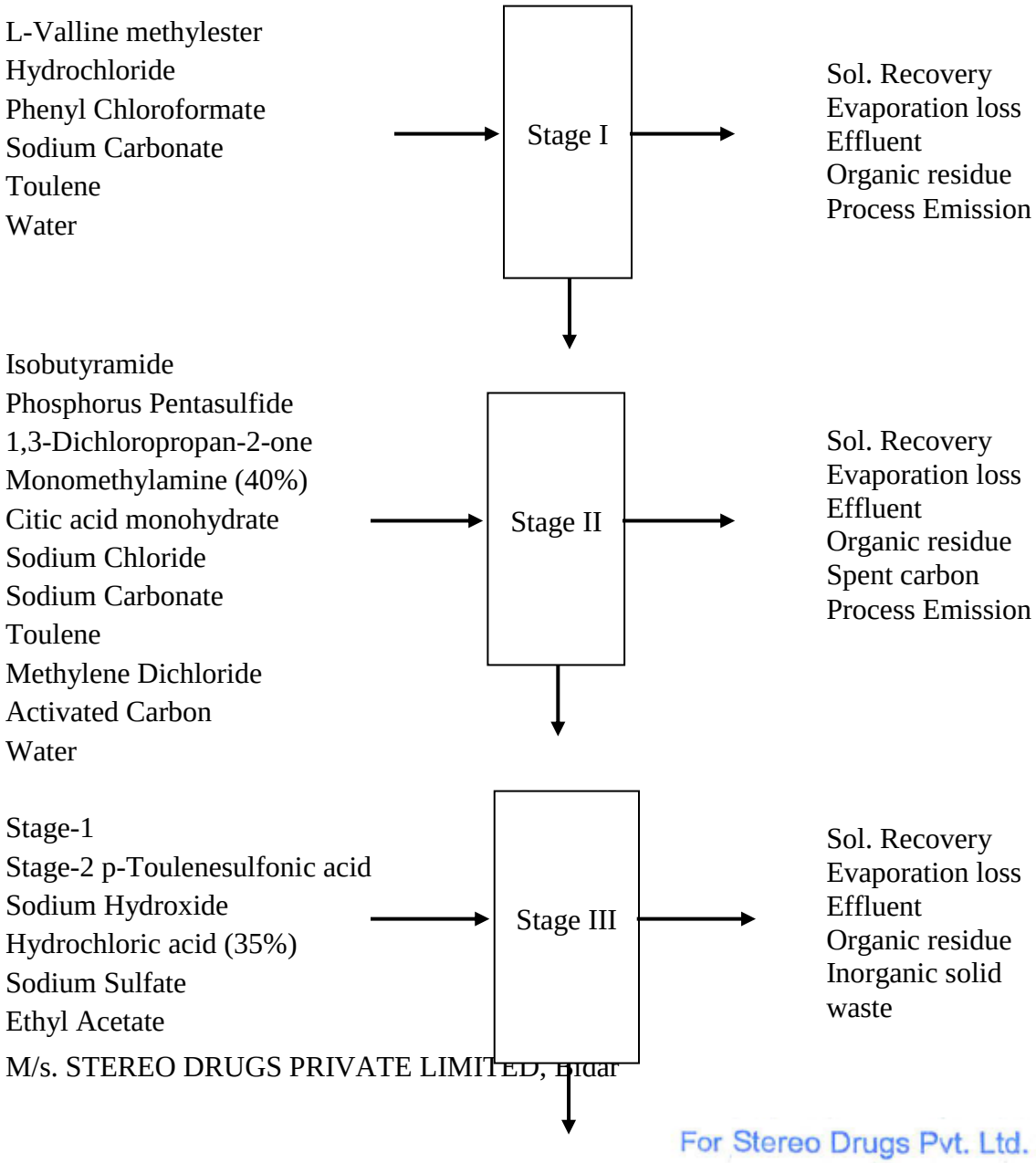
Stage-2: Isobutyramide reacts with Phosphorus Pentasulfide, 1,3-Dichloropropan-2-one and Monomethylamine in presence of Sodium Carbonate base in Toulene and Methylene Dichloride are as solvent media to get Stage-2 compound.

Stage-3: Condensation of Stage-1 compound and Stage-2 compound in presence of Sodium hydroxide in Ethyl acetate and n-Heptane are as solvent media to get (S)-Methyl-2-(3-((2-isopropylthiazol-4-yl) methylureido)-3-methylbutanoate.

Flow chart:



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n-Heptane
Hyflow Water

(S)-Methyl-2-(3-((2-isopropylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanoate

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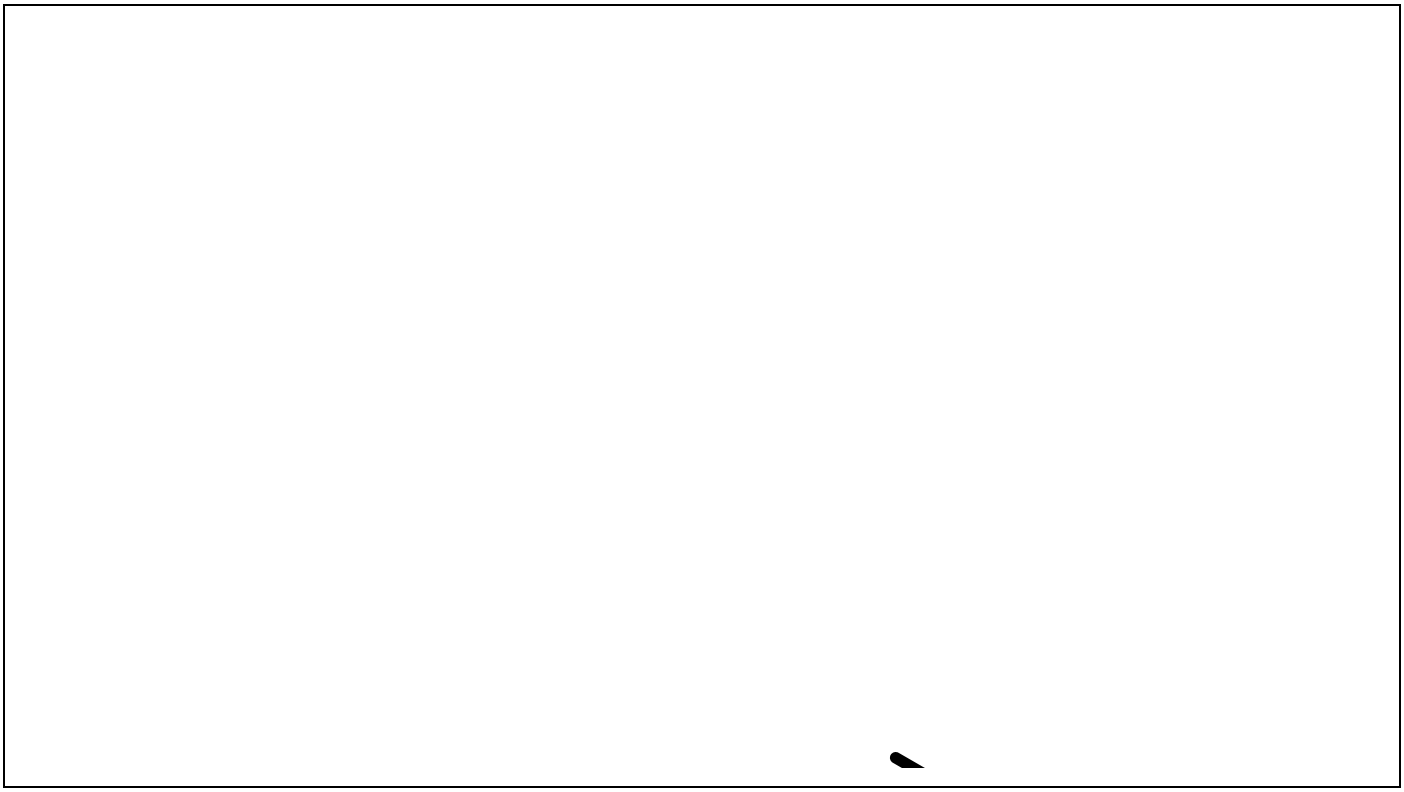
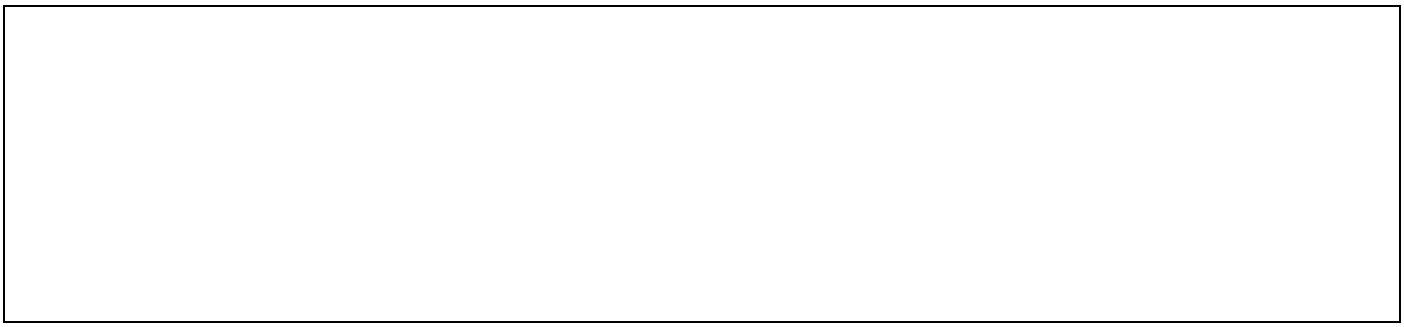
Route of synthesis of product:

Stage-1:



Stage-2:



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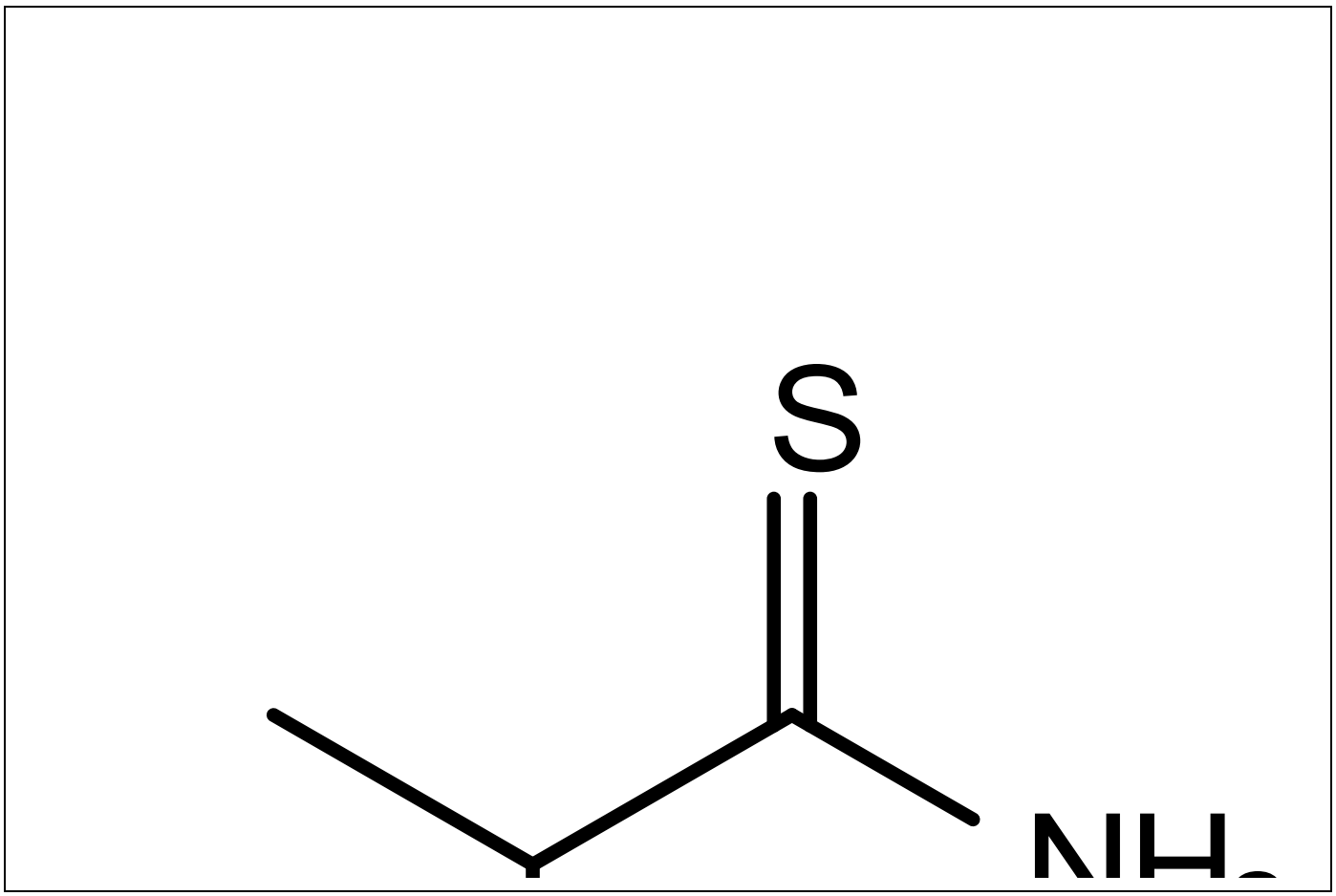

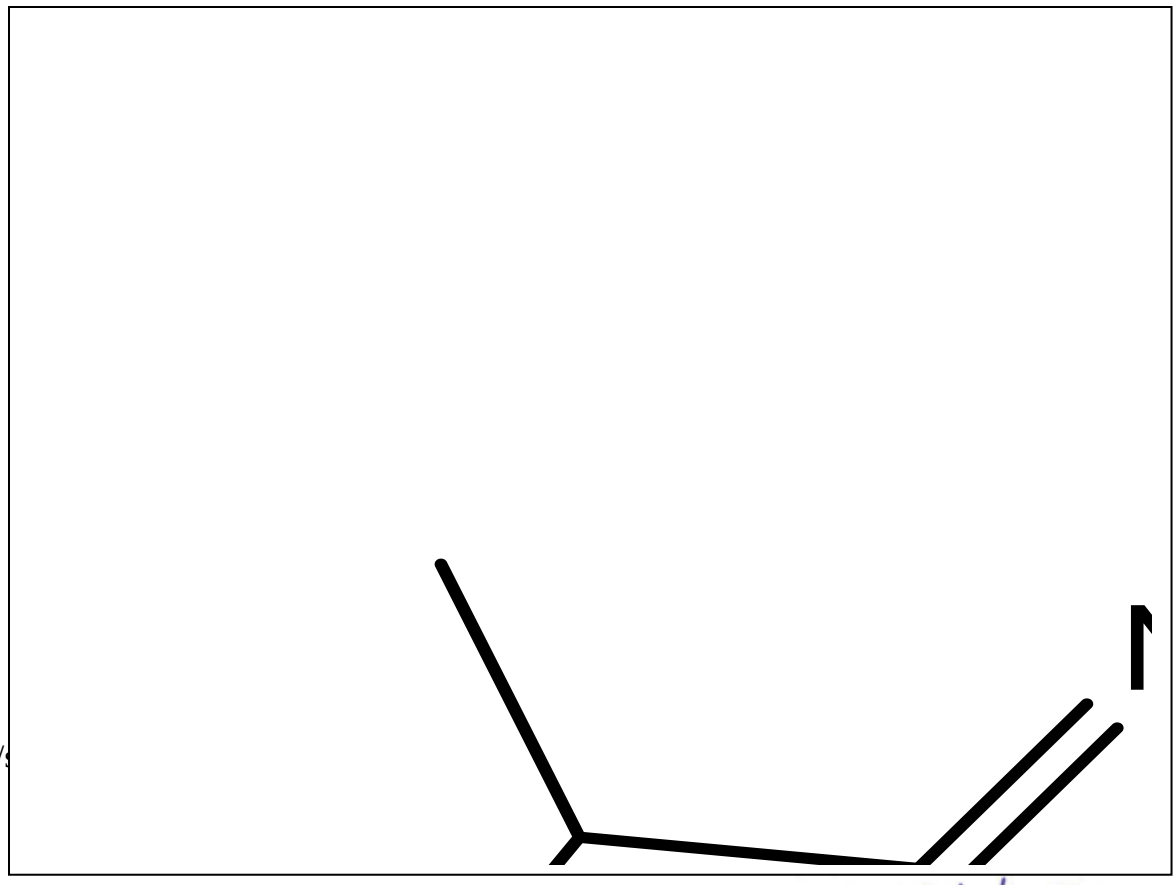

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Stage-I:

Mole Balance:

Input	No. of moles	Mol.Wt.
L-Valline methylester	1	167.5
Hydrochloride Phenyl Chloroformate	1	156.5
Sodium Carbonate	1	106
Total input		**430**

Output	No. of moles	Mol.Wt.
Stage-I	1	251
Sodium chloride	2	117
Carbon Dioxide	1	44
Water	1	18
Total output		**430**

Material Balance:

Input	kg
L-Valline methylester	117
Hydrochloride Phenyl Chloroformate	127
Sodium Carbonate	100
Toulene	750
Water	1500
Total Input	**2594**

Output	kg
Product	
Stage-I	150
Recovery	
Toulene	705
Toulene loss	30
Aqueous	
Effluent (Sodium Chloride 88.34, Sodium Phenoxide 13.1, Sodium Carbonate 13.99, gen.water 12.57, Water 1500)	1628
Organic Residue	
Un-reacted Organic Impurities (Organic Impurities 25.33, Toulene 15)	40.33
Process Emissions	
Process Emissions (Carbon Dioxide)	40.67
Total Output	**2594**

Stage-II:

Mole Balance:

Input	No. of moles	Mol.Wt.
Isobutyramide	5	435
Phosphorus Pentasulfide	1	222
1,3-Dichloropropan-2-one	5	635
Monomethylamine	5	155
Sodium Carbonate	5	530
Total input		**1977**

Output	No. of moles	Mol.Wt.
Stage-II	5	850
Phosphorus Pentoxide	1	142
Sodium chloride	10	585
Water	10	180
Carbon Dioxide	5	220
Total output		**1977**

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Material Balance:

Input	kg		Output	kg
Isobutyramide	65		**Product**	
Phosphorus Pentasulfide	40		Stage-II	105
1,3-Dichloropropan-2-one	95		**Recovery**	
Monomethylamine (40%)	100		Toulene	611
Citic acid monohydrate	36		Toulene loss	26
Sodium Chloride	46		Methylene Dichloride	341
Sodium Carbonate	100		Methylene Dichloride loss	22
Toulene	650		**Aqueous**	
Methylene Dichloride	370		Effluent (Sodium Chloride 133.41, Phosphorus Pentoxide 25.59, Sodium Sulfide 12, Sodium Carbonate 4.49, Citic acid 32.91, Monomethylamine 16.84, gen.water 29.99, Watre from Monomethylamine 60, Water 1500)	1815.23
Activated Carbon	6			
Water	1500			
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 22.12, Toulene 13, Methylene Dichloride 7)	42.12
			Spent Carbon	
			Spent Carbon	6
			Process Emissions	
			Process Emissions (Carbon Dioxide)	39.65
Total Input	**3008**		**Total Output**	**3008**

Stage-III:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-I	1	251
Stage-II	1	170
Sodium Hydroxide	1	40
Total input		**461**

Output	No. of moles	Mol.Wt.
(S)-Methyl-2-(3-((2-isopropylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanoate	1	327
Sodium Phenoxide	1	116
Water	1	18
Total output		**461**

Material Balance:

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Input	kg		Output	kg
Stage-I	150		**Product**	
Stage-II	105		(S)-Methyl-2-(3-((2-isopropylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanoate	175
p -Toulenesulfonic acid	3		**Recovery**	
Sodium Hydroxide	50		Ethyl Acetate	372
Hydrochloric acid (35%)	100		Ethyl Acetate loss	20
Sodium Sulfate	15		n-Heptane	1395
Ethyl Acetate	400		n-Heptane loss	75
n-Heptane	1500		**Aqueous**	
Hyflow	7		Effluent (Sodium Phenoxide 69.32, Sodium Chloride 38.17, Hydrochloric acid 11.18, p -Toulenesulfonic acid 3, Ethyl Acetate 4, Water from Hydrochloric acid 65, gen.water 22.51, Water 3000)	3213.18
Water	3000		**Organic Residue**	
			Un-reacted Organic Impurities (Organic Impurities 23.82, Ethyl Acetate 4, n-Heptane 30)	57.82
			Inorganic Solid Waste	
			Inorganic Solid Waste (Sodium Sulfate 15, Hyflow 7)	22
Total Input	**5330**		**Total Output**	**5330**

3. (S)-3-(3-FLUORO-4-MORPHOLINOPHENYL)-5-(HYDROXYMETHYL) OXAZOLIDIN-2-ONE

Description:

Stage-1: 3,4-Difluoronitrobenzene is treated with Morpholine in prsence of Sodium Carbonate base to get Stage-1 compound in Water media.

Stage-2: Stage-1 compound is undergo Hydrogenation in presence of Palladium carbon then reacts with Methyl chloroformate in presence of Sodium Bicarbonate base to obtain Stage-2 compound in Ethyl acetate acts as a solvent media.

For Stereo Drugs Pvt. Ltd.

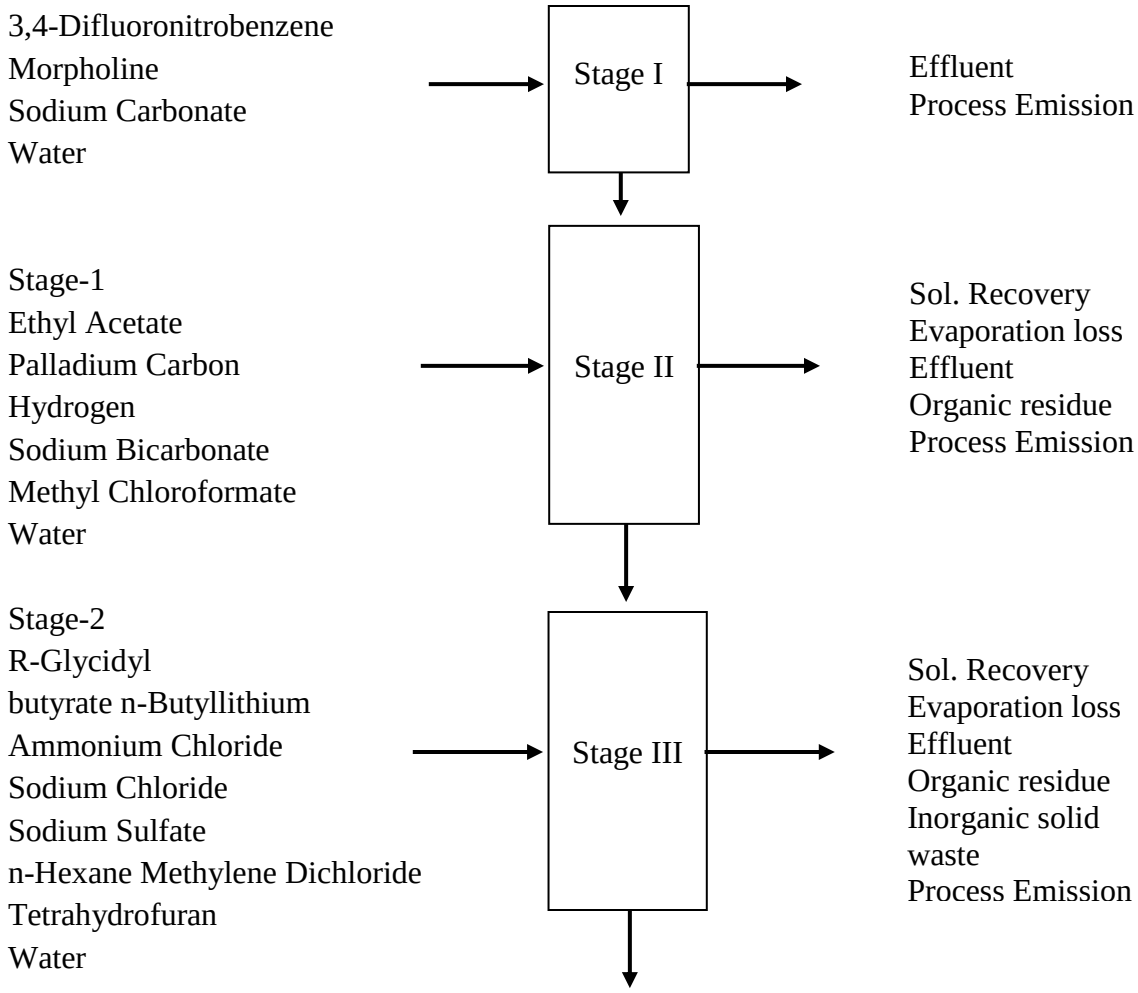
Managing Director

Stage-3: Stage-2 compound is further treated with R-Glycidyl butyrate, n-Butyllithium in presence of Ammonium chloride to get (S)-3-(3-Fluoro-4-morpholinophenyl)-5-(hydroxymethyl) oxazolidin-2-one in n-Hexane and Methylene Dichloride are as solvent media.

For Stereo Drugs Pvt. Ltd.

Managing Director

Flow chart:

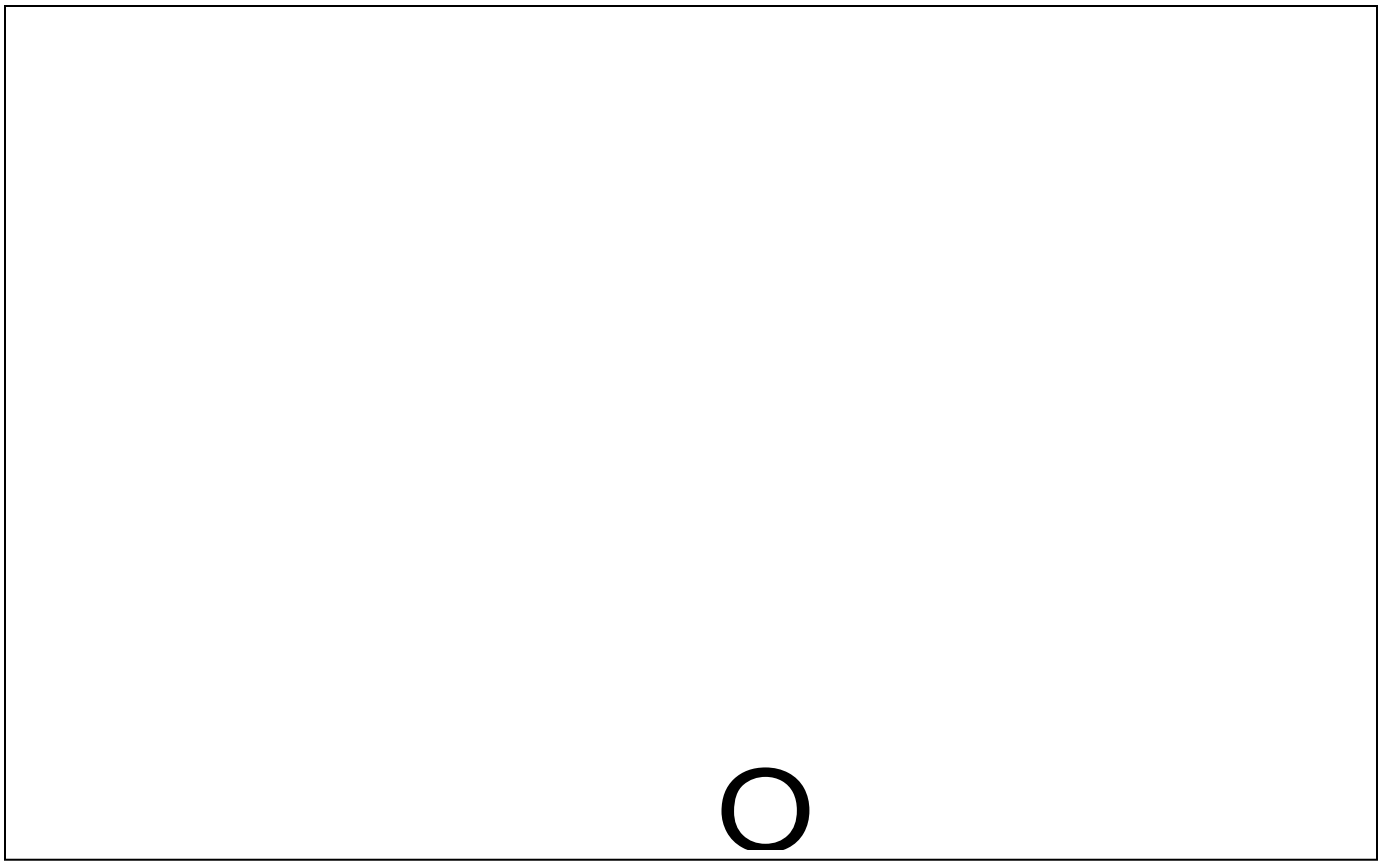


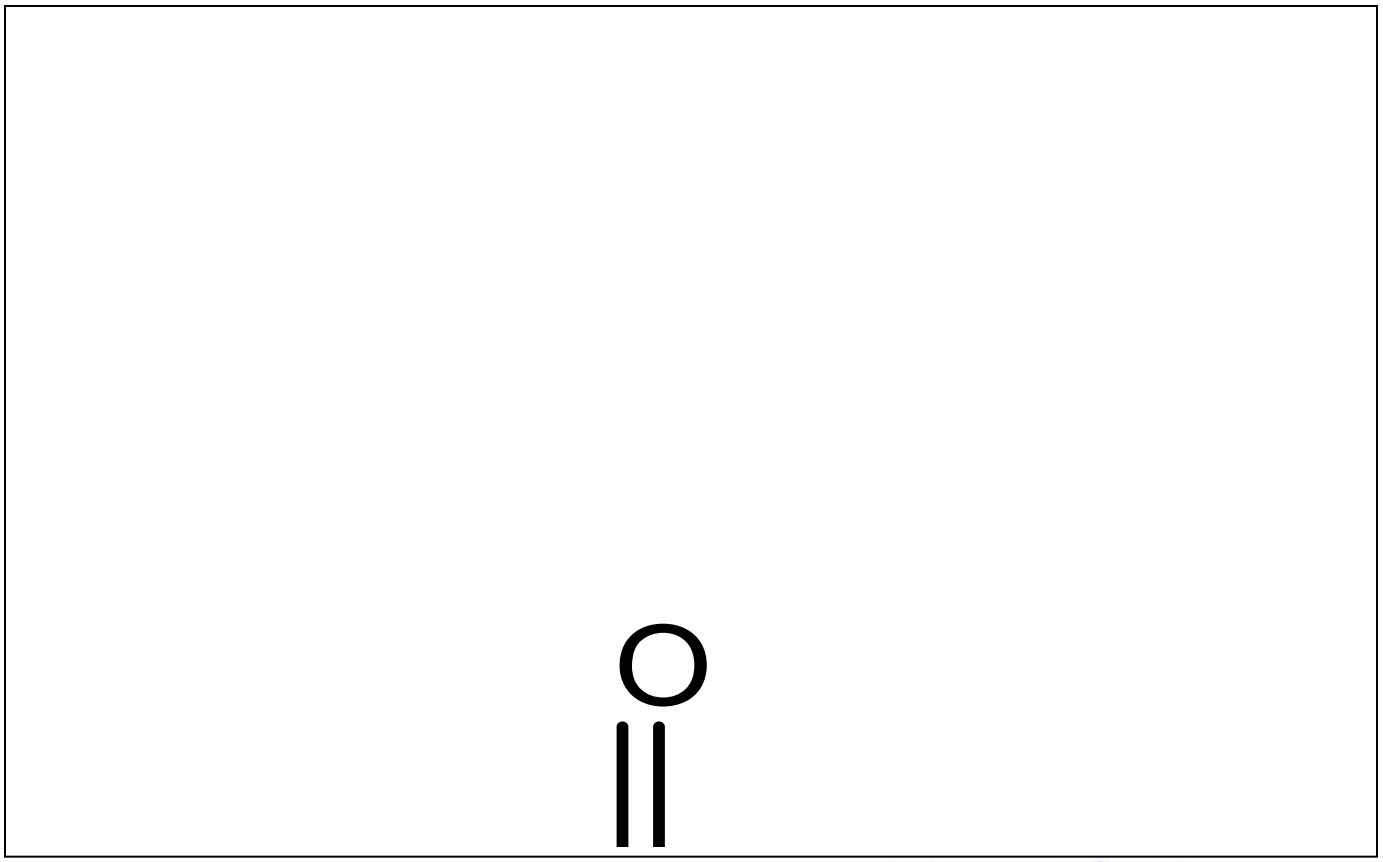
(S)-3-(3-Fluoro-4-morpholinophenyl)-5-(hydroxymethyl) oxazolidin-2-one

For Stereo Drugs Pvt. Ltd.

Managing Director

Route of synthesis of product:





Managing Director

Stage-I:

Mole Balance:

Input	No. of moles	Mol.Wt.
3,4-Difluoronitrobenzene	1	159
Morpholine	1	87
Sodium Carbonate	½	53
Total input		**299**

Output	No. of moles	Mol.Wt.
Stage-I	1	226
Sodium Fluoride	1	42
Water	½	9
Carbon Dioxide	½	22
Total output		**299**

Material Balance:

Input	kg		Output	kg
3,4-Difluoronitrobenzene	26		**Product**	
Morpholine	17		Stage-I	33
Sodium Carbonate	20		**Aqueous**	
Water	300		Effluent (Sodium Fluoride 6.87, Sodium Carbonate 11.33, Morpholine 2.77, Organic compound 3.96, gen. water 1.47, Water 300)	326.4
			Process Emissions	
			Process Emissions (Carbon Dioxide)	3.6
Total Input	**363**		**Total Output**	**363**

For Stereo Drugs Pvt. Ltd.

Managing Director

Stage-II:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-I	1	226
Hydrogen	3	6
Methyl Chloroformate	1	94.5
Sodium Bicarbonate	1	84
Total input		**410.5**

Output	No. of moles	Mol.Wt.
Stage-II	1	254
Sodium chloride	1	58.5
Water	3	54
Carbon Dioxide	1	44
Total output		**410.5**

Material Balance:

Input	kg
Stage-I	33
Ethyl Acetate	100
Palladium Carbon	1
Hydrogen	2
Sodium Bicarbonate	15
Methyl Chloroformate	15
Water	200
Total Input	**366**

Output	kg
Product	
Stage-II	30
Recovery	
Ethyl Acetate	93
Ethyl Acetate loss	5
Palladium Carbon	1
Aqueous	
Effluent (Sodium Chloride 9.28, Sodium Bicarbonate 1.66, Methanol 0.41, Ethyl Acetate 1, gen.water 7.88, Water 200)	220.23
Organic Residue	
Un-reacted Organic Impurities (Organic Impurities 7.09, Ethyl Acetate 1)	8.09
Process Emissions	
Process Emissions (Carbon Dioxide 7.54, Hydrogen 1.14)	8.68
Total Output	**366**

Stage-III:

Mole Balance:

Input	No. of moles	Mol. Wt.
Stage-II	1	254
R-Glycidyl butyrate	1	144
n-Butyllithium	1	64
Ammonium Chloride	1	53.5
Water	3	54
Total input		**569.5**

Output	No. of moles	Mol. Wt.
((S)-3-(3-Fluoro-4-morpholinophenyl)-5-(hydroxymethyl) oxazolidin-2-one	1	296
Methanol	1	32
Butanol	1	74
Butyric acid	1	88
Lithium Chloride	1	42.5
Ammonium Hydroxide	1	35
Hydrogen	1	2
Total output		**569.5**

For Stereo Drugs Pvt. Ltd.

Managing Director

Material Balance:

Input	kg		Output	kg
Stage-II	30		**Product**	
R-Glycidyl butyrate	17		((S)-3-(3-Fluoro-4-morpholinophenyl)-5-(hydroxymethyl) oxazolidin-2-one	25
n-Butyllithium	8		**Recovery**	
Ammonium Chloride	20		n-Hexane	46.5
Sodium Chloride	10		n-Hexane loss	2.5
Sodium Sulfate	3		Methylene Dichloride	92
n-Hexane	50		Methylene Dichloride loss	6
Methylene Dichloride	100		Tetrahydrofuran	46.5
Tetrahydrofuran	50		Tetrahydrofuran loss	2.5
Water	600		**Aqueous**	
			Effluent (Lithium Chloride 5.31, Ammonium Hydroxide 4.37, Sodium Chloride 10, Ammonium Chloride 13.31, Butyric acid 10.39, Methanol 3.78, Butanol 9.25, Tetrahydrofuran 1, Water 593.37)	650.78
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 9.96, Methylene Dichloride 2, n- Hexane 1)	12.96
			Inorganic Solid Waste	
			Inorganic Solid Waste (Sodium Sulfate)	3
			Process Emissions	
			Process Emissions (Hydrogen)	0.26
Total Input	**888**		**Total Output**	**888**

4. DARUNAVIR

Description:

For Stereo Drugs Pvt. Ltd.

Managing Director

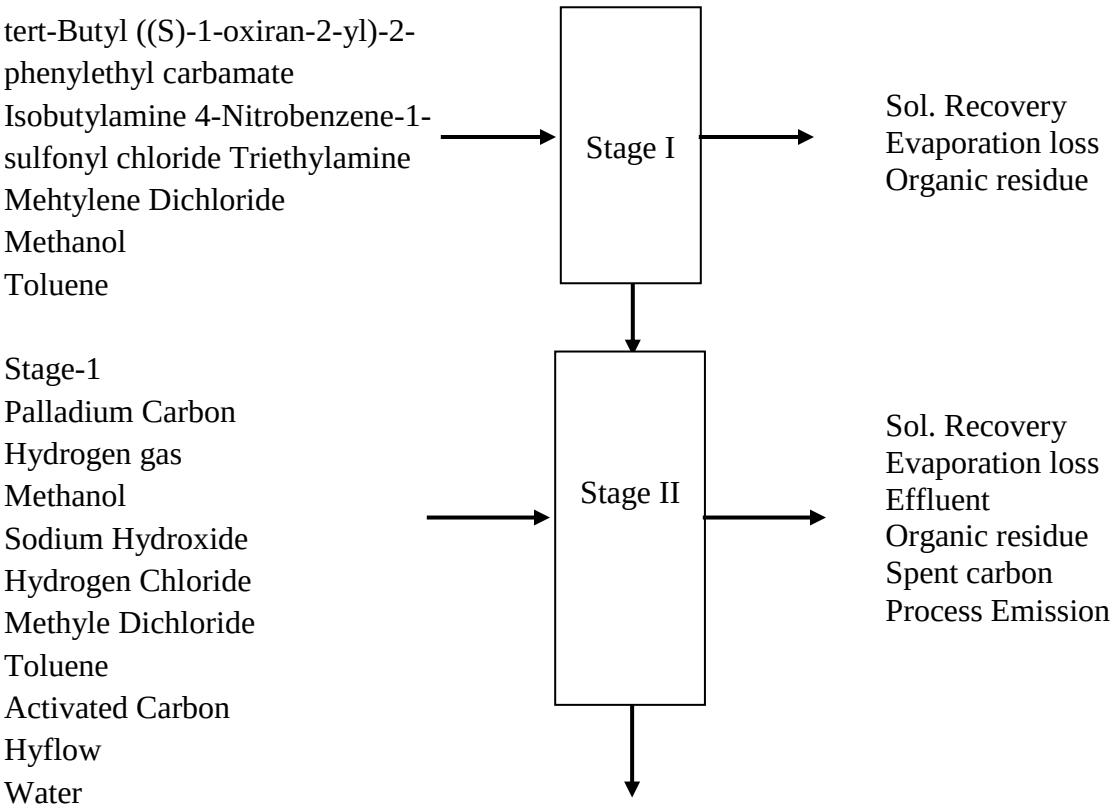
Stage-1: tert -Butyl ((S)-1-oxiran-2-yl)-2-phenylethyl carbamate is reacts with Isobutylamine and 4-Nitrobenzene-1-sulfonyl chloride in presence of Triethylamine base in Mehtylene Dichloride and Toluene are as Solvent mediato get Stage-1 compound.

Stage-2: Stage-1 compound is undergo Hydrogenation with Hydrogen gas in presence of Palladium carbon as catalyst in Methyle dichloride and Toluene are as solvent media to get Stage-2 compound.

Stage-3: (3aS , 4S ,6aR)-4-Methoxytetra hydrofuro[2,3-c]furan-2-(3H)-one is treated with p -Nitrop chloroformate followed by Reduction with Sodium Borohydride in presence of Acetic acid in Ethyl acetate and Toluene are as solvent media to get Stage-3 compound.

Stage-4: Stage-2 compound is reacts with Stage-3 compound in Ethyl acetate and Methanol are as solvent media toget finally Darunavir pure product.

Flow chart:



For Stereo Drugs Pvt. Ltd.

Managing Director

(3aS, 4S,6aR)-4-Methoxytetra hydrofuro[2,3-c]furan-2-(3H)-one
Sodium Borohydride
p-Nitrophenyl chloroformate
DBU
1-Methyl-1H-imidazole
Acetic acid
Methylene Dichloride
Toluene
Ethyl Acetate
Isopropyl Alcohol
Methanol
Amberlite IR 120H resin
Water

→ Stage III →

Sol. Recovery
Evaporation loss
Effluent
Organic residue
Inorganic solid waste
Process Emission

Stage-2
Stage-3
Methanol
Ethyl Acetate
Activated Carbon
Hyflow

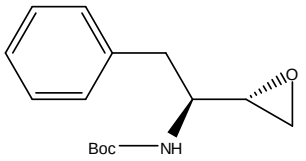
→ Stage IV →

Sol. Recovery
Evaporation loss
Organic residue
Spent carbon

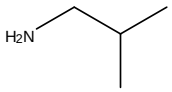
Darunavir

Route of synthesis of product:

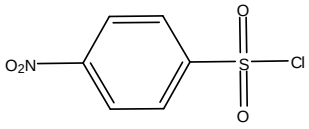
STEP-1



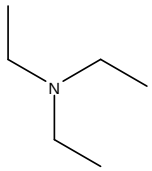
tert-butyl (*S*)-1-((*S*)-oxiran-2-yl)-2-phenylethylcarbamate
Chemical Formula: $C_{15}H_{21}NO_3$
Molecular Weight: 263.33



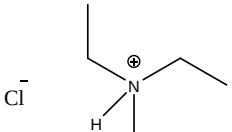
2-methylpropan-1-amine
Chemical Formula: $C_4H_{11}N$
Molecular Weight: 73.14

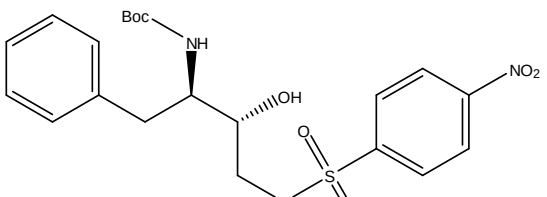


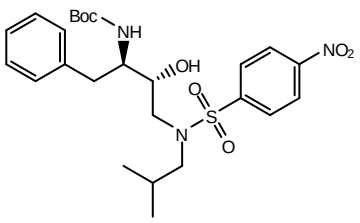
4-nitrobenzene-1-sulfonyl chloride
Chemical Formula: $C_6H_4ClNO_4S$
Molecular Weight: 221.62



triethylamine
Chemical Formula: $C_6H_{15}N$
Molecular Weight: 101.19







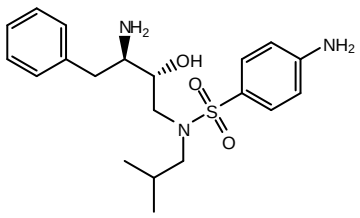
tert-butyl (2*R*,3*R*)-3-hydroxy-4-(*N*-isobutyl-4-nitrophenylsulfonamido)-1-phenylbutan-2-ylcarbamate
Chemical Formula: $C_{25}H_{35}N_3O_7S$
Molecular Weight: 521.63

+ $3H_2$ +

Chemical Formula: H_6
Molecular Weight: 6.05

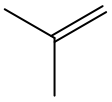
HCl

Chemical Formula: ClH
Molecular Weight: 36.46



4-amino-*N*-((2*R*,3*R*)-3-amino-2-hydroxy-4-phenylbutyl)-*N*-isobutylbenzenesulfonamide
Chemical Formula: $C_{20}H_{29}N_3O_3S$
Molecular Weight: 391.53

$2H_2O$ + HCl +



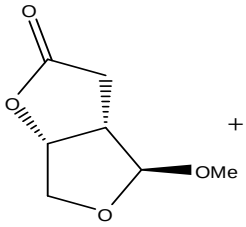
+ CO_2

Chemical Formula: H_4O_2
Molecular Weight: 36.03

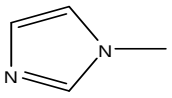
Chemical Formula: ClH
Molecular Weight: 36.46

2-methylprop-1-ene
Chemical Formula: C_4H_8
Molecular Weight: 56.11

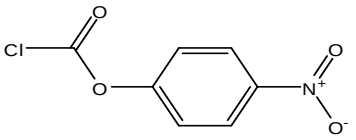
Chemical Formula: CO_2
Molecular Weight: 44.01



+ $NaBH_4$ +



+



(3a*S*,4*S*,6a*R*)-4-methoxytetrahydrofuro[2,3-*c*]furan-2(3*H*)-one
Chemical Formula: $C_7H_{10}O_4$
Molecular Weight: 158.15

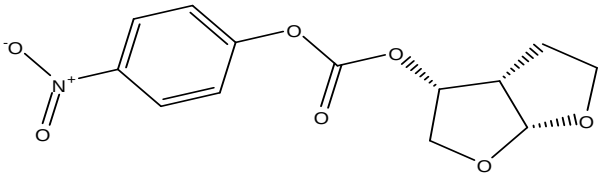
Chemical Formula: BH_4Na
Molecular Weight: 37.83

1-methyl-1*H*-imidazole
Chemical Formula: $C_4H_6N_2$
Molecular Weight: 82.10

4-nitrophenyl carbonochloridate
Chemical Formula: $C_7H_4ClNO_4$
Molecular Weight: 201.56

H_2O
water
C. Formula: H_2O
Mol. Weight: 18.02

+ MeOH
methanol
C.Formula: CH_4O
Mol Weight: 32.04



+ NaOH +

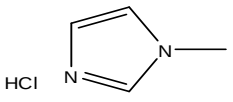
$B(OH)_3$
boricacid
C.Formula: BH_3O_3
Mol.Weight: 61.83

(3*R*,3a*S*,6a*R*)-hexahydrofuro[2,3-*b*]furan-3-yl 4-nitrophenyl carbonate
Chemical Formula: $C_{13}H_{13}NO_7$
Molecular Weight: 295.24

C.Formula: NaOH
Mol.Weight: 40.00

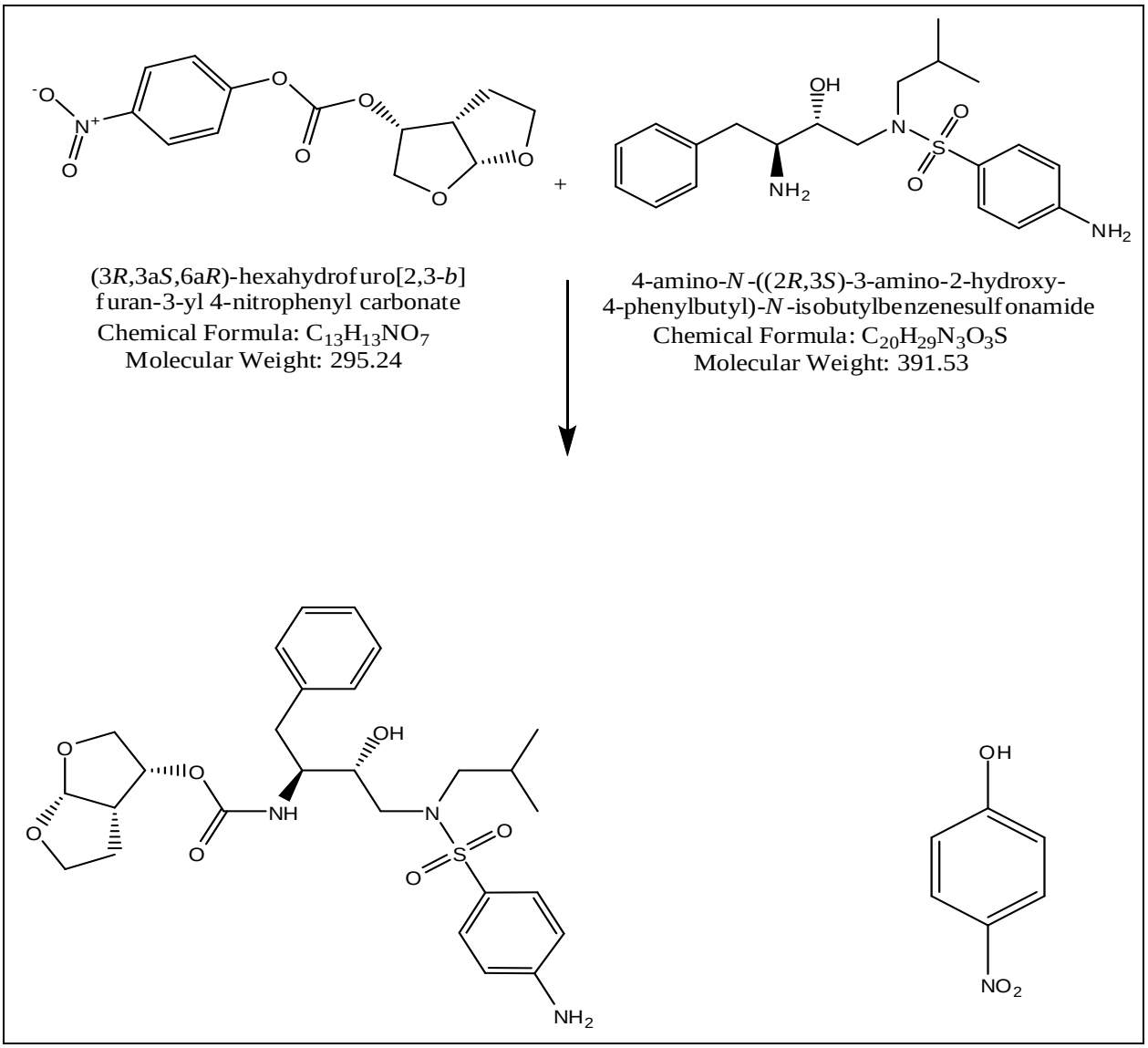
MeOH
methanol
C.Formula: CH_4O
Mol Weight: 32.04

+



Chemical Formula: $C_4H_7ClN_2$
Molecular Weight: 118.56

Managing Director



Stage-I:

Mole Balance:

Input	No. of moles	Mol. Wt.
tert -Butyl ((S) -1-oxiran-2-yl)-2- phenylethyl carbamate	1	263
Isobutylamine	1	73
4-Nitrobenzene-1-sulfonyl chloride	1	221.5
Triethylamine	1	101
Total input		**658.5**

Output	No. of moles	Mol.Wt.
Stage-I	1	521
Triethylamine Hydrochloride	1	137.5
Total output		**658.5**

For Stereo Drugs Pvt. Ltd.

Managing Director

Material Balance:

Input	kg		Output	kg
tert -Butyl ((S) -1-oxiran-2-yl)-2-phenylethyl carbamate	25		**Product**	
Isobutylamine	20		Stage-I	46
4-Nitrobenzene-1-sulfonyl chloride	22		**Recovery**	
Triethylamine	19		Mehtylene Dichloride	345
Mehtylene Dichloride	375		Mehtylene Dichloride loss	22
Methanol	250		Methanol	233
Toluene	100		Methanol loss	12
			Toluene	94
			Toluene loss	4
			Isobutylamine	10
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 4.46, Isobutylamine 3.06, Triethylamine Hydrochloride 13.08, Triethylamine 9.4, Mehtylene Dichloride 8, Methanol 5, Toluene 2)	45
Total Input	**811**		**Total Output**	**811**

Stage-II:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-I	1	521
Hydrogen gas	3	6
Water	1	18
Total input		**545**

Output	No. of moles	Mol.Wt.
Stage-II	1	391
tert -Butanol	1	74
Water	2	36
Carbon Dioxide	1	44
Total output		**545**

Material Balance:

Input	kg		Output	kg
Stage-I	46		**Product**	
Palladium Carbon	1		Stage-II	25
Hydrogen gas	2		**Recovery**	
Methanol	900		Methanol	837
Sodium Hydroxide	23		Methanol loss	45
Hydrogen Chloride	21		Methylene Dichloride	552

For Stereo Drugs Pvt. Ltd.

Managing Director

Methyle Dichloride	600		Methylene Dichloride loss	36
Toluene	200		Toluene	188
Activated Carbon	1		Toluene loss	8
Hyflow	15		Palladium Carbon	1
Water	330		**Aqueous**	
			Effluent (Sodium Chloride 33.65, tert -Butanol 6.53, Methanol 9, gen.water 13.53, Water 328.41)	391.12
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 9.53, Methyle Dichloride 12, Methanol 9, Toluene 4)	34.53
			Spent Carbon	
			Spent Carbon (Carbon 1, Hyflow 15)	16
			Process Emissions	
			Process Emissions (Hydrogen 1.47, Carbon Dioxide 3.88)	5.35
Total Input	**2139**		**Total Output**	**2139**

Stage-III:

Mole Balance:

Input	**No. of moles**	**Mol. Wt.**
(3aS , 4S ,6aR)-4-Methoxytetra hydrofuro[2,3-c]furan-2-(3H)-one	1	158
Sodium Borohydride	1	38
Acetic acid	1	60
p -Nitrophenyl chloroformate	1	201.5
Water	3	54
1-Methyl-1H -imidazole	1	82
Total input		**593.5**

Output	**No. of moles**	**Mol. Wt.**
Stage-III	1	295
Sodium Acetate	1	82
Boric acid	1	62
1-Methyl-1H –imidazole Hydrochloride	1	118.5
Methaol	1	32
Hydrogen	2	4
Total output		**593.5**

Material Balance:

Input	**kg**		**Output**	**kg**
(3aS , 4S ,6aR)-4-Methoxytetra hydrofuro[2,3-c]furan-2-(3H)-one	36		**Product**	
Sodium Borohydride	15		Stage-III	34

For Stereo Drugs Pvt. Ltd.

Managing Director

p -Nitrophenyl chloroformate	60
DBU	3
1-Methyl-1H -imidazole	28
Acetic acid	44
Methylene Dichloride	250
Toluene	150
Ethyl Acetate	350
Isopropyl Alcohol	600
Methanol	250
Amberlite IR 120H resin	7
Water	220
Total Input	**2013**

Recovery	
Methylene Dichloride	230
Methylene Dichloride loss	15
Toluene	141
Toluene loss	6
Ethyl Acetate	326
Ethyl Acetate loss	17
Isopropyl Alcohol	558
Isopropyl Alcohol loss	30
Methanol	233
Methanol loss	12
Aqueous	
Effluent (Sodium Acetate 32.36, Boric acid 24.46, 1-Methyl imidazole Hydrochloride 35.29, 1-Methyl imidazole Acetate 6.22, Acetic acid 17.69, Methanol 12.29, Water 197.43)	325.74
Organic Residue	
Un-reacted Organic Impurities (Organic Impurities 33.22, p -Nitrophenol 9.72, DBU 3, Toluene 3, Methylene Dichloride 5, Ethyl Acetate 7, Isopropyl Alcohol 12)	72.94
Inorganic Solid Waste	
Inorganic Solid Waste (Amberlite IR 120H resin)	7
Process Emissions	
Process Emissions (Hydrogen 2.24, Carbon Dioxide 3.08)	5.32
Total Output	**2013**

Stage-IV:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-II	1	295
Stage-III	1	391
Total input		**686**

Output	No. of moles	Mol.Wt.
Darunavir	1	547
p -Nitrophenol	1	139
Total output		**686**

For Stereo Drugs Pvt. Ltd.

Managing Director

Material Balance:

Input	kg		Output	kg
Stage-II	25		**Product**	
Stage-III	34		Darunavir	40
Methanol	500		**Recovery**	
Ethyl Acetate	375		Methanol	465
Activated Carbon	3.5		Methanol loss	25
Hyflow	10		Ethyl Acetate	349
			Ethyl Acetate loss	19
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 7.22, Methanol 10, Ethyl Acetate 7, p -Nitrophenol 11.78)	36
			Spent Carbon	
			Spent Carbon (Carbon 3.5, Hyflow 10)	13.5
Total Input	**947.5**		**Total Output**	**947.5**

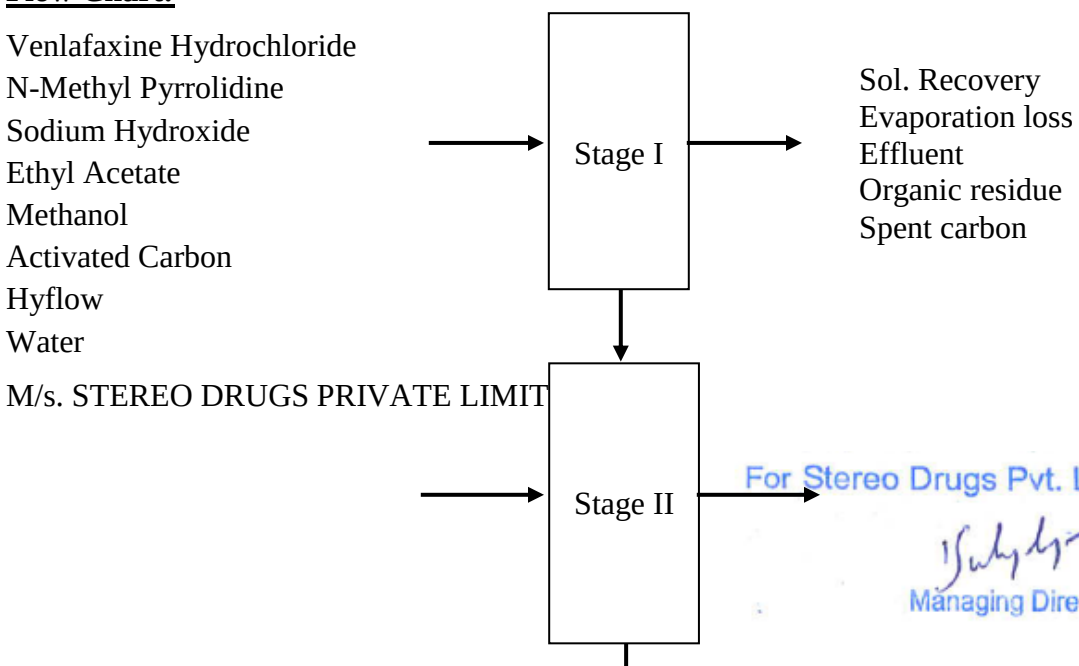
5. DESVENLAFAXINE SUCCINATE MONOHYDRATE

Description:

Stage-1: Venlafaxine Hydrochloride is reacted with Sodium sulfide in the presence of N-Methyl Pyrrolidine to yield Desvenlafaxine base.

Stage-2: Venlafaxine base is salt formation with Succinic acid and then purified with Ethyl Acetate and Methanol to yield Desvenlafaxine Succinate Monohydrate Pure.

Flow Chart:



For Stereo Drugs Pvt. Ltd.

Managing Director

Desvenlafaxine base
Succinic acid
Methanol
Toluene
Activated Carbon
Hyflow
Water

Sol. Recovery
Evaporation loss
Organic residue
Spent carbon

Desvenlafaxine Succinate Monohydrate

Stage-I:

Mole Balance:

Input	No. of moles	Mol. Wt.
Venlafaxine Hydrochloride	1	313.5
Sodium Hydroxide	2	80
Total input		**393.5**

Output	No. of moles	Mol.Wt.
Desvenlafaxine	1	263
Sodium Chloride	1	58.5
Sodium Methoxide	1	54
Water	1	18
Total output		**393.5**

Material Balance:

Input	kg
Venlafaxine Hydrochloride	100
N-Methyl Pyrrolidine	350
Sodium Hydroxide	35
Ethyl Acetate	1500
Methanol	3620
Activated Carbon	5
Hyflow	10
Water	2600

Output	kg
Product	
Desvenlafaxine base	75
Recovery	
Ethyl Acetate	1410
Ethyl Acetate loss	75
Methanol	3400
Methanol loss	180
N-Methyl Pyrrolidine	330
N-Methyl Pyrrolidine loss	13
Aqueous	
Effluent (Sodium Chloride 18.66, Sodium Methoxide 17.22, Sodium Hydroxide 9.48, Methanol 40, N-Methyl Pyrrolidine 7, gen.water 5.74, Water 2600)	2698.1
Organic Residue	
Un-reacted Organic Impurities	23.9

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Managing Director

			(Organic Impurities 8.9, Ethyl Acetate 15)	
			Spent Carbon	
			Spent Carbon (Carbon 5, Hyflow 10)	15
Total Input	**8220**		**Total Output**	**8220**

Stage-II:

Mole Balance:

Input	**No. of moles**	**Mol.Wt.**
Desvenlafaxine	1	263
Succinic acid	1	118
Water	1	18
Total input		**399**

Output	**No. of moles**	**Mol.Wt.**
Desvenlafaxine Succinate Monohydrate	1	399
Total output		**399**

Material Balance:

Input	**kg**		**Output**	**kg**
Desvenlafaxine base	75		**Product**	
Succinic acid	48		Desvenlafaxine Succinate Monohydrate	100
Methanol	300		**Recovery**	
Toluene	700		Methanol	279
Activated Carbon	10		Methanol loss	15
Hyflow	5		Toluene	660
Water	6		Toluene loss	28
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 13.78, Succinic acid 14.35, Water 0.87, Methanol 6, Toluene 12)	47
			Spent Carbon	
			Spent Carbon (Carbon 1, Hyflow 15)	15
Total Input	**1144**		**Total Output**	**1144**

6. DAPOXETINE HYDROCHLORIDE

Description:

Stage-1: 3-Chloro-1-phenylpropan-1-one was reduction with Sodium Borohydride in presence of Methanol, Sodium Bicarbonate and Acetic acid. After completion of the reaction the recation mixture and add Water and extract with Methylene Dichloride. Collect total Methylene Dichloride layer and wash with Water and concentrte to obtain Stage-1 compound.

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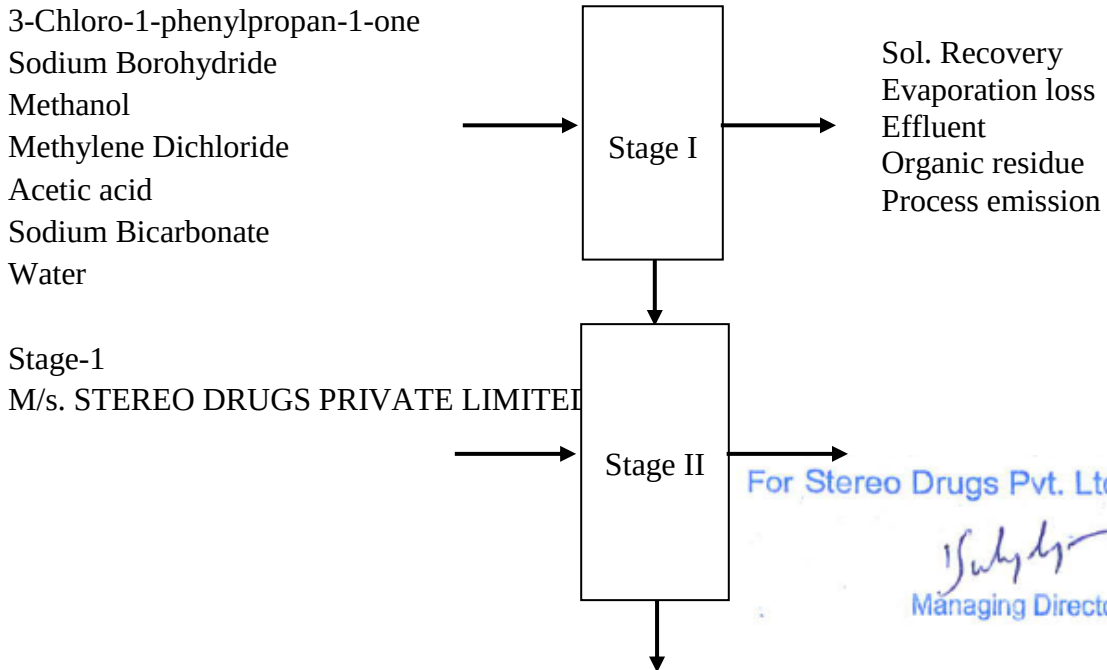
Stage-2: Stage-21 was react with Naphthalen-1-ol in presence of Potassium Hydroxide in Dimethyl Sulfoxide. Reaction mass heat to100-110ºC, maintain for 7-8 hrs. Reaction mass quench into water and extract with Toluene, Collect total Toluene layer and wash with Water. Concentrate Toluene layer to obtain Stage-2 product.

Stage-3: Stage-2 ccompound was dissolved in Methyl Isobutyl Ketone and add Methanesulfonyl Chloride in presence of basei.e Triethylamine, Heat to 5-10 mints at 25-35ºc. 3-(Naphthalen-1-yloxy)-1-phenylpropyl methanesulfonate dissolved in 4-Dimethylamino pyridine in presence of dissoved Oxalic acid and add Toluene. take organic layer and wash with Isopropyl Alcohol and Acetone to get Stage-3 compound.

Stage-4: Stage-3 Compound dissolved in Water and basify with Sodium Hydroxide in presence of Methylene Dichloride. After completion of the reaction, charge water to the R.M. RM to add L(+)-Tartaric acid add with water and Ethyl Acetate and treated with D(-)-Tartaric acid with Water and Ethyl Acetate. Separate the layers, take organic layer and wash with water and Ethyl acetate to get Stage-4 compound.

Stage-5: Stage-4 compound was treated with Hydrogen Chloride in presence Methylene Dichloride and Water and bsifiy with Caustic lye. After completion fo the reaction, the recation mixture was RT and washed with Ethyl Acetate to obtain crude. Cool to 5-10ºc, pH=2 adjust with Isopropyl Alcohol Hydrochloride. Separate the layers and wash the org layer Wash with Ethyl Acetate give Dapoxetine Hydrochloride.

Flow Chart:



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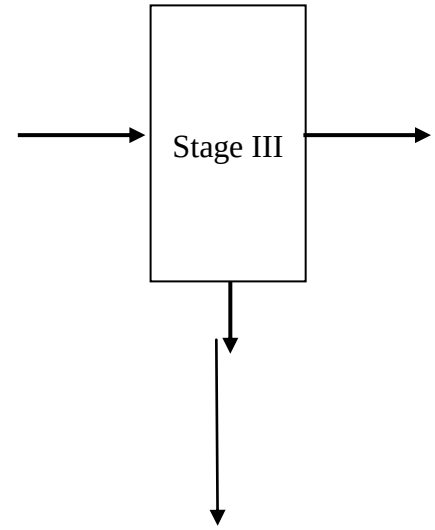
Naphthalene-1-ol
Potassium Hydroxide
Dimethyl Sulfoxide
Toluene
Sodium Hydroxide (5%)
Petroleum Ether
Water

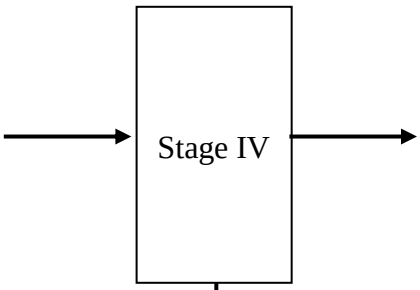
Sol. Recovery
Evaporation loss
Effluent
Organic residue

Stage-2
Methyl Isobutyl Ketone
Triethylamine
Methanesulfonyl chloride
4-Dimethylamino pyridine
Dimethylamine (40%)
Oxalic acid
Toluene
Methylene Dichloride
Isopropyl Alcohol
Acetone
Water



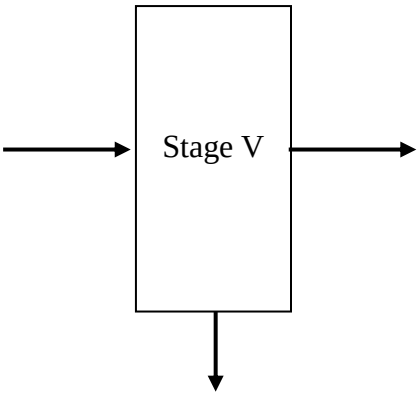
Sol. Recovery
Evaporation loss
Effluent
Organic residue

Stage-3
Methylene Dichloride
Sodium Hydroxide (50%)
L(+)-Tartaric acid
Ethyl Acetate
Water



Sol. Recovery
Evaporation loss
Effluent
Organic residue

Stage-4
Methylene Dichloride
Sodium Hydroxide (50%)
Carbon
Isopropyl Alcohol
Hydrochloride (15%)
Ethyl Acetate
Hyflow
Water



Sol. Recovery
Evaporation loss
Effluent
Organic residue
Spent carbon
Process emission

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Managing Director

Dapoxetine Hydrochloride

Stage-I:

Mole Balance:

Input	No. of moles	Mol. Wt.
3-Chloro-1-phenylpropan-1-one	4	674
Sodium Borohydride	1	38
Water	4	72
Acetic acid	1	60
Total input		**844**

Output	No. of moles	Mol.Wt.
Stage-I	4	682
Sodium Acetate	1	82
Boric acid	1	62
Water	1	18
Total output		**844**

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Material Balance:

Input	kg		Output	kg
3-Chloro-1-phenylpropan-1-one	90		**Product**	
Sodium Borohydride	6		Stage-I	80
Methanol	250		**Recovery**	
Mehtylene Dichloride	250		Mehtylene Dichloride	230
Acetic acid	10		Mehtylene Dichloride loss	15
Sodium Bicarbonate	1		Methanol	232.5
Water	630		Methanol loss	12.5
			Aqueous	
			Effluent (Sodium Acetate 13.67, Boric acid 9.8, Sodium Bicarbonate 0.27, Methanol 5, gen.water 2.55, Water 619.07)	650.36
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 11.07, Mehtylene Dichloride 5)	16.07
			Process Emissions	
			Process Emissions (Hydrogen 0.19, Carbon Dioxide 0.38)	0.57
Total Input	**1237**		**Total Output**	**1237**

Stage-II:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-I	1	170.5
Naphthalen-1-ol	1	144
Potassium Hydroxide	1	56
Total input		**370.5**

Output	No. of moles	Mol.Wt.
Stage-II	1	278
Potassium Chloride	1	74.5
Water	1	18
Total output		**370.5**

Material Balance:

Input	kg		Output	kg
Stage-I	80		**Product**	
Naphthalen-1-ol	69		Stage-II	115
Potassium Hydroxide	28		**Recovery**	
Dimethyl Sulfoxide	400		Toluene	188
Toluene	200		Toluene loss	8
Sodium Hydroxide (5%)	200		Petroleum Ether	139.5

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Petroleum Ether	150		Petroleum Ether loss	7.5
Water	400		Dimethyl Sulfoxide	376
			Dimethyl Sulfoxide loss	16
			Aqueous	
			Effluent (Potassium Chloride 34.96, Potassium naphtholate 1.81, Potassium Hydroxide 1.16, Sodium Hydroxide 10, Dimethyl Sulfoxide 8, gen.water 8.63, Water from Sodium Hydroxide 190, Water 400)	654.56
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 15.44, Petroleum Ether 3, Toluene 4)	22.44
Total Input	**1527**		**Total Output**	**1527**

Stage-III:

Mole Balance:

Input	**No. of moles**	**Mol. Wt.**
Stage-II	1	278
Methanesulfonyl chloride	1	114.5
Triethylamine	1	101
Dimethylamine	1	45
Oxalic acid	1	90
Total input		**628.5**

Output	**No. of moles**	**Mol. Wt.**
Stage-III	1	395
Methanesulfonic acid	1	96
Triethylamine Hydrochloride	1	137.5
Total output		**628.5**

Material Balance:

Input	**kg**		**Output**	**kg**
Stage-II	115		**Product**	
Methyl Isobutyl Ketone	500		Stage-III	145
Triethylamine	45		**Recovery**	
Methanesulfonyl chloride	50		Methyl Isobutyl Ketone	470
4-Dimethylamino pyridine	0.01		Methyl Isobutyl Ketone loss	20
Dimethylamine (40%)	50		Toluene	141
Oxalic acid	38		Toluene loss	6
Toluene	150		Methylene Dichloride	506
Methylene Dichloride	550		Methylene Dichloride loss	33
Isopropyl Alcohol	150		Isopropyl Alcohol	139.5
Acetone	200		Isopropyl Alcohol loss	7.5

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Managing Director

Water	1200		Acetone	186
			Acetone loss	10
			Aqueous	
			Effluent (Triethylamine Hydrochloride 60.04, Triethylamine 0.9, Methanesulfonic acid 41.92, Dimethylamine 1.38, Methyl Isobutyl Ketone 10, 4-Dimethylamino pyridine 0.01, Oxalic acid 0.77, Water from Dimethylamine 30, Water 1199.59)	1344.61
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 18.4, Toluene 3, Methylene Dichloride 11, Isopropyl Alcohol 3, Acetone 4)	39.4
Total Input	**3048.01**		**Total Output**	**3048.01**

Stage-IV:

Mole Balance:

Input	No. of moles	Mol.Wt.
Stage-III	1	395
L(+)-Tartaric acid	1	150
Sodium Hydroxide	2	80
Total input		**625**

Output	No. of moles	Mol.Wt.
Stage-IV	½	227.5
Isomer	½	227.5
Sodium Oxalate	1	134
Water	2	36
Total output		**625**

Material Balance:

Input	kg		Output	kg
Stage-III	145		**Product**	
Methylene Dichloride	500		Stage-IV	80
Sodium Hydroxide (50%)	60		**Recovery**	
L(+)-Tartaric acid	56		Methylene Dichloride	460
Ethyl Acetate	1000		Methylene Dichloride loss	30
Water	1000		Ethyl Acetate	930
			Ethyl Acetate loss	50
			Aqueous	
			Effluent (Sodium Oxalate 49.19, Sodium Hydroxide 0.63, Ethyl Acetate 10, Water from Sodium Hydroxide 30, gen.water	1103.04

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			13.22, Water 1000)	
			Organic Residue	
			Un-reacted Organic Impurities (Organic Impurities 7.02, Isomer 80, L(+)-Tartaric acid 0.94, Ethyl Acetate 10, Methylene Dichloride 10)	107.96
Total Input	**2761**		**Total Output**	**2761**

Stage-V:

Mole Balance:

Input	**No. of moles**	**Mol.Wt.**
Stage-IV	1	455
Sodium Hydroxide	2	80
Hydrogen Chloride	1	36.5
Total input		**571.5**

Output	**No. of moles**	**Mol.Wt.**
Dapoxetine Hydrochloride	1	341.5
Sodium Tartrate	1	194
Water	2	36
Total output		**571.5**

Material Balance:

Input	**kg**		**Output**	**kg**
Stage-4	80		**Product**	
Methylene Dichloride	400		Dapoxetine Hydrochloride	50
Sodium Hydroxide (50%)	30		**Recovery**	
Carbon	4		Methylene Dichloride	368
Isopropyl Alcohol Hydrochloride(15%)	63		Methylene Dichloride loss	24
Ethyl Acetate	200		Isopropyl Alcohol	50
Hyflow	10		Isopropyl Alcohol loss	2.5
Water	500		Ethyl Acetate	186
			Ethyl Acetate loss	10
			Aqueous	
			Effluent (Sodium Tartrate 34.11, Sodium Hydroxide 0.93, Ethyl Acetate 2, Water from Sodium Hydroxide 15, gen.water 6.34, Water 500)	558.38
			Organic Residue	
			Unreacted Organic Impurities (Organic Impurities 10.04, Methylene Dichloride 8, Ethyl Acetate 2, Isopropyl Alcohol 1.05)	21.09

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			Spent Carbon	
			Spent Carbon (Carbon 4, Hyflow 10)	14
			Process Emissions	
			Process Emissions (Hydrogen Chloride)	3.03
Total Input	**1287**		**Total Output**	**1287**

7. PREGABALIN

Description:

Lyrica (pregabalin) is an anti-epileptic drug, also called an anticonvulsant. It works by slowing down impulses in the brain that cause seizures. Lyrica also affects chemicals in the brain that send pain signals across the nervous system.

Lyrica is used to control seizures and to treat fibromyalgia. It is also used to treat pain caused by nerve damage in people with diabetes (diabetic neuropathy), herpes zoster (post-herpetic neuralgia, or neuropathic pain associated with spinal cord injury.

Lyrica may also be used for other purposes not listed in this medication guide.

Raw material required:

Sl.No	Name of the Raw material	C.C
1	(S)-benzyl 3-(hydroxymethyl)-5-methylhexanoate	1.572
2	Tosyl chloride	1.289
3	Sodium Azide	0.4188
4	TEA	0.8
5	Toluene	0.22
6	DMSO	0.5
7	Hydrogen	0.0272
8	Pd on Charcoal	0.04
9	THF	0.16

Brief manufacturing process:

For Stereo Drugs Pvt. Ltd.

Managing Director

Stage-1: This stage contains two stages.

STEP-A:

The reaction of (S)-benzyl 3-(hydroxymethyl)-5-methylhexanoate compound with tosyl chloride in presence of TEA and Toluene solvent medium yields the tosylate compound. The reaction proceeds as per the below equation.

STEP-B:

The tosylate compound which is formed in step-A is treated with sodium azide in presence of DMSO solvent medium forms the stage-1 compound.

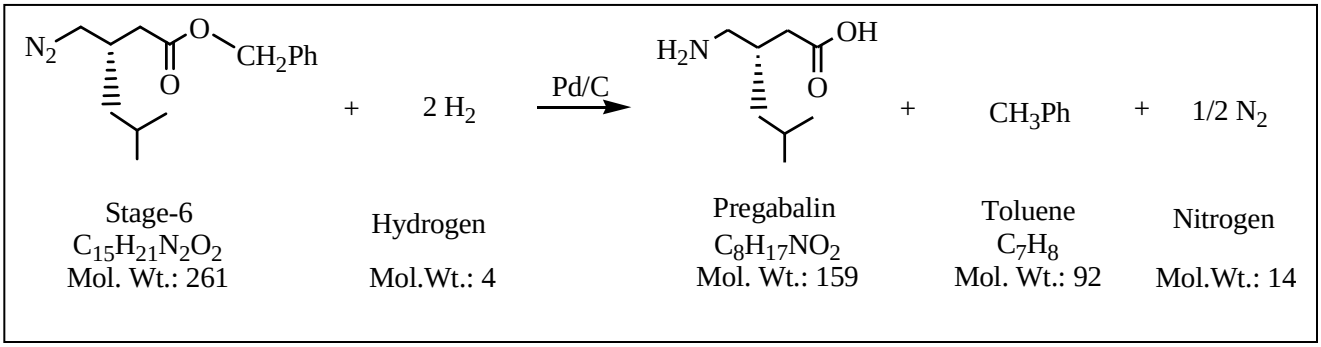
Stage-2:

Finally, the Azide compound is reduced and debenzylated with H2, Pd/C in presence of THF solvent medium forms the final compound.

Route of synthesis of product:

Stage-1:
STEP-A:

Stage-2:



For Stereo Drugs Pvt. Ltd.

Managing Director

Flow chart:

For Stereo Drugs Pvt. Ltd.

Managing Director

Material balance of the product stage wise:

PRAGABILIN Stage No-1					
			Batch Size in Kg		250
			Production per month in Kg		500
			No. of Batches per month		2
Name of the input	Quantity in Kg		Name of the output		Quantity in Kg
(S)-benzyl 3-(hydroxymethyl)-5-methylhexanoate	393		Stage-1		410.4
Tosyl chloride	322.3		Organic waste		22.4
Sodium Azide	104.7		Tolene Recovery		1045.0
TEA	200.0		Toluene loss		55.0
Toluene	1100.0		Un-reacted input		66
Water	2000.0		Waste water		2405.0
DMSO	100.0		Inorganic Waste	305.0	
			DMSO	100.0	
			By_product		
			TEA HCl		216.2
Total	4220		Total		4220

Pragabeline Stage No-2					
			Batch Size in Kg		250
			Production per month in Kg		500
			No. of Batches per month		2
Name of the input	Quantity in Kg		Name of the output		Quantity in Kg
Stage-1	410.4		Final Product		250.0
Hydrogen	6.8		Organic waste		0.5
Pd on Charcoal	10.0		THF Recovery		760.0
THF	800.0		THF loss		40.0
Water	150.0		Pd on Charcoal		10.0
			Waste water		150.0
			Nitrogen Emission		44.0
			Toluene from process		122.7
Total	1377.2		Total		1377.2

For Stereo Drugs Pvt. Ltd.

Managing Director

Water requirement:

Consumption of water in lit/batch	Quantity in lits /Batch	Source
Stage I	2000	Tankers from Out side
Stage II	150	
Total	2150	

Wastewater generation and characteristics of wastewater:

WASTE GENERATION PER BATCH IN Kg										
Stage No	Waste water		TDS		COD		Solid waste			
	LTDS	HTDS	Kg	Mg/ltr	Kg	Mg/Ltr	Inorganic	Organic	Spent carbon	Emission
1	0.0	2405.0	30.5	0.0	0.0	0.0	305.0	22.6	0.0	0.0
2	150.0	0	0	0.0	0.0	0.0	0.0	0.5	0.0	44.0
Total	**150.0**	**2405.0**	**30.5**	**0.0**	**0.0**	**0.0**	**305**	**23.1**	**0**	**44.0**

Solid waste generation characteristics & method of disposal:

Inorganic	Organic	Spent carbon	Emission
305.0	22.6	0.0	0.0
0.0	0.5	0.0	44.0
305	**23.1**	**0**	**44.0**

Bi product details:

Stage	Name of the bi-product	Quantity in kg/Batch
Stage I	TEA HCl	216.2
Stage II		0

Solvent usage, recovery & loss details in kg:

SL.No	Name of the solvent used in kg	Used	Recovery	Loss due to distillation
1	Toulene	1100	1045	55
2	THF	800	760	40

8. KETOROLAC TROMETHAMINE

Description:

For Stereo Drugs Pvt. Ltd.

Managing Director

Ketorolac is used for the short-term treatment of moderate to severe pain in adults. It is usually used before or after medical procedures or after surgery. Reducing pain helps you recover more comfortably so that you can return to your normal daily activities. This medication is a non steroidal anti-inflammatory drug (NSAID). It works by blocking your body's production of certain natural substances that cause inflammation. This effect helps to decrease swelling, pain, or fever.

Raw material required:

S.No	Name of the Raw material	C.C
1	Benzoyl Pyrrol	0.2274
2	Perchloric acid	0.1404
3	Dibenzoyl peroxide catalyst	0.107
4	Cyclohexane	0.052
5	2,5-dimethoxy-pent-1-ene	
6	Tromethamine	
7	NaOH	
8	Acetone	
9	MeOH	

Brief manufacturing process:

Benzoyl Pyrrole on chlorination with perchloric acid in presence of Dibenzoyl peroxide catalyst and cyclohexane solvent media gives 5-chloro-2-benzoyl Pyrrole

5-Chloro-2-benzoyl Pyrrole oncondensation with 2,5-dimethoxy-pent-1-ene in presence of Sodium hydroxide, Acetone and Methanol as solvent media gives Ketorolac

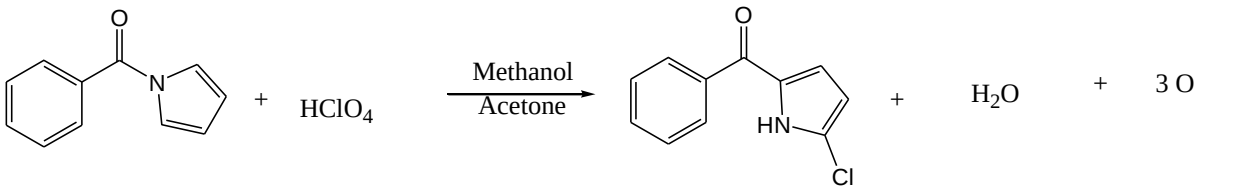
Ketorolac on salt formation with Tromethamine in presence of Acetone solvent media gives Ketorolac Tromethamone

Route of synthesis of product:

Stage-1

For Stereo Drugs Pvt. Ltd.

Managing Director



Benzoyl Pyrrole.
$C_{11}H_9NO$
Mol. Wt.: 171.20

Perchloric Acid

Mol. Wt.: 100.5

5-chloro-2-benzoyl Pyrrole
$C_{11}H_8ClNO$
Mol. Wt.: 205.64

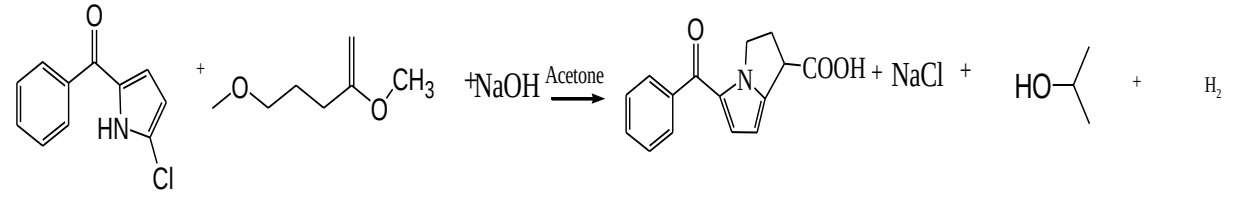
Water

Mol. Wt.: 18

Oxygen

Mol. Wt.: 16

Stage-2



5-chloro-2-benzoyl Pyrrole
$C_{11}H_8ClNO$
Mol. Wt.: 205.64

2,5-Dimethoxy-pent-1-ene
$C_7H_{14}O_2$
Mol. Wt.: 130.18

Sod.Hydroxide

Mol. Wt.: 40

Ketorolac
$C_{15}H_{13}NO_3$
Mol. Wt.: 255.27

Sod.Chlpride

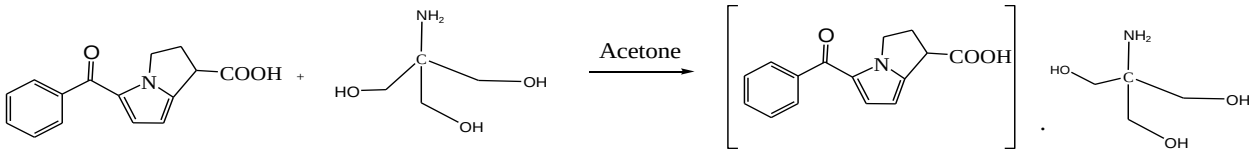
Mol. Wt.: 58.5

Propan-2-ol
C_3H_8O
Mol. Wt.: 60.10

HYdrogen

Mol. Wt.:2

Stage-3



Ketorolac
$C_{15}H_{13}NO_3$
Mol. Wt.: 255.27

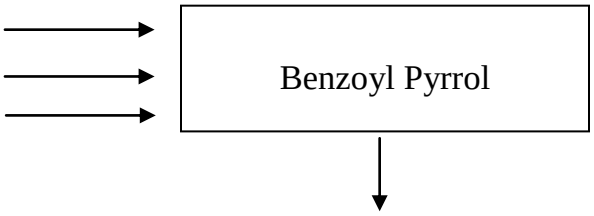
Tromethamine
$C_4H_{11}NO_3$
Mol. Wt.: 121.14

Ketorolac tromethamine
C19H24N2O6
Mol. Wt.: 376.4

Flow chart:

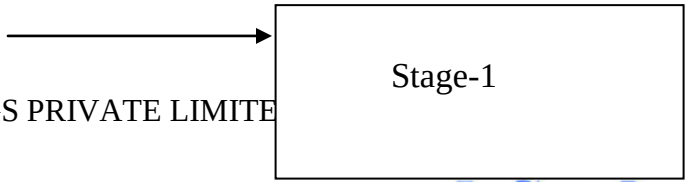
Stage-1:

$HClO_4$
MeOH
Acetone



Stage-2:

2,5-dimethoxy
pent-1-ene



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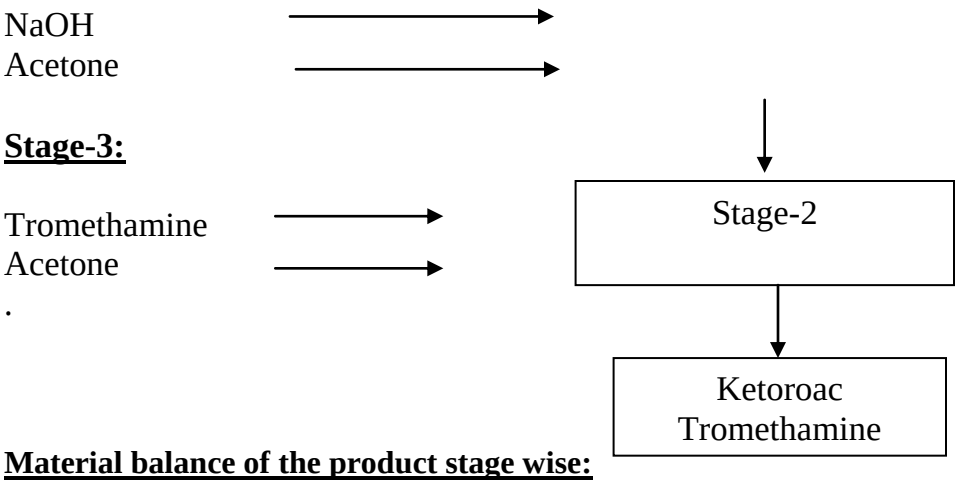

Material balance of the product stage wise:

KETOROLAC TROMETHAMINE Stage No-1				
			Batch Size in Kg	500
			Production per month in kg	1000
			No. of Batches per month	2
Name of the Input	**Quantity In kg**		**Name of the out put**	**Quantity in Kg**
Benzoyl Pyrrol	113.7		Stage-2	136.6
Perchloric acid	70.2		**Solvent Recovery**	
Dibenzoyl peroxide catalyst	53.5		Cyclohexane	574
Cyclohexane	600.0		**Solvent loss**	
Water	300.0		Cyclohexane	26.0
			Organic Waste	3.5
			Waste water	365.5
			input Water 300.0	
			Dibenzoyl peroxide 53.5	
			Water from process 12.0	
			Emissions	
			Oxygen	31.8
Total	1137.4		Total	1137.4

Water requirement:

Consumption of water in lit/batch	Quantity in lits /Batch	Source of water

For Stereo Drugs Pvt. Ltd.
Managing Director

Stage	300	Out side

Wastewater generation and characteristics of wastewater:

Stage No	Waste water		TDS		COD		Solid waste		Spent carbon	Emission
	LTDS	HTDS	Kg	Mg/ltr	Kg	Mg/Ltr	Inorganic	Organic		
1	0	365.5	53.5	146374.8	1.05	1438.2	53.5	3.5	0	31.9
2	0	378.7	38.9	102719.8	1.36	1796.8	38.9	4.5	0	1.3
3	300	0	0	0	1.27	2116.6	0	4.2	0	0
Total	**300.00**	**744.2**	**92.4**	**249094.6**	**3.68**	**5351.6**	**92.4**	**12.2**	**0.00**	**33.2**

Solid waste generation characteristics & method of disposal:

Solid waste		Spent carbon	Emission
Inorganic	Organic		
53.5	3.5	0	31.9
38.9	4.5	0	1.3
0	4.2	0	0
92.4	**12.2**	**0.00**	**33.2**

Bi product details:

Stage	**Name of the bi-product**	**Quantity in kg/Batch**
Stage I	Nil	Nil

Solvent usage, recovery & loss details in kg:

Sl.No	**Name of the solvent used in kg**	**Used**	**Recovery**	**Loss due to distillation**
1	Cyclohexane	**600**	**574**	**26**

9. SITAGLIPTIN PHOSPHATE MONOHYDRATE

Description:

Sitagliptin belongs to the group of diabetes medications called *DPP-4 inhibitors*. It works by increasing the amount of *incretin* released by the intestine. Incretin is a hormone that raises

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Managing Director

insulin levels when blood sugar is high and decreases the amount of sugar made by the body. Sitagliptin is used alone or in combination with other medications to improve blood sugar levels in adults with type 2 diabetes. This medication should be used as part of an overall diabetes management plan that includes a diet and exercise program.

Raw material required:

S.No	Name of the Raw material	C.C
1	1-[3-(triflouromethyl)-5,6-dihydro [1,2,4] triazolo[4,3-a]pyrazin-7 (8H)-yl]-4-(2,4,5-trifluorphenyl)butane-1,3-dione	1.5524
2	(R)-1-phenyl ethyl amine	0.2428
3	Hydrogen	0.008
4	Catalyst -5% Platinum on carbon	0.1552
5	Isopropanol	0.3
6	Acetic acid	1.6
7	Phosphoric acid	0.4
8	Catalyst -Palladium carbon	0.0776
9	Activated carbon	0.05

Brief manufacturing process:

Sitagliptin phosphate monohydrate is produced by treating of 1-[3-(triflouromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a] pyrazin-7 (8H)-yl] -4- (2,4,5-trifluorphenyl) butane- 1,3-dione with (R)-phenylethyl amine and Pt/C to separate Z isomer which was treated with H3PO4 and IPA. Further on Hydrogenation in presence of Palladium on Charcoal the product is obtained.

The process takes place as per the below equation

Route of synthesis of product:

Stage-1

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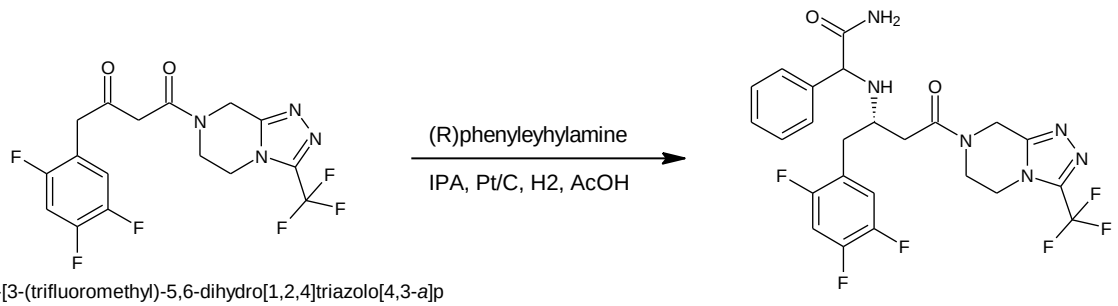
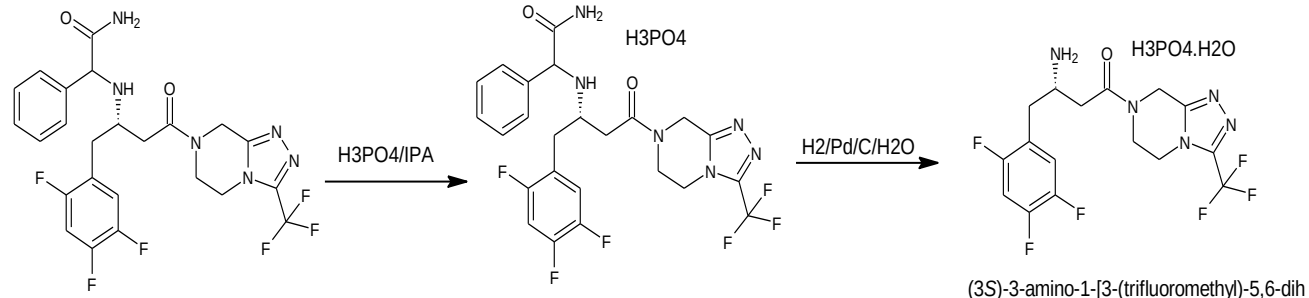


1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)butane-1,3-dione

(3*S*)-3-(2-phenylacetamido)amino-1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)butan-1-one

Stage-2



(3*S*)-3-(2-phenylacetamido)amino-1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)butan-1-one

(3*S*)-3-(2-phenylacetamido)amino-1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)butan-1-one phasphate

(3*S*)-3-amino-1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)butan-1-one phasphate

(Sitagliptin phosphate monohydrate)

Flow chart:

Stage-1:

(R)-Phenylethylamine
Pt/C, Hydrogen
IPA
AcOH

→ 1-[3-(triflouromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a] pyrazin-7 (8H)-yl] -4- (2,4,5-trifluorphenyl) butane- 1,3-dione

Stage-2:

H_3PO_4
IPA

→ Stage-1

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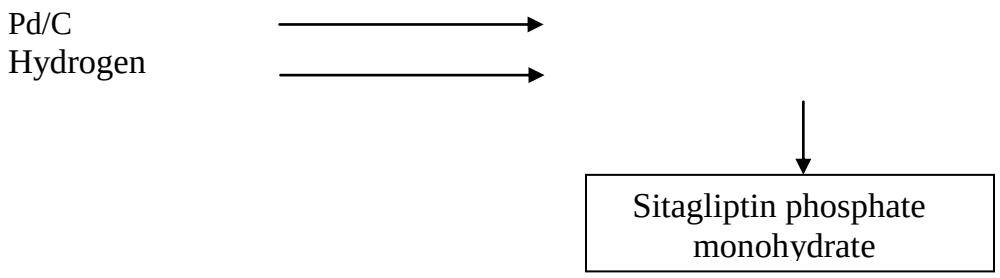

Material balance of the product stage wise:

SITAGLIPTIN PHOSPHATE MONOHYDRATE **Stage: 1**					
			Batch Size in Kg		250
			Production per month in Kg		500
			No. of batches per month		4
Name of the input	Quantity in Kg		Name of the out put		Quantity in Kg
1-[3-(triflouromethyl)-5,6-dihydro [1,2,4] triazolo[4,3-a]pyrazin-7 (8H)-yl]-4-(2,4,5-trifluorphenyl)butane-1,3-dione	388.1		Stage-1		194.1
(R)-1-phenyl ethyl amine	60.7		**Recovery**		
Hydrogen	1.0		Isopropanol		1425.0
Catalyst -5% Platinum on carbon	38.8		Acetic acid		400.0
Isopropanol	1500.00		Catalyst-5% Platinum on carbon		38.8
Acetic acid	400		**Loss**		
			Isopropanol		75.0
			(R)-1-phenyl ethyl amine		57.8
			Organic Waste		4.9
			By-product		
			Isomer of input		193.0
Total	2388.6				2388.6

SITAGLIPTIN PHOSPHATE MONOHYDRATE **Stage-2**					
Name of the input	**Quantity in Kg**		**Name of the out put**		**Quantity in Kg**
Stage-1	194.1		Final Product		250.0
Phosphoric acid	100.0		**Recovery**		0

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Hydroen	1.0		Isopropanol		1425.0
Catalyst -Palladium carbon	19.4		Spent Catalyst-		19.4
Isopropanol	1500.00		**Loss**		
Water	400.00		Isopropanol		75.0
Activated carbon	12.5		**Organic Waste**		3.9
			Waste Water		441.2
			Input Water	400.0	
			Excess Phosphoric acid	41.2	
			Spent activated carbon		12.5
Total	2227.0		Total		2227.2

Water requirement:

Consumption of water in lit/batch	**Quantity in kgs/Batch**	**Source**
Stage –I	100	Out side
Stage – II	0	
Stage –III	0	
	100	

Wastewater generation and characteristics of wastewater:

Stage	**Qty generate**	**Method of treatment**	**Mode of disposal**
Stage – I to III	116.7	Will be sent to MEE for Treatment after neutralisation	Treated effluent will be distilled in MEE
	0		
	441.2		
Total	557.9		

Stage	**Qty Generated /batch in kg**	**P^H**	**TDS mg/l**	**COD mg/l**	**BOD mg/l**
Stage – I to III	557.9	6.8	0	2100	1200

Stage No	**Waste water**		**TDS**		**COD**		**Solid waste**			
	LTDS	**HTDS**	**Kg**	**Mg/ltr**	**Kg**	**Mg/Ltr**	**Inorganic**	**Organic**	**Spent carbon**	**Emission**
1	0.0	116.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2	0.0	441.2	0.0	0.0	0.0	0.0	0	3.9	12.5	0.0
Total	0.00	557.9	0.0	0.0	0.00	0.0	0.00	3.53	0.83	0.00

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Solid waste generation characteristics & method of disposal:

Solid waste			
Inorganic	**Organic**	**Spent carbon**	**Emission**
0.0	0.0	0.0	0.0
0	3.9	12.5	0.0
0.00	3.53	0.83	0.00

Bi product details:

stage	Name of the bi-product	Quantity in kg/Batch
Stage I	Isomer of input	193
Stage II	--	0
Stage III		0

Solvent usage, recovery & loss details in kg:

SL.No	Name of the solvent used in kg	Used	Recovery	Loss due to distillation
1	Methanol	**100**	**95**	**5**
2	**-I**sopropano	**-3000**	**2850-**	**150-**

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

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

For Stereo Drugs Pvt. Ltd.

Managing Director

Source of water is from open well and bore well and estimated as 20.3 KLD. Power requirement of the project is 180KVA 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. Coling tower blow down

Volume of Process waste water & Boiler blow down.

As already mentioned only three drugs are manufactured at a time during the colander month subject to the extent of maximum effluent load permitted by the KSPCB in the consent.

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 of 10 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

For Stereo Drugs Pvt. Ltd.

Managing Director

- 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 Hazardous 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 biological treatment plant & 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

For Stereo Drugs Pvt. Ltd.

Managing Director

4. SITE ANALYSIS

(i) Connectivity:

Project site is well connected by an asphalted road which is located at a distance of about 6.9 Km from Bidar and near state highway SH-105 (Bidar-Humnabad road) just 900m away from the Factory entrance.

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

Land is owned by M/s Stereo Drugs 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 western side from the Bidar town with the distance of 6.9 km. The elevation in the project site is 659 meter above mean sea level. An area covering 10 km radius, with project site as centre, is considered as the Study area.

(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 Stereo Drugs Private Limited has the necessary concrete structures for the production. Only few types of equipment have to be installed.

PLANT LAYOUT

For Stereo Drugs Pvt. Ltd.

Managing Director

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 4,000 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 1677.34 Sqmt of leveled freehold land in developed KIADB Industrial Area at Bidar. The Plant Facilities have been designed and set up with the objective 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

For Stereo Drugs Pvt. Ltd.

Managing Director

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.

Soil samples from the following stations were collected & analyzed.

(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

For Stereo Drugs Pvt. Ltd.

Managing Director

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 = 4000 Sqmt

Builtup area = 1677.34 Sqmt

Road area = 1208 Sqmt

Greenbelt area = 1114.66 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

For Stereo Drugs Pvt. Ltd.

Managing Director

6. PROPOSED INFRASTRUCTURE

i. **Industrial Area**: The proposed project is coming in KIADB Industrial area.

ii. **Residential Area**: NA.

iii. **Greenbelt:** 1,406 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 6.9 Km from Bidar and near state highway SH-105 (Bidar-Humnabad road) just 900m 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
- 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 3mARL 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

For Stereo Drugs Pvt. Ltd.

Managing Director

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.
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

For Stereo Drugs Pvt. Ltd.

Managing Director

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:

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 Hazardous 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.

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Managing Director

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 180KVA, which is being met from GESCOM. DG sets of about 125 KVA 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.**

There is not much additional project cost as it is an existing unit. The gross value of existing infrastructure is Rs. 7 Crores. The infrastructure needed for the proposed modification 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 and export opportunities to the country.

For Stereo Drugs Pvt. Ltd.

Managing Director