Verification of Pollution Load

For

Change of Product Mix

Of

M/s. Neuland Laboratories Limited, Unit-3

Sy. No. 10, Flat No. 3-72,
IDA, Gaddapotharam village, Jinnaram Mandal,
Sangareddy district, Telangana

Submitted to

Regional Pollution Control Board, Telangana
For CFE Application

Empanelled Environmental Auditor

M/s. Pragathi Labs & Consultants Pvt. Ltd

(Recognized by MINISTRY OF ENVIRONMENT FORESTS & CLIMATE CHANGE, GOVT. OF INDIA)
NABET Certificate No.—NABET/EIA/2124/RA 0237
Plot No. B15 &16, Industrial Estate
Behind PCB, Sanath Nagar
Hyderabad - 500 0018

LIST OF CONTENTS

LIST OF TABLES

LIST OF ANNEXURES

1. INTRODUCTION

M/s. Neuland Laboratories Limited is incorporate under Companies Act, 1956 with its registered office at 11th Floor (5th Level), Phoenix IVY Building, Plot No. 573A-III,Road No.82, Jubilee Hills, Hyderabad with existing plant for the manufacturing of bulk drugs and intermediates. The unit is located at Sy. No. 10, Plat No. 3-72, IDA Gaddapotharam, Jinnaram Mandal, Sangareddy District of Telangana State.

1.1 Existing and Proposed Products of the Unit

As per the Expansion Consent Order obtained in 2023, the industry is allowed to manufacture 20 products with individual capacities mentioned therein at any given point of time. The existing production quantities are given in **Table 1.1**

Table 1.1 Production Quantities of the Existing Products

No.	Name of the Product	Quantity (TPM)
1	Ata zanavir	1
2	Bilastin	5
3	Ciprofloxacin Hydrochloride	50
4	Dorzolamide Hydrochloride	1
5	Enalapril Maleate	2
6	Entacapone	10
7	Escitalopram Oxalate	1
8	Ipratropium Bromide	1
9	Itraconazole	10
10	Labetalol Hydrochloride	5
11	Lacosomide	2
12	Levetiracetam	30
13	Levofloxavin Hemihydrate	5
14	Mirtazapine	5
15	Moxifloxacin Hydrochloride Monohydrate	5
16	Olanzpaine	1
17	Sevelamer Carbonate	10
18	Sotalol Hydrochloride	5
19	Ursodeoxycholic Acid	4
20	Development products	5
Total		**157**

Due to the change in marketing demand of the products, the management decided to discontinue 7 of the existing 20 products and proposes to manufacture 7 new products. The proposed products with production quantities are given in **Table 1.2**

Table 1.2 Production Quantities of the Proposed Products (TPM)

No.	Name of the Product	Quantity (TPM)
1	Ciprofloxacin Hydrochloride	39
2	Dorzolamide Hydrochloride	1
3	Enalapril Maleate	2
4	Entacapone	10
5	Escitalopram Oxalate	1
6	Ipratropium Bromide	1
7	Itraconazole	10
8	Labetalol Hydrochloride	5
9	Levetiracetam	30
10	Levofloxavin Hemihydrate	5
11	Mirtazapine	5
12	Sotalol HCl	5
13	Bempodoic acid	10
14	Diferasirox	1
15	Sabam HCl	6
16	Xanomeline Tartrate	4
17	Viloxazine HCL	4
18	LYT -100 (Deupirfenidone)	0.3
19	Sitagliptin Phosphate Monohydrate	1
20	Development products	5
Total		**145.3**

The list of Starting Raw Materials (SRM) and no. of stages proposed for the proposed change is given in **Table 1.3.**

Table 1.3 List of Starting Raw Material for Proposed Products

No.	Name of the Product	Capacity (TPM)	No. of Stages proposed	Raw material	Quantity (kg/day)
1	Ciprofloxacin Hydrochloride	39	1	*Q.Acid*	1359.47
2	Dorzolamide Hydrochloride	1	8	*Dihydrothieno thio pyran sulphonamide*	16.67
3	Enalapril Maleate	2	3	*Michael addition product*	73.34
4	Entacapone	10	2	*3,4-dihydroxy-nitrobenzaldehyde*	366.66
5	Escitalopram Oxalate	1	3	*Hydroxy compound*	56.66
6	Ipratropium Bromide	1	3	*Ipratropium Condensation Product*	20.00
7	Itraconazole	10	2	*Itraconazole hydroxylcompound*	233.33
8	Labetalol Hydrochloride	5	3	*Benzyl acetone*	73.02
9	Levetiracetam	30	4	*Propionaldehyde (SRM)*	504.00
10	Levofloxavin Hemihydrate	5	2	*Q-Acid (SRM)*	166.67
11	Mirtazapine	5	4	*2 -Chloronicotinonitrile*	140.00
12	Sotalol HCl	5	4	*Methane Sulfonyl Chloride*	100.00

13	Bempodoic acid	10	3	*1-bromo-5-chloropentane*	133.332
14	Diferasirox	1	1	*Salicyclic acid*	50.68
15	Sabam HCl	6	2	*Propionaldehyde*	344.82
16	Xanomeline Tartrate	4	4	*Nicotinaldehyde*	576.66
17	Viloxazine HCL	4	3	*2-Ethoxy phenol*	276
18	LYT -100 (Deupirfenidone)	0.3	3	*5-bromo 2-methoxy pyridine*	8
19	Sitagliptin Phosphate Monohydrate	1	4	*2-(2,4,5-Trifluorophenyl) acetic acid*	24.75
20	Development products	5	--	--	--

2.0 ANTICIPATED POLLUTION LOAD

In order to understand the change in pollution load, a detailed material balance is calculated for each and every product with the help of Root of Synthesis (ROS).

With the help of material balance

1. Estimated the quantity of effluent generation along with the pollution load,
2. Solid waste quantity and its nature
3. Gaseous emissions (process) and its composition
4. Solvent recovery and wastage

The above is used for comparing the pollution load as the proponent is going for product change, as per the recent guidelines of "Change in product mix" on 23rd November, 2016.

2.1 Water requirement, Effluent generation & its characteristics

From the material balance of the existing products water requirement, effluent discharge and it's characteristics are given in **Table 2.1**.

Table 2.1 Water Requirement & Effluent Generation for Existing Products

No.	Name of the Product	Water (LPD)	HTDS Effluent (LPD)	LTDS Effluent (LPD)
1	Ata zanavir	576.61	754.67	0
2	Bilastin	4891.24	5506.33	0
3	Ciprofloxacin HCl	27403.10	29567.54	0
4	Dorzolamide HCl	3067.28	1349.77	1817.03
5	Enalapril Maleate	2100.11	2370.85	0
6	Entacapone	6666.60	7345.93	0
7	Escitalopram Oxalate	3499.65	2278.27	1382.20
8	Ipratropium Bromide	1667	764.99	930.49
9	Itraconazole	10666.56	11251.55	0
10	Labetalol Hydrochloride	631.09	959.69	0
11	Lacosomide	3224.63	4133.65	0
12	Levetiracetam	17000	18458	3500
13	Levofloxavin Hemihydrate	7166.81	6355.13	1220.02
14	Mirtazapine	7000.14	8071.44	0
15	Moxifloxacin	833.35	1088.36	0
16	Olanzpaine	4566.21	3369.20	1403.29
17	Sevelamer Carbonate	1587.29	2028.55	0
18	Sotalol Hydrochloride	2250.05	2807.22	0
19	Ursodeoxycholic Acid	1366.63	1987.86	0
20	Development products	3836	3632.92	337.27
Total		**110000**	**114081.93**	**10590.30**

From the material balance of the proposed products water requirement, effluent discharge and its characteristics are given in **Table 2.2**.

Table 2.2 Water Requirement & Effluent Generation for Proposed Products (LPD)

No.	Name of the Product	Water (LPD)	HTDS Effluent (LPD)	LTDS Effluent (LPD)
1	Ciprofloxacin Hydrochloride	21374.37	23062.64	0.00
2	Dorzolamide Hydrochloride	3067.28	1349.77	1817.03
3	Enalapril Maleate	2100.11	2370.85	0.00
4	Entacapone	6666.60	7345.93	0.00
5	Escitalopram Oxalate	3499.65	2278.27	1382.20
6	Ipratropium Bromide	1667.00	764.99	930.49
7	Itraconazole	10666.56	11251.55	0.00
8	Labetalol Hydrochloride	631.09	959.69	0.00
9	Levetiracetam	17000.00	18458.00	3500.00
10	Levofloxavin Hemihydrate	7166.81	6355.13	1220.02
11	Mirtazapine	7000.14	8071.44	0.00
12	Sotalol HCL	2250.05	2807.22	0.00
13	Bempodoic acid	13166.48	15890.99	0.00
14	Diferasirox	1025.00	1083.50	0.00
15	Sabam HCl	1213.79	2565.74	46.24
16	Xanomeline Tartrate	2269.90	2213.76	0.00
17	Viloxazine HCL	1396.49	1426.99	257.64
18	LYT -100 (Deupirfenidone)	794.17	997.25	0.00
19	Sitagliptin Phosphate Monohydrate	753.00	976.98	16.86
20	Development products	5947.28	3632.92	1397.23
Total		**109655.76**	**113863.62**	**10567.71**

Comparison has been made for the list of proposed, existing, newly proposed and continued products. To calculate the available loads for the proposed change of product mix, subtracted continued products loads from the total existing load.

Table 2.3 Comparison of Water Requirement

Particulars	Effluent (LPD)
Total water requirement for Proposed Products	109655.76
Water requirement for Existing products (Worst case)	110000
Available water for Proposed Change	**110000**

Table 2.4 Comparison of Effluent Generation

Particulars	Effluent (LPD)
Total HTDS Effluent generation by Proposed Products	113863.62
Total LTDS Effluent generation by Proposed Products	10567.71
HTDS Effluent generation by Existing products (Worst case)	114081.93
LTDS Effluent generation by Existing products (Worst case)	10590.30

Available HTDS & LTDS effluent load for Proposed Change	**114081.93 & 10590.30**

2.2 Product Wise Solid Waste Generation

The Product Wise Solid Waste generation of the existing products are listed in **Table 2.5.**

Table 2.5 Product Wise Solid Waste Generation for Existing Products (kg/day)

No.	Name of the Product	Organic residue	Forced evaporation salts	Inorganic residue
1	Ata zanavir	21.58	69.29	0.00
2	Bilastin	743.70	508.75	0.00
3	Ciprofloxacin HCl	325.49	1423.79	217.87
4	Dorzolamide HCl	26.01	56.22	0.00
5	Enalapril Maleate	17.93	195.34	0.00
6	Entacapone	374	383.33	0.00
7	Escitalopram Oxalate	67.53	35.83	20.00
8	Ipratropium Bromide	10.87	8.34	0.00
9	Itraconazole	116.67	409.33	0.00
10	Labetalol Hydrochloride	0.00	223.16	0.00
11	Lacosomide	586.75	576.29	0.00
12	Levetiracetam	1099.00	3113.00	660.00
13	Levofloxavin Hemihydrate	186.67	243.34	0.00
14	Mirtazapine	123.67	297.17	760.57
15	Moxifloxacin	153.34	173.34	0.00
16	Olanzpaine	27.46	94.86	38.33
17	Sevelamer Carbonate	0.00	317.57	0.00
18	Sotalol Hydrochloride	99.50	378.51	0.00
19	Ursodeoxycholic Acid	134.52	284.53	22.67
20	Development products	135.35	288.91	56.56
Total		**4250.02**	**9080.88**	**1775.98**

The values obtained from material balance are used to estimate quality and quantity for the proposed product change. The solid waste generation for proposed products are given in the **Table 2.6.**

Table 2.6 Product Wise Solid Waste Generation for Proposed Products (kg/day)

No.	Name of the Product	Organic residue	Forced evaporation salts	Inorganic residue
1	Ciprofloxacin Hydrochloride	253.88	1110.55	169.93
2	Dorzolamide Hydrochloride	26.01	56.22	0
3	Enalapril Maleate	17.93	195.34	0
4	Entacapone	374.00	383.33	0
5	Escitalopram Oxalate	67.53	35.83	20.00

6	Ipratropium Bromide	10.87	8.34	0
7	Itraconazole	116.67	409.33	0
8	Labetalol Hydrochloride	0.00	223.16	0.00
9	Levetiracetam	1099.00	3113.00	660.00
10	Levofloxavin Hemihydrate	186.67	243.34	0
11	Mirtazapine	123.67	297.17	760.57
12	Sotalol HCL	99.50	378.51	0
13	Bempodoic acid	526.14	765.14	124.33
14	Diferasirox	202.37	113.90	12.81
15	Sabam HCl	341.74	659.53	0
16	Xanomeline Tartrate	364.07	572.46	0.00
17	Viloxazine HCL	27.80	165.91	8.46
18	LYT -100 (Deupirfenidone)	142.60	21.96	0.00
19	Sitagliptin Phosphate Monohydrate	6.68	38.21	28.98
20	Development products	135.33	288.91	0
Total		**4122.45**	**9080.13**	**1785.07**

Table 2.7 Comparison for Organic & Inorganic residue, Forced Evaporation Salts (kg/day)

Particulars	Effluent (LPD)
Total organic & Inorganic residue generation for proposed products	4122.45 & 1785.07
Total Forced Evaporation Salts for proposed products	9080.13
Total organic & Inorganic residue generation for Existing products	4250.02 & 1775.98
Total Forced Evaporation Salts for Existing products	9080.88
Available organic, Inorganic residue & Forced Evaporation Salts for Proposed Change	**4250.02 , 1775.98 & 9080.88**

2.3 Spent Carbon

From the material balance of the spent carbon for existing and proposed products are calculated and given in Table **2.8 & 2.9**

Table 2.8 Spent Carbon for Existing Products (kg/day)

No.	Name of the Product	Spent carbon
1	Ata zanavir	0.00
2	Bilastin	58.33
3	Ciprofloxacin HCl	348.58
4	Dorzolamide HCl	14.50
5	Enalapril Maleate	12.00
6	Entacapone	433.33
7	Escitalopram Oxalate	8.33
8	Ipratropium Bromide	5.00
9	Itraconazole	100.00
10	Labetalol Hydrochloride	90.01
11	Lacosomide	54.72
12	Levetiracetam	300.00

No.	Name of the Product	Spent carbon
13	Levofloxavin Hemihydrate	55.00
14	Mirtazapine	71.67
15	Moxifloxacin	66.67
16	Olanzpaine	8.33
17	Sevelamer Carbonate	79.36
18	Sotalol Hydrochloride	46.67
19	Ursodeoxycholic Acid	0.00
20	Development products	57.65
Total		**1810.17**

Table 2.9 Spent Carbon for proposed Products (kg/day)

No.	Name of the Product	Spent carbon
1	Ciprofloxacin Hcl	271.89
2	Dorzolamide	14.50
3	Enalapril Maleate	12.00
4	Entacapone	433.33
5	Escitalopram	8.33
6	Ipratropium Bromide	5.00
7	Itraconazole	100.00
8	Labetalol	90.01
9	Levetricetum	300.00
10	Levofloxacin	55.00
11	Mirtazapine	71.67
12	Sotalol	46.67
13	Bempodoic acid	0.00
14	Diferasirox	6.00
15	Sabam HCl	0.00
16	Xanomeline Tartrate	0.00
17	Viloxazine HCL	15.03
18	LYT -100 (Deupirfenidone)	1.25
19	Sitagliptin Phosphate Monohydrate	2.72
20	Development products	57.65
Total		**1491.05**

Table 2.10 Comparison for Spent Carbon (kg/day)

Particulars	Effluent (LPD)
Total Spent Carbon for Proposed products	1491.05
Total Spent Carbon for Existing products (Worst case)	1810.17
Available Spent Carbon load	**1810.17**

For the proposed change spent carbon load is 1491.05 Kg/day, and it is 319.12 kg less than the existing operation. However, spent carbon is collected and stored to dispose to TSDF for incineration and authorized cement industry for use in kilns.

2.4 COD Load

From the material balance of the existing and proposed products COD load for Existing Products are given in Table **2.11 & 2.12.**

Table 2.11 COD load for Existing Products (kg/day)

No.	Name of the Product	COD Load
1	Ata zanavir	11.06
2	Bilastin	162.23
3	Ciprofloxacin Hcl	660.48
4	Dorzolamide	31.19
5	Enalapril Maleate	114.76
6	Entacapone	392.16
7	Escitalopram	185.96
8	Ipratropium Bromide	47.26
9	Itraconazole	275.20
10	Labetalol	38.80
11	Lacosomide	146.73
12	Levetricetum	200.20
13	Levofloxacin	115.67
14	Mirtazapine	199.60
15	Moxifloxacin	75.00
16	Olanzpaine	68.66
17	Sevelamer carbonate	23.81
18	Sotalol	70.98
19	Ursodeoxycholic acid	23.62
20	Development products	93.53
Total		**2936.90**

Table 2.12 COD load for Proposed Products (kg/day)

No.	Name of the Product	COD Load
1	Ciprofloxacin Hcl	515.17
2	Dorzolamide	31.19
3	Enalapril Maleate	114.76
4	Entacapone	392.16
5	Escitalopram	185.96
6	Ipratropium Bromide	47.26
7	Itraconazole	275.20
8	Labetalol	38.80
9	Levetricetum	200.20
10	Levofloxacin	115.67
11	Mirtazapine	199.60
12	Sotalol	70.98
13	Bempodoic acid	126.65
14	Diferasirox	44.66
15	Sabam HCl	31.89

No.	Name of the Product	COD Load
16	Xanomeline Tartrate	294.77
17	Viloxazine HCL	21.95
18	LYT -100 (Deupirfenidone)	111.47
19	Sitagliptin Phosphate Monohydrate	0.00
20	Development products	93.53
Total		**2911.87**

Table 2.13 Comparison of COD load (kg/day)

Particulars	Effluent (LPD)
Total COD load for Proposed products	2911.87
Total COD load for Existing products (Worst case)	2936.90
Available COD load	**2936.90**

2.5 Process Emissions

Process Emissions from the existing and proposed operation are given in Table **2.14 & 2.15.**

Table 2.14 Process Emissions for Existing Products (kg/day)

No.	Name of the Product	Process Emissions
1	Ata zanavir	8.27
2	Bilastin	36.96
3	Ciprofloxacin HCl	0.00
4	Dorzolamide HCl	0.17
5	Enalapril Maleate	14.00
6	Entacapone	0.00
7	Escitalopram Oxalate	0.00
8	Ipratropium Bromide	0.00
9	Itraconazole	0.00
10	Labetalol Hydrochloride	10.84
11	Lacosomide	8.96
12	Levetiracetam	341.00
13	Levofloxavin Hemihydrate	0.00
14	Mirtazapine	0.00
15	Moxifloxacin	0.00
16	Olanzpaine	0.00
17	Sevelamer Carbonate	21.52
18	Sotalol Hydrochloride	49.33
19	Ursodeoxycholic Acid	0.00
20	Development products	17.67
Total		**508.72**

Table 2.15 Process Emissions for Proposed Products (kg/day)

No.	Name of the Product	Process Emissions
1	Ciprofloxacin Hcl	0.00
2	Dorzolamide	0.17
3	Enalapril Maleate	14.00
4	Entacapone	0.00
5	Escitalopram	0.00
6	Ipratropium Bromide	0.00
7	Itraconazole	0.00
8	Labetalol	10.84
9	Levetricetum	341.00
10	Levofloxacin	0.00
11	Mirtazapine	0.00
12	Sotalol	49.33
13	Bempodoic acid	0.00
14	Diferasirox	0.00
15	Sabam HCl	0.00
16	Xanomeline Tartrate	0.24
17	Viloxazine HCL	0.00
18	LYT -100 (Deupirfenidone)	0.00
19	Sitagliptin Phosphate Monohydrate	6.25
20	Development products	17.67
Total		**439.51**

Table 2.16 Comparison of Process Emissions (kg/day)

Particulars	Effluent (LPD)
Total Process Emissions for Proposed products	439.51
Total Process Emissions for Existing products (Worst case)	508.72
Available Process Emission load	**508.72**

3.0 ENVIRONMENT MANAGEMENT PLAN

3.1 Water and Waste water

The total raw water requirement for plant is 531 KLD; outside tankers are the source to fulfil the water requirement. The total water requirement and effluent generation from each and every unit is given in **Table 3.1**.

The proposed production quantity is not exceeding the existing capacity. Existing machinery is adequate to produce the desired quantity of new products. No additional amount of water is needed for the proposed production.

Table 3.1 Details of Water Requirement and Effluent Generation

Description		Input Water (KLD)		Effluent generation (KLD)	
No.	**Description**	**Fresh**	**Recycled**	**HTDS**	**LTDS**
1	Process	110		114	11
2	Process washings	35		27	8
3	Boiler Make up	40	108		40
4	Cooling		170		20
5	DM plant regeneration	33		8	
6	Scrubber		5	5	
7	Domestic	20			20
8	Gardening	10			
Total		**248**	**283**	**154**	**99**
Grand Total		**531**		**253**	

3.2 Segregation of Effluent stream

High Concentration Stream

The process, process washings, scrubber and QC lab effluent will have high concentration in terms of TDS. These effluents shall be well treated in existing treatment plant. The industry has adopted Zero Liquid Discharge System (ZLDS). Hence, no effluent can be discharged to the outside environment.

Low Concentration Stream

The effluent coming from RO/DM plant, domestic activities can have low concentrations of TDS. Process low TDS effluent along with other effluents shall be treated in existing ETP.

There is no discharge of effluent to the surroundings from the plant site. Because the plant has adopted the Multiple Effect Evaporating System (MEE) followed by Agitated Thin Film Dryer (ATFD), which can make the discharge quantity is to zero by forced evaporation of water and other solvents.

RO reject shall be treated in ATFD and permeate water shall be reused as a makeup water for boiler and cooling tower.

3.3 Gaseous Emission

3.3.1 Process Emissions

Carbon dioxide is major composition of existing and proposed process emissions. One of the proposed products (Levetiracetam) releases 87 % of the total emissions of the proposed change. These can be released into the environment safely and other gases can be treated in existing double stage scrubbers, if any.

Volatile Organic Compounds (VOCs) Emission

Evaporation losses of solvents in the plant is controlled by the circulation of chilled brine, transfer of solvents by using pumps instead of manual handling, closed centrifuges, providing primary and secondary condensers to all the reactor vents and all the solvent storage tanks and keeping solvent storage in ground storage tanks with closed pipeline to reactors.

3.3.2 Fugitive Emissions

In proposed change of product mix the productivity is not exceeding the existing production and no increase in flue gas emissions or change in major activity is anticipated. However the existing emissions are discussed in the following paragraphs.

Boiler

Boiler with 10 TPH is installed to meet the steam requirements of the existing process; no further steam generating sources are required for the proposing products. The boiler is provided with bag filter and cyclone separators to control the emissions. Existing flue emission details are given in **Table 3.3.**

Table 3.2 Stack Emission Sources

Stack attached to	Fuel	Fuel Consumption	Stack Height (m)
8 TPH Boiler	Coal	30 TPD	30
3 TPH Boiler (Stand by)		--	
1000 KVA D.G. Set	Diesel Oil	---	10 + building height
725 KVA D.G. Set	Diesel Oil	---	5.4 + building height
2500 KVA D. G Set	Diesel Oil	---	6.3 + building height

D. G. Set

Presently there are 3 D.G. sets are available (1 x 1250, 1x725 & 1 x 2250 KVA) in the unit. No additional source is required for proposed change.

3.4 Solid Waste

The solid waste generation for each product of existing and proposed as we discussed earlier chapter, process residue and spent carbon to be collected and disposed to cement plants for co-processing. Inorganic and forced evaporation salts to TSDF for secured land filling after stabilizing the waste chemicals.
Mixed spent solvent/Distillation bottom residue will be disposed to TSDF for incineration and Authorized Cement plants for co-processing.

Disposal of used oil is to authorize re-processors/recyclers. After detoxification, the hazardous waste containers and liners such as HDPE drums, MS drums, Carboys, Fiber boards and Poly bags are to be disposed to the outside agencies.

Electronic waste (E- waste) generated in the industry will be sent to Authorized recyclers.

3.5 Noise levels

The main sources of noise are D.G. sets and boiler. These are provided with acoustic enclosures to control the noise levels. Ear plugs are provided to the persons, who are working nearest to the noise generating sources.

4.0 EXECUTIVE SUMMARY

The proponent is going for change of product mix. By doing the material balance the details regarding water requirement, wastewater generation and its characteristics, solid waste generation, process emissions are quantified. These values are compared with existing unit values. The details of these studies are summarized below

4.1 Comparative Production Quantity

The industry operating to manufacture 20 products with capacity and the combination mentioned in latest CFO. In worst case the production should not exceed 5233.35 kg/day of finished products.

Presently the unit proposes to manufacture the 20 finished products (given in chapter 1) with capacity of 4843.33 kg in a day.

4.2 Water Consumption and Effluent Generation

No additional water is required for the proposed change of products and also the effluent generation from the proposed change will not exceed the existing load. The existing machinery and all other utilities are adequate for the proposed one.

4.3 Comparative Quantity of Solid Waste Generation

Generated process waste, spent carbon and mixed spent solvent shall be collected and disposed to TSDF for incineration and authorized cement plants for co-processing. Forced evaporation salts shall be sent to secured land filling. Recovered solvent can be reused within the plant premises.

Disposal of used oil is to authorised re-processors/recyclers. After detoxification, the hazardous waste containers and liners such as HDPE drums, MS drums, Carboys, Fiber boards and Poly bags are to be disposed to the outside agencies.

Table 4.1 Solid Waste Generation and its Disposal Method

S.No	Type of Waste	Quantity	Disposal Option
1	Process Organic residue	4.6 TPD	Shall be disposed to Cement Units for Co-processing/ AFRF facilities for pre-processing (or) M/s. TSDF, Dundigal for pre-processing to be sent to Cement units for Co-processing.
2	Off Specification / Rejected	10 Kg/day	
3	Spent Carbon	1.81 TPD	
4	ETP Sludge	5 TPD	
5	Distillation bottom residue	2.1 TPD	
6	MEE Salts	10.15 TPD	Shall be sent to TSDF for land filling after stabilization
7	Process Inorganic residue	1.8 TPD	

Table 4.2 Solid Waste Generation and its recycling option

S.No	Type of Waste	Quantity	Disposal Option
1	Spent solvents	60 KLD	The industry shall operate Solvent Recovery Plant within the plant premises in case of utilization of Multiple Solvents/ for recovery of Mixed Solvents/ Spent Solvents, which cannot be distilled by Simple Distillation. Solvents shall be recovered to the maximum extent possible and shall be reused. The Spent/Mixed Solvents, which cannot be reused in the plant, shall be disposed to the End Users/Authorized Cement manufacturing units for Co-processing /AFRF facilities for pre-processing / TSDF, Dundigal for incineration. The industry shall not dispose Spent Solvents / Mixed Spent Solvents to the traders/recyclers.
2	Mixed Spent Solvents	2 KLD	
3	Used Oil/ Waste Lubricating Oil	60 LPD	Authorized Re-processors / Recyclers
4	Hazardous used containers	500 Nos/Month	After Complete detoxification, it shall be disposed to the outside agencies.
5	General Solid Waste	160 Kg/day	Shall be disposed as per Solid Waste Management Rules, 2016
6	Lead Acid Batteries	5 Nos/Month	
7	E-Waste	50 Kg/day	Authorized Re-processors / Recyclers
8	Coal Ash (boiler)	21.2 TPD	Sold to brick manufactures

4.4 Comparative quantity of Process emissions

Composition of process emissions for proposed change is only Carbon dioxide and that shall be released into the environment safely.

Summary

After detailed study of material balance, water requirement, effluent generation and solid waste generation has been worked for the proposed plant and the results are compared with the existing facilities. The comparison of dropped load and new proposed load has been given in **Table 4.3**.

Table 4.3 Comparison of Overall Pollution Load

Parameter	Existing	Proposed	Change
Water ,KLD	110	109.6	-0.4
COD load, kg/day	2936.90	2911.87	- 25.03
Spent carbon, kg/day	1810.17	1491.05	-319.12
Organic residue, kg/day	4250.02	4122.45	-127.57
In Organic residue, kg/day	1775.98	1785.07	+ 9.09
Process Emissions, kg/day	508.72	439.51	- 69.21
Spent solvent KLD	60	59.1	-0.9
High TDS Effluent, LPD	114081.93	113863.62	-218.31
Low TDS Effluent, LPD	10590.30	10567.71	-22.59

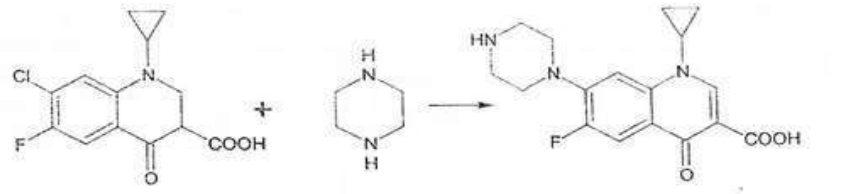
The above tables indicating that the pollution loads for the proposed change of product mix are not exceeding the consent limits.

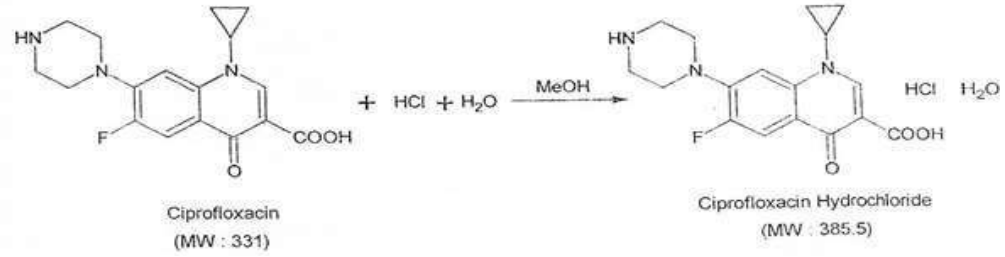
Material Balance for the Proposed Products

1. Ciprofloxacin Hydrochloride

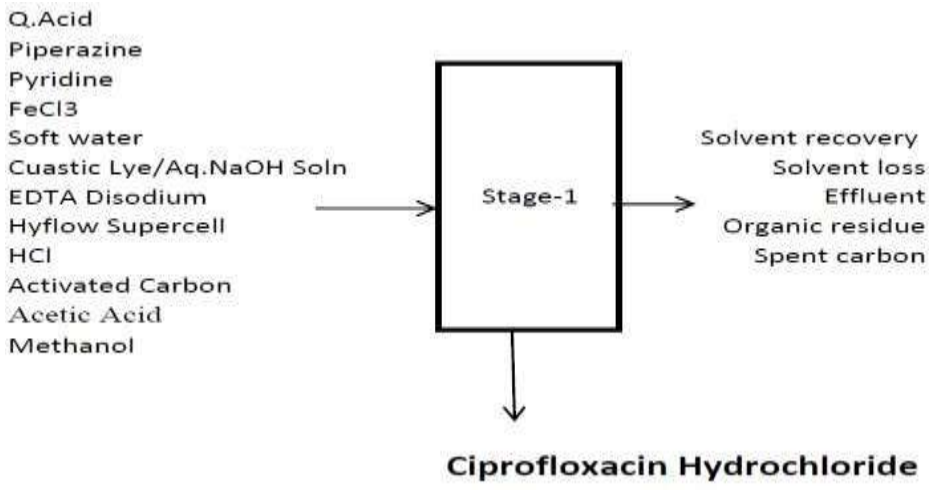
Process Description with Route of Synthesis

Stage-I: Q-acid is reacted with Piperzine to produce Ciprofloxacin, which again reacts with Hydrochloric acid and water in presence of Methanol, Pyridine and Acetic acid to produce pure compound of Ciprofoxacin Hydrochloride





Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Pyridine	1178.40	**Product 1**	**382.50**
Piperazine	155.00	**Solvent recovery**	
FeCl3	30.00	Methanol	4640.00
Soft water	6289.00	Methanol loss	27.55
Sodium hydroxide flakes	200.00	Pyridine	1168.26
EDTA Disodium	33.50	Pyridine loss	7.19
Hyflow Supercell	50.00	Acetic acid	230.00
HCl	124.71	Acetic acid loss	2.24
Activated Carbon	80.00	**Effluent**	
Acetic Acid	241.50	Methanol	21.10
Methanol	4688.64	Pyridine	2.95
Q.Acid	400.00	Acetic acid	9.26
		FeCl3	30.00
		Water from HCl	81.05
		Water	6289.00
		EDTA Disodium	33.50
		NaCl	137.33
		NaOH	125.93
		Gen. water	22.57
		Piperzine	55.62
		Organic residue	
		Q-acid	74.70
		Inorganic residue	
		Hyflow Supercell	50.00
		Spent carbon	**80.00**
Total	**13470.75**	**Total**	**13470.75**

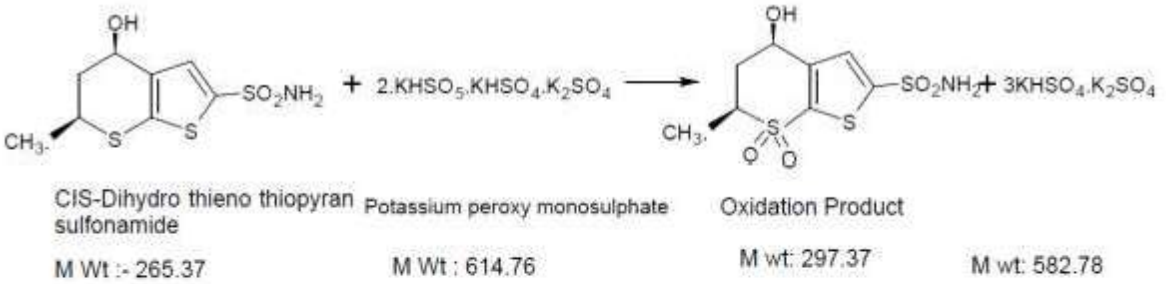
Anticipated Pollution Load

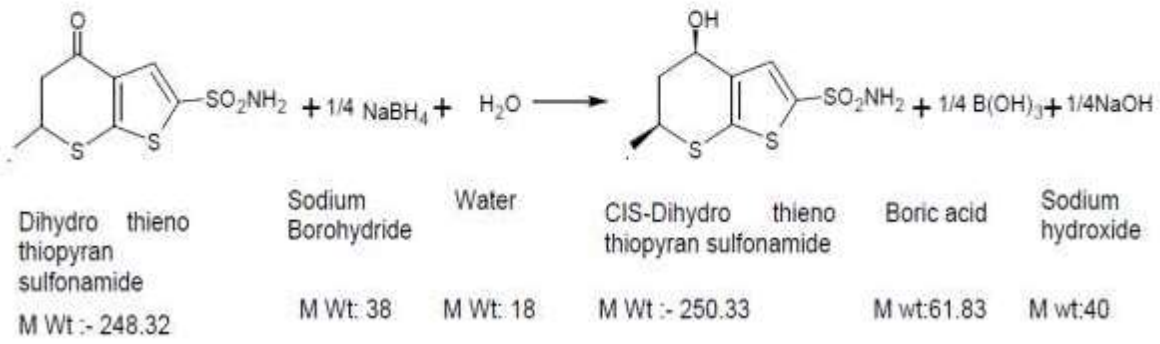
No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporati on salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	382.50	6289.00	6785.74	0.00	6038.26	36.98	33.31	326.76	151.58	74.70	80.00	0.00	50.00
Pollution Load per Day													
Total	1300	21374.37	23062.64	0.00	20522.19	124.66	113.21	1110.55	515.17	253.88	271.89	0.00	169.93

2. Dorzolamide Hydrochloride

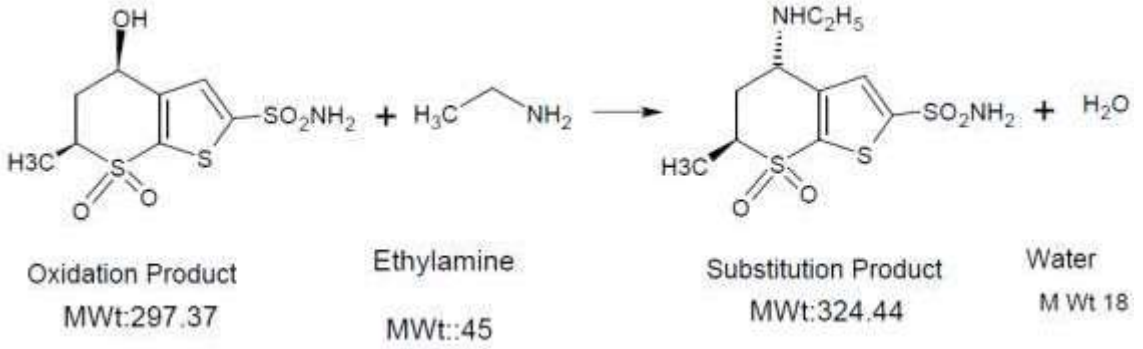
Process Description with Route of Synthesis

Stage-I: Dihydro thieno thiopyran sulphonamide is reacted with Sodium borohydride and water in presence of Methanol to produce CIS-Dihydro thieno thipyran sulphanimide, which again reacts with Potassium peroxy monosulphate to produce Oxidation product (stage-I).

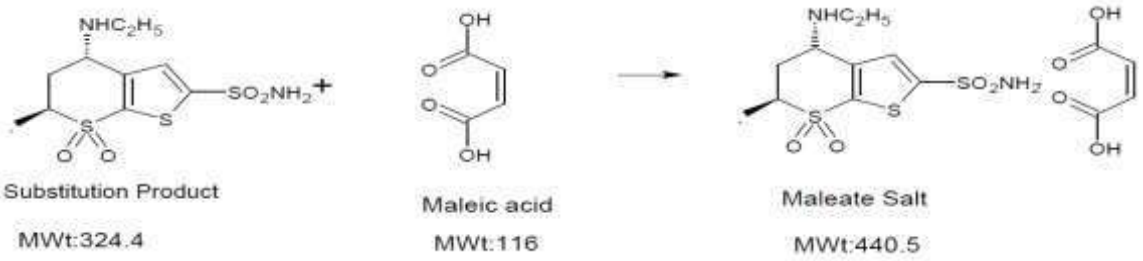




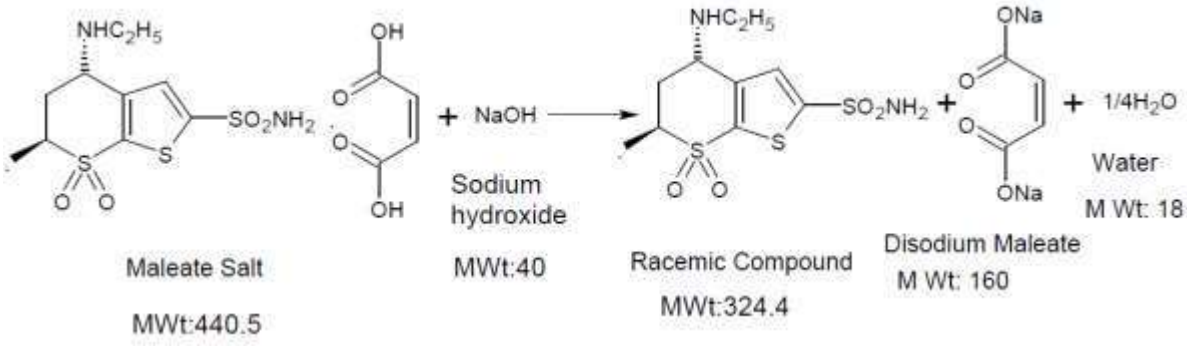
Stage-II: Stage-I compound is reacted with Ethylamine in presence of Tetrahydrofuran to produce stage-II compound.



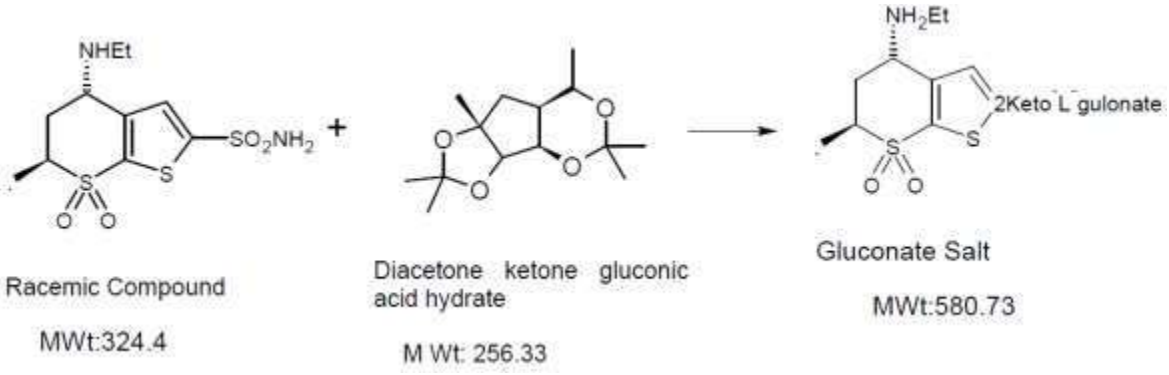
Stage-III: Stage-II compound is reacted with Maleic acid in presence of Acetone to produce stage-III compound.



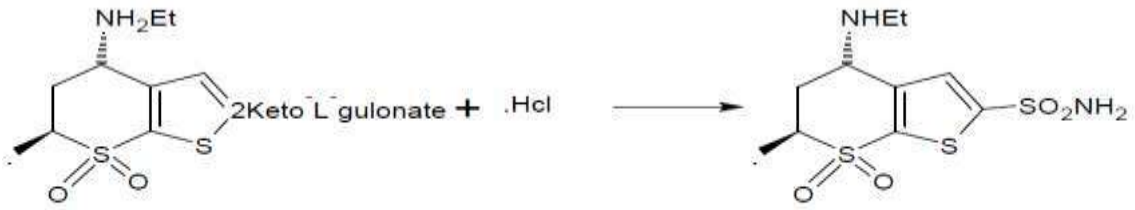
Stage-IV: Stage-III compound is reacted with Sodium hydroxide to produce Racemic compound.



Stage-V: Formed Racemic compound is reacted with Diacetone ketone gluconic acid hydrate in presence of industrial methylated spirit (IMS) to produce Gluconate salt.



Stage-VI: Formed Gluconate salt is reacted with Hydrochloric acid in presence of Sodium hydroxide to produce Dorzolamide free base.



Gluconate Salt
MWt:580.73

Hydrochloric Acid
M Wt: 36.5

DZ Free Base
M Wt: 324.4

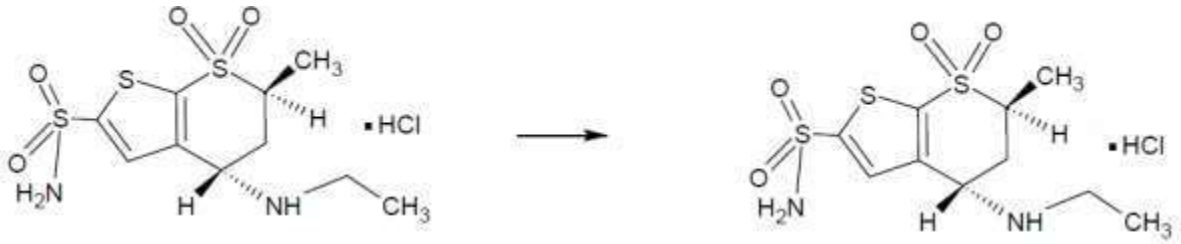
Stage-VII: Dorzolamide free base is reacted with is again reacted with Methonalic hydrochloric acid in presence of Methanol and Isopropyl alcohol to produce Dorzolamide hydrochloride pure.

Dorzolamide Free base
MWt:324.4

Hydrochloric acid
M Wt: 36.5

Dorzolamide Hydrochloride pure
MWt:360.91

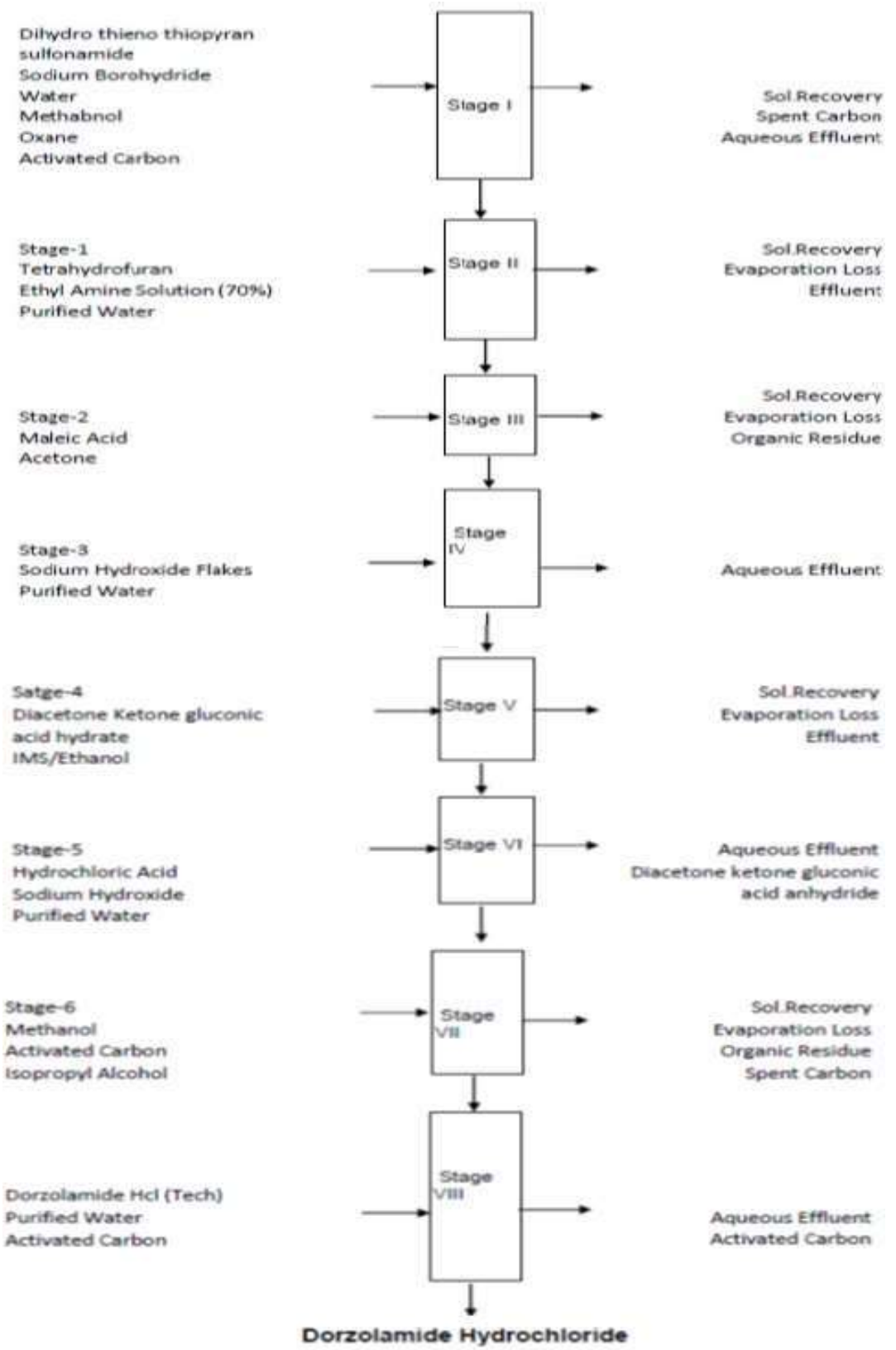
Stage-VIII: Dorzolamide hydrochloric acid is purified with activated carbon to get pharma grade Dorzolamide hydrochloride.



Dorzolamide
MWt:360.9

Dorzolamide
MWt:360.9

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Dihydro thieno thiopyran sulphonamide	100.00	**Product**	
Sodium Borohydride	4.00	Product	115.00
Water	4200.00	**Recovery**	
Methanol	960.00	Methanol	800.00
Potassium peroxy monosulphate	240.00	Methanol loss	18.00
Activated Carbon	20.00	**Effluent**	
		Water	4194.00
		Methanol	142.00
		Sodium hydroxide	4.00
		Boric acid	6.00
		Potassium salt	225.00
		Spent carbon	**20.00**
Total	**5524.00**	**Total**	**5524.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-I	115.00	**Product**	
Tetrahydrofuran	800.00	Stage-II	120.00
Purified Water	5000.00	**Recovery**	
Ethyl Amine Solution (70%)	80.00	Tetrahydrofuran	750.00
		Tetrahydrofuran loss	45.00
		Effluent	
		Water	5000.00
		Tetrahydrofuran	15.00
		Water from Ethylamine	56.00
		Ethylamine	4.00
		Organic residue	
		Stage-1	5.00
Total	**5995.00**	**Total**	**5995.00**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-II	120.00	**Product**	
Maleic Acid	42.00	Stage-III	160.00
Acetone	1000.00	**Recovery**	
		Acetone	950.00
		Acetone loss	35.00
		Organic residue	
		Stage-2	2.00
		Acetone	15.00
Total	**1162.00**	**Total**	**1162.00**

Stage-IV			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-III	160.00	**Product**	

Sodium Hydroxide Flakes	28.00	Stage-IV	115.00
Purified Water	2400.00	**Effluent**	
		Water	2400.00
		Generated water	13.00
		Disodium maleate	57.00
		Organic residue	
		Stage-3	3.00
Total	**2588.00**	**Total**	**2588.00**

Stage-V			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-IV	115.00	**Product**	
Diacetone Ketone gluconic acid hydrate	91.00	Stage-V	200.00
IMS/Ethanol	2400.00	**Solvent recovery**	
Hydrochloric Acid (35%)	15.00	IMS/Ethanol	2350.00
Sodium hydroxide	10.00	IMS/Ethanol loss	50.00
Purified Water	3200.00	**Effluent**	
		Water	3200.00
		Hydrochloric Acid (35%)	15.00
		Sodium hydroxide	10.00
		Organic residue	
		Stage-4	3.00
		Diacetone Ketone gluconic acid hydrate	3.00
Total	**5831.00**	**Total**	**5831.00**

Stage-VI			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-V	200.00	**Product**	
Hydrochloric Acid	40.00	Stage-VI	105.00
Sodium Hydroxide	30.00	**Effluent**	
Purified Water	1000.00	Water	1000.00
		Water from HCl	26.00
		Sodium Hydroxide	30.00
		Organic residue	
		Stage-5	14.00
		Diacetone Ketone gluconic acid hydrate.HCl	95.00
Total	**1270.00**	**Total**	**1270.00**

Stage-VII			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-VI	105.00	**Product**	
Methanol	900.00	Dorzolamide Hcl (Tech)	110.00
Activated Carbon	32.00	**Solvent recovery**	
Isopropyl Alcohol	1500.00	Methanol	829.00
Methanolic Hcl (29-30%)	41.00	Methanol loss	100.00
		Isopropyl Alcohol	1491.00
		Isopropyl Alcohol loss	9.00
		Emission	

		HCl	1.00
		Organic residue	
		Stage-6	6.00
		Spent carbon	**32.00**
Total	**2578.00**	**Total**	**2578.00**

Stage-VIII			
Input	**kg/batch**	**Output**	**kg/batch**
Dorzolamide Hcl (Tech)	110.00	**Product**	
Purified Water	2600.00	Dorzolamide Hcl pure	100.00
Activated Carbon	35.00	**Effluent**	
		Water	2600.00
		Organic residue	
		Stage-6	10.00
		Spent carbon	**35.00**
Total	**2745.00**	**Total**	**2745.00**

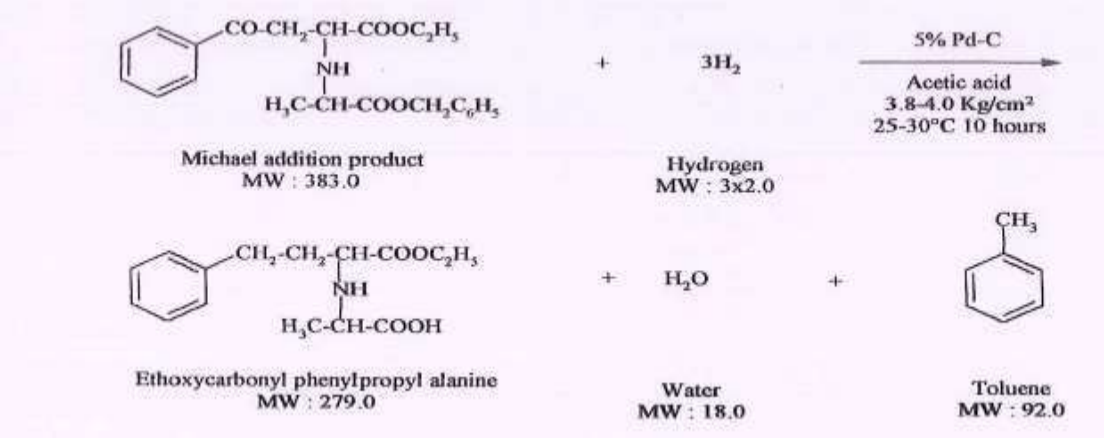
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	4200.00	4571.00	0.00	800.00	18.00	142.00	235.00	142.00	0.00	20.00	0.00	0.00
2	0.00	5000.00	0.00	5075.00	750.00	45.00	15.00	0.00	45.12	5.00	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00	950.00	35.00	0.00	0.00	0.00	17.00	0.00	0.00	0.00
4	0.00	2400.00	2470.00	0.00	0.00	0.00	0.00	57.00	0.00	3.00	0.00	0.00	0.00
5	0.00	3200.00	0.00	3225.00	2350.00	50.00	0.00	15.25	0.00	6.00	0.00	0.00	0.00
6	0.00	1000.00	1056.00	0.00	0.00	0.00	0.00	30.00	0.00	109.00	0.00	0.00	0.00
7	0.00	0.00	0.00	0.00	2320.00	109.00	0.00	0.00	0.00	6.00	32.00	1.00	0.00
8	100.00	2600.00	0.00	2600.00	0.00	0.00	0.00	0.00	0.00	10.00	35.00	0.00	0.00
Pollution Load per Day													
1	0.00	700.14	761.99	0.00	133.36	3.00	23.67	39.17	23.67	0.00	3.33	0.00	0.00
2	0.00	833.50	0.00	846.00	125.03	7.50	2.50	0.00	7.52	0.83	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00	158.37	5.83	0.00	0.00	0.00	2.83	0.00	0.00	0.00
4	0.00	400.08	411.75	0.00	0.00	0.00	0.00	9.50	0.00	0.50	0.00	0.00	0.00
5	0.00	533.44	0.00	537.61	391.75	8.34	0.00	2.54	0.00	1.00	0.00	0.00	0.00
6	0.00	166.70	176.04	0.00	0.00	0.00	0.00	5.00	0.00	18.17	0.00	0.00	0.00
7	0.00	0.00	0.00	0.00	386.74	18.17	0.00	0.00	0.00	1.00	5.33	0.17	0.00
8	16.67	433.42	0.00	433.42	0.00	0.00	0.00	0.00	0.00	1.67	5.83	0.00	0.00
Total	**16.67**	**3067.28**	**1349.77**	**1817.03**	**1195.24**	**42.84**	**26.17**	**56.22**	**31.19**	**26.01**	**14.50**	**0.17**	**0.00**

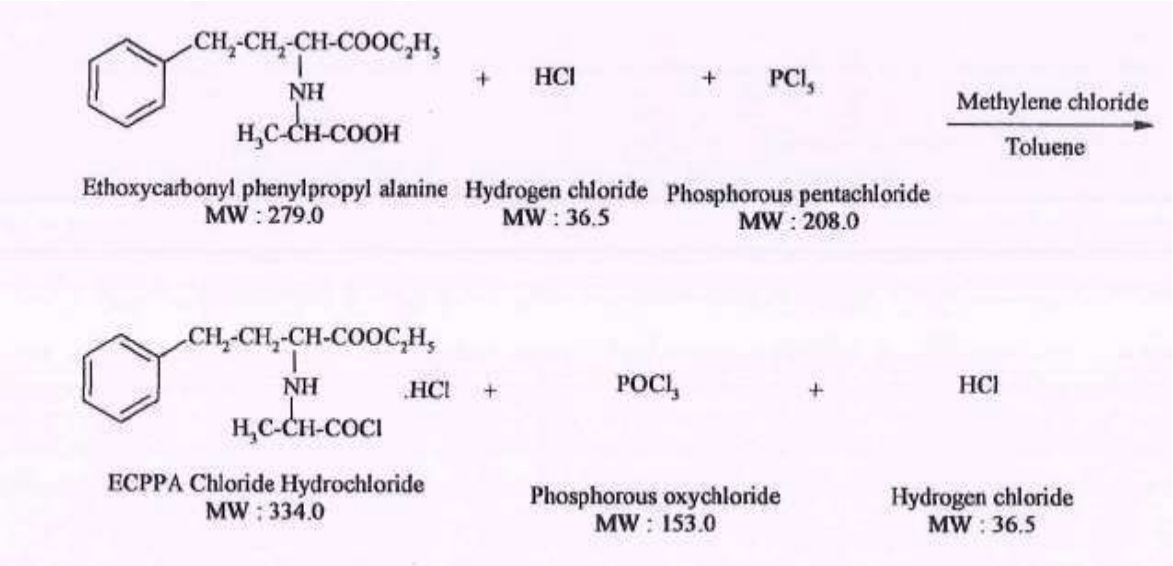
3. Enalapril Maleate

Process Description with Route of Synthesis

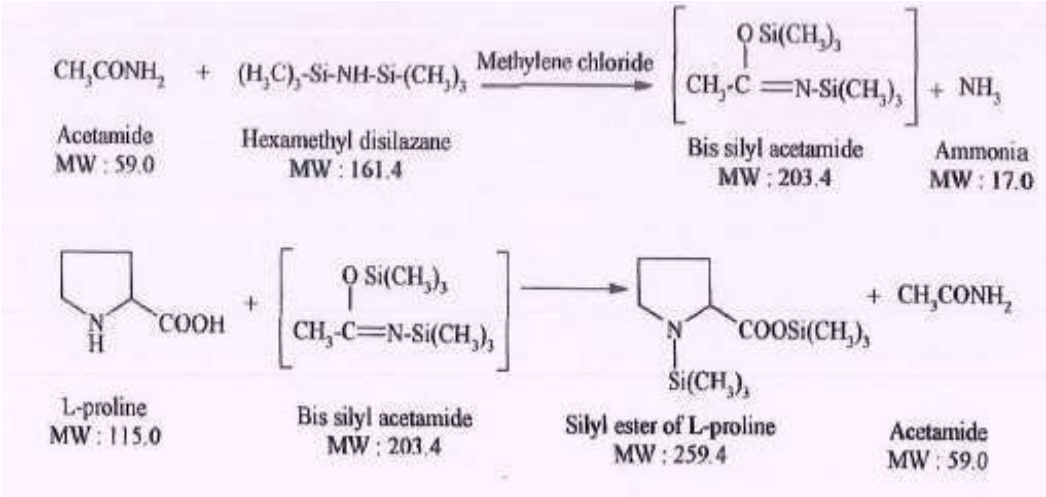
Stage-I: Michael addition product as its sulphate salt in Acetic acid is hydrogenated in presence of 5 % Palladium carbon catalyst to produce Ethoxy carbonyl phenyl propyl alanine (ECPPA).

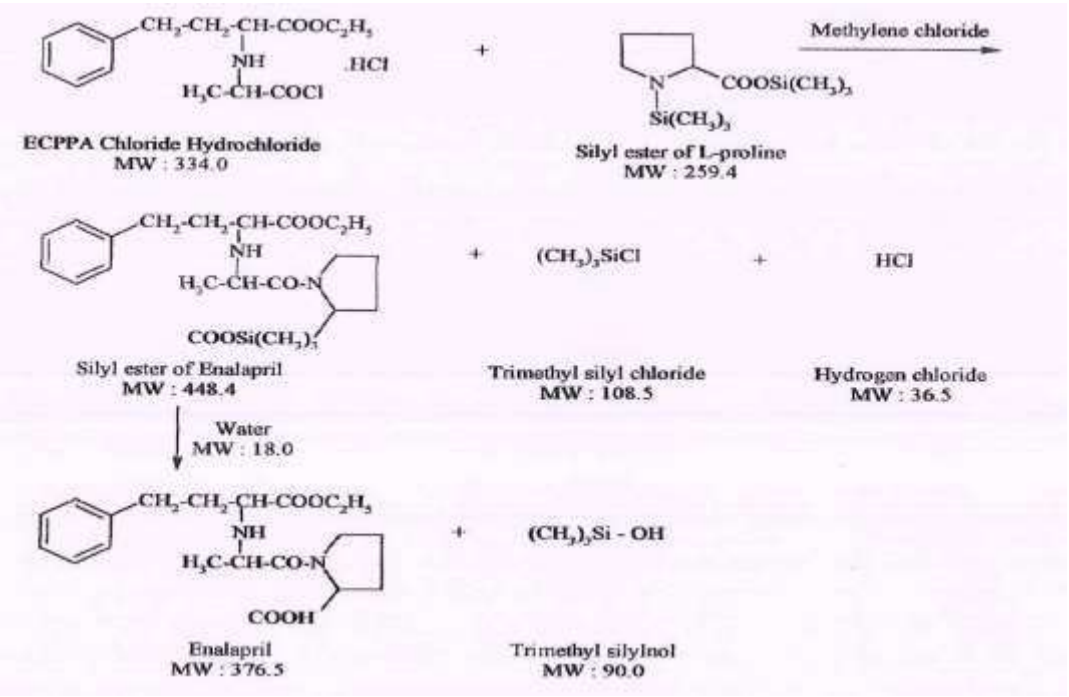


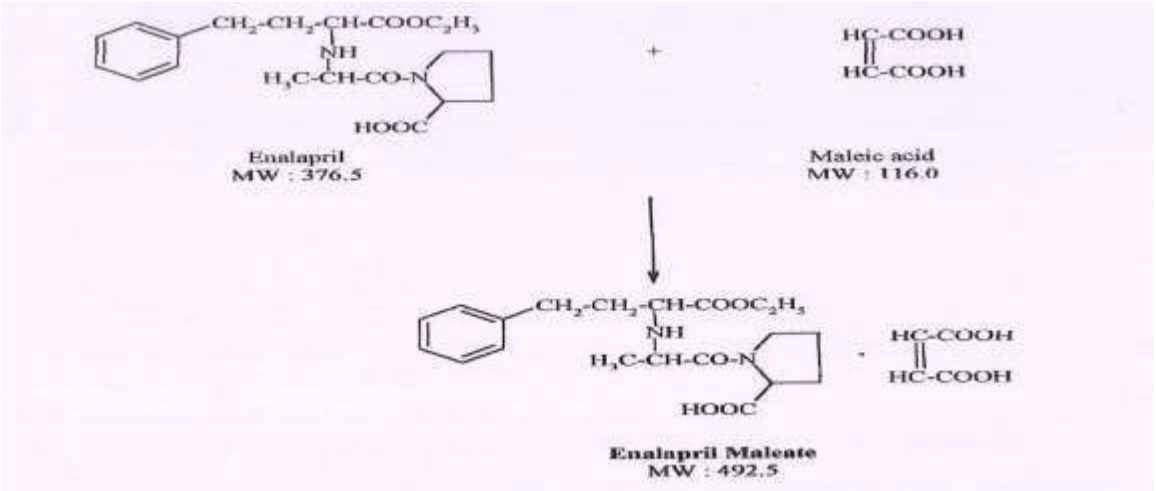
Stage-II: Ethoxy carbonyl phenyl propyl alanine (ECPPA) in Toluene and Methylene chloride is reacted with Phosphorus pentachloride to give ECPPA chloride hydrochloride.



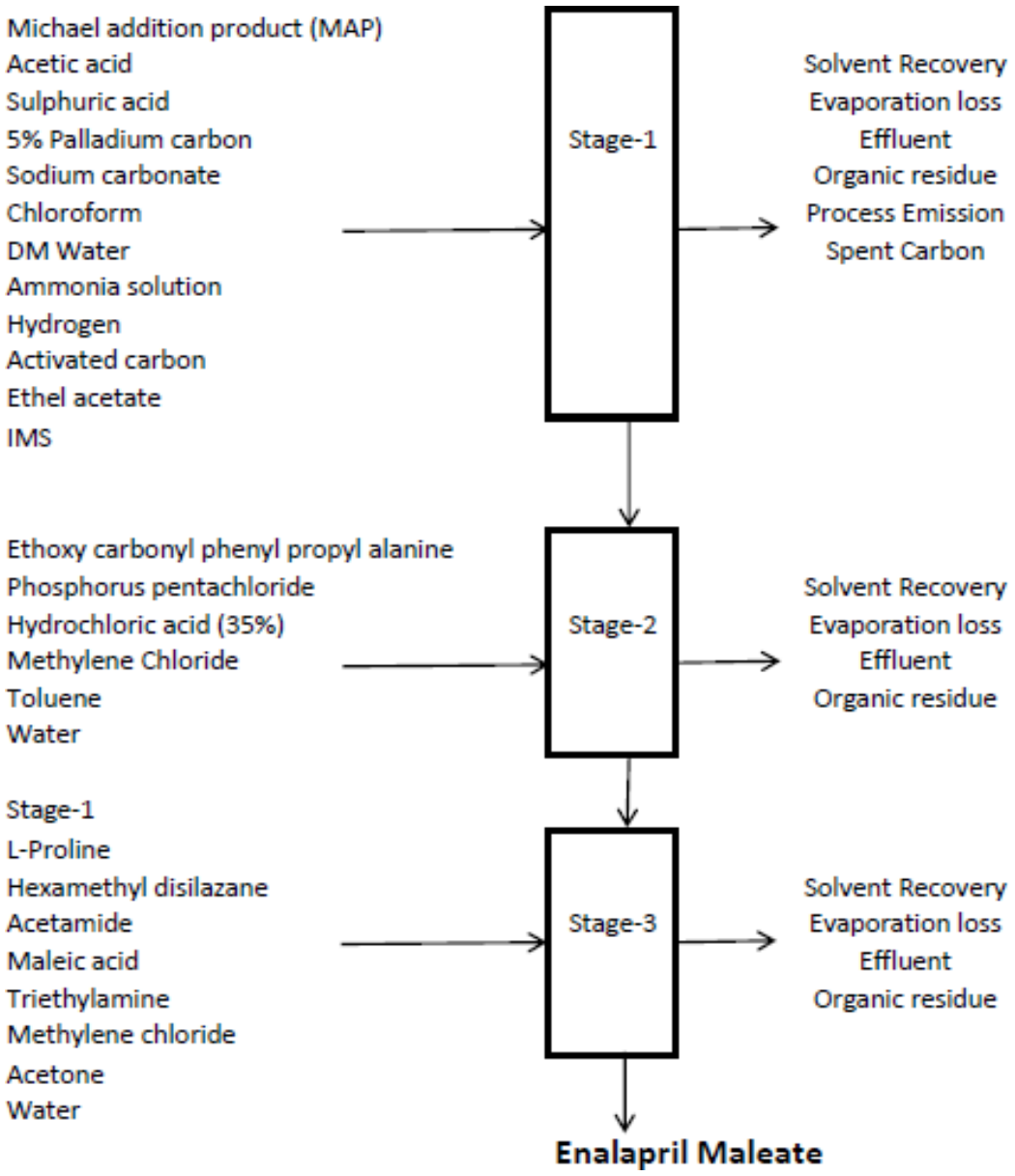
Stage-III: Acetamide in Methylene chloride is separately treated with Hexamethyl disilazane and refluxed to give Bis silyl acetamide. To this, Proline is added and refluxed to give the Silyl ester of proline. The silyl ester is reacted with ECPPA chloride hydrochloride to give Enalapril, which is reacted with Maleic acid in presence of Acetone to produce Enalapril maleate.


CH3CONH2 + (H3C)3-Si-NH-Si-(CH3)3 Methylene chloride
Acetamide MW : 59.0
Hexamethyl disilazane MW : 161.4
Bis silyl acetamide MW : 203.4
Ammonia MW : 17.0
L-proline MW : 115.0
Bis silyl acetamide MW : 203.4
Silyl ester of L-proline MW : 259.4
Acetamide MW : 59.0


ECPPA Chloride Hydrochloride MW : 334.0
Methylene chloride
Silyl ester of L-proline MW : 259.4
Silyl ester of Enalapril MW : 448.4
Trimethyl silyl chloride MW : 108.5
Hydrogen chloride MW : 36.5
Water MW : 18.0
Enalapril MW : 376.5
Trimethyl silylnol MW : 90.0


Enalapril MW : 376.5
Maleic acid MW : 116.0
Enalapril Maleate MW : 492.5

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Michael addition product (MAP)	110.00	**Ethocycarbonyl phenylpropyl alanine (ECPPA)**	**80.00**
Acetic acid	100.00	**Solvent recovery**	
Sulphuric acid	47.00	Acetic acid	99.00
5% Palladium carbon	18.00	Acetic acid loss	1.00
Sodium carbonate	51.00	Chloroform	92.00
Chloroform	100.00	Chloroform loss	8.00
DM Water	500.00	Ethel acetate	95.00
Ammonia solution	6.00	Ethel acetate loss	5.00
Hydrogen	2.00	IMS	11.00
Sodium chloride	25.00	IMS loss	2.00
Ethel acetate	100.00	**Effluent**	
IMS	13.00	Toluene	26.00
		Gen. water	5.00
		Sodium sulphate	68.00
		Gen. water	10.00
		Sodium chloride	25.00
		Ammonia solution	6.00
		Water	500.00
		Emissions	
		Carbon dioxide	21.00
		Spent carbon	**18.00**
Total	**1072.00**	**Total**	**1072.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Ethoxy carbonyl phenyl propyl alanine	75.00	**Product**	
Phosphorus pentachloride	100.00	Stage-II	80.00
Hydrochloric acid (35%)	13.00	**Recovery**	
Methylene Chloride	220.00	Methylene Chloride	200.00
Toluene	402.00	Methylene Chloride loss	20.00
Water	550.00	Toluene	400.00
		Toluene loss	2.00
		Effluent	
		Water	550.00
		HCl	4.60
		Water from HCl	8.40
		Phosphorus oxychloride	36.80
		Phosphorus pentachloride	50.00
		Organic Residue	
		Ethoxy carbonyl phenyl propyl alanine	8.20
Total	**1360.00**	**Total**	**1360.00**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-II	80.00	**Product**	
L-Proline	30.00	Enalapril maleate	100.00
Hexamethyl disilazane	50.00	**Recovery**	
Acetamide	23.00	Methylene Chloride	300.00
Maleic acid	29.00	Methylene Chloride loss	50.00
Triethylamine	13.00	Acetone	310.00
Methylene chloride	350.00	Acetone loss	10.00
Acetone	340.00	**Effluent**	
Water	2100.00	Water	2096.30
Sodium chloride	40.00	Trimethyl silyl hydroxide	22.10
		Trimethyl silyl chloride	18.30
		Triethylamine	13.00
		Ammonium chloride	10.90
		Sodium chloride	40.00
		Acetic acid	20.00
		Acetamide	23.00
		Maleic acid	5.40
		Hexamethyl disilazane	17.30
		Organic Residue	
		Stage-1	12.10
		L-Proline	6.60
Total	**3055.00**	**Total**	**3055.00**

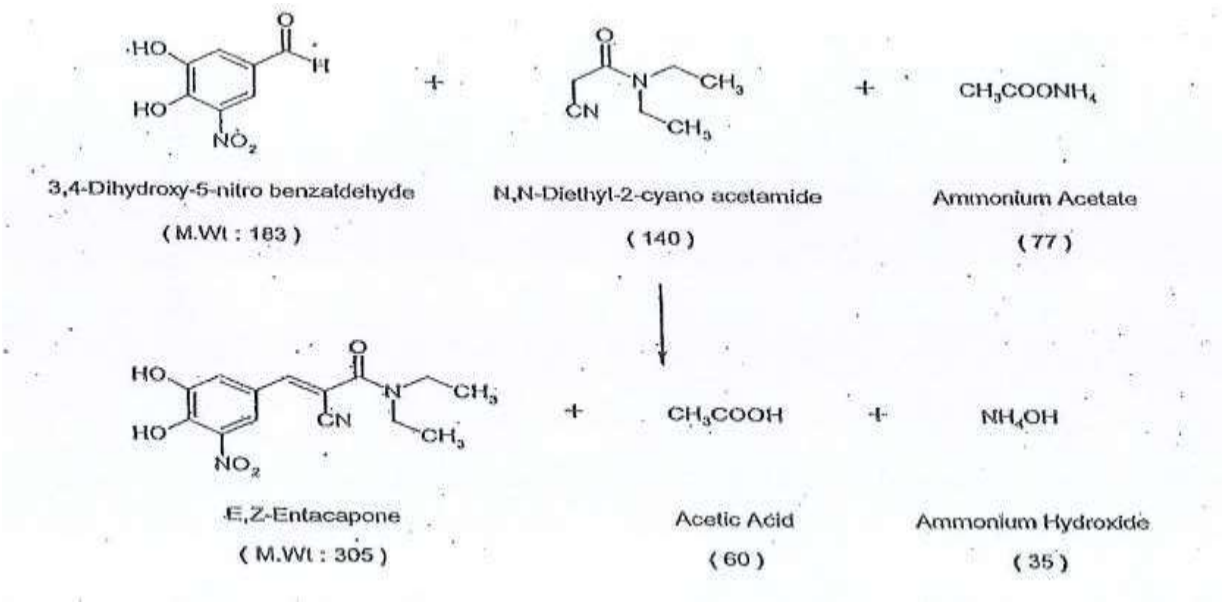
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	500.00	640.00	0.00	297.00	16.00	26.00	93.00	81.12	0.00	18.00	21.00	0.00
2	0.00	550.00	649.80	0.00	600.00	22.00	0.00	91.40	0.00	8.20	0.00	0.00	0.00
3	100.00	2100.00	2266.30	0.00	610.00	60.00	20.00	108.60	91.01	18.70	0.00	0.00	0.00
Pollution Load per Day													
1	0.00	333.35	426.69	0.00	198.01	10.67	17.33	62.00	54.08	0.00	12.00	14.00	0.00
2	0.00	366.69	433.22	0.00	400.02	14.67	0.00	60.94	0.00	5.47	0.00	0.00	0.00
3	66.67	1400.07	1510.94	0.00	406.69	40.00	13.33	72.40	60.68	12.47	0.00	0.00	0.00
Total	**66.67**	**2100.11**	**2370.85**	**0.00**	**1004.72**	**65.34**	**30.67**	**195.34**	**114.76**	**17.93**	**12.00**	**14.00**	**0.00**

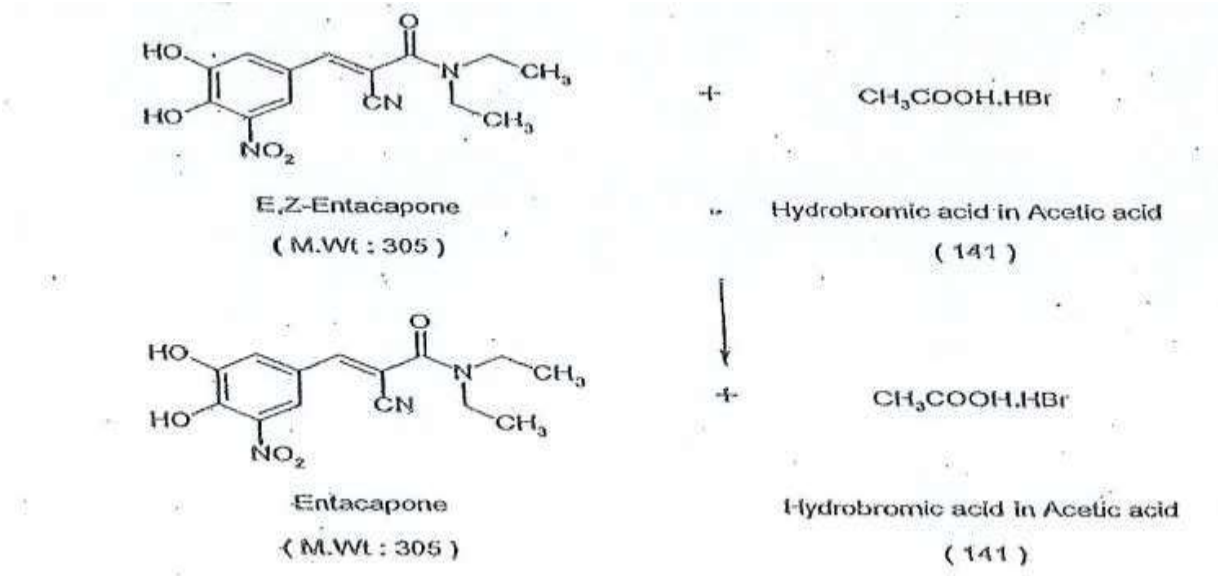
4. Entacapone

Process Description with Route of Synthesis

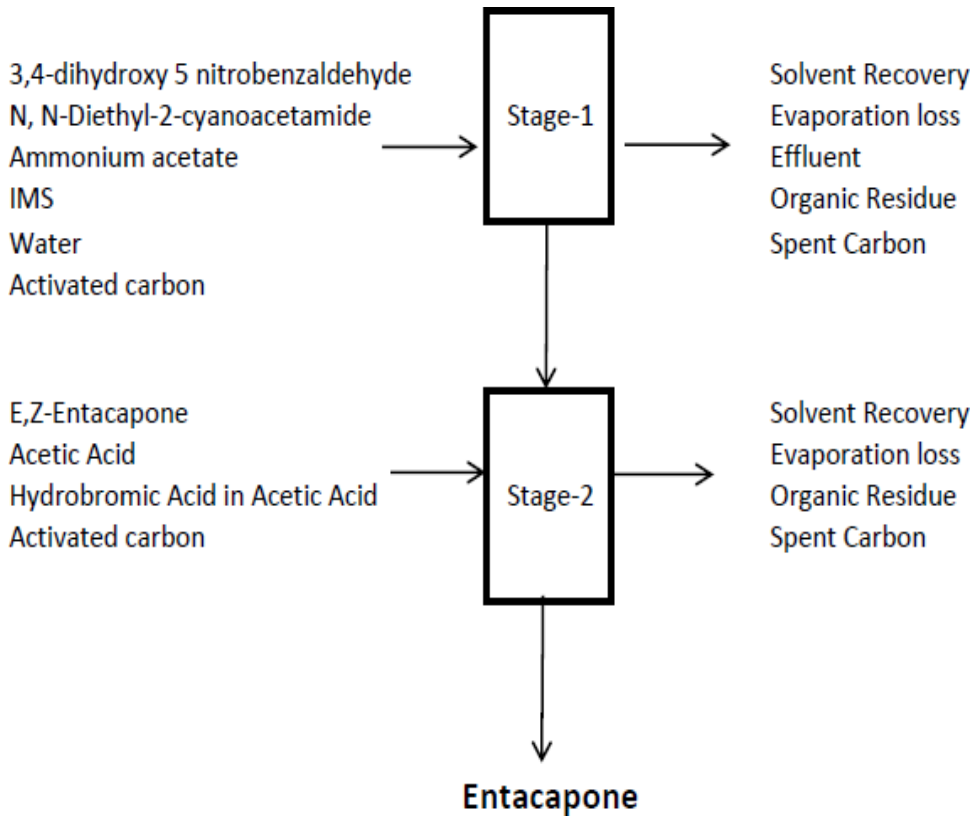
Stage-I: 3,4-Dihydroxy-5-nitro benzaldehyde is reacted with N,N-Diethyl-2-cyano acetamide and Ammonium acetate in presence of IMS to produce E,Z-Entacapone.



Stage-II: E,Z-Entacapone is purified to pharama grade in presence Hydrobromic acid in Acetic acid.



Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
3,4-dihydroxy 5 nitrobenzaldehyde	110.00	**Stage 1**	
N,N-Diethyl-2-cyanoacetamide	110.00	E,Z-Entacapone	**130.00**
Ammonium acetate	66.00	**Solvent recovery**	
IMS	940.00	IMS	900.00
Water	2000.00	IMS loss	10.00
Activated carbon	80.00	**Effluent**	
Sodium chloride	100.00	Water	2000.00
		Ammonium acetate	33.20
		Acetic acid	25.60
		Ammonium hydroxide	15.00
		IMS	30.00
		Sodium chloride	100.00
		Spent carbon	**80.00**
		Organic residue	
		3,4-dihydroxy 5 nitrobenzaldehyde	32.00
		N,N-Diethyl-2-cyanoacetamide	50.20
Total	**3406.00**	**Total**	**3406.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
E,Z-Entacapone	130.00	**Product**	
Acetic Acid	600.00	Entacapone	100.00
Hydrobromic Acid in Acetic Acid	43.00	**Solvent recovery**	
Activated carbon	50.00	Acetic Acid	595.00
		Acetic Acid loss	5.00
		Hydrobromic Acid in Acetic Acid	43.00
		Organic residue	
		E,Z-Entacapone	30.00
		Spent carbon	**50.00**
Total	**823.00**	**Total**	**823.00**

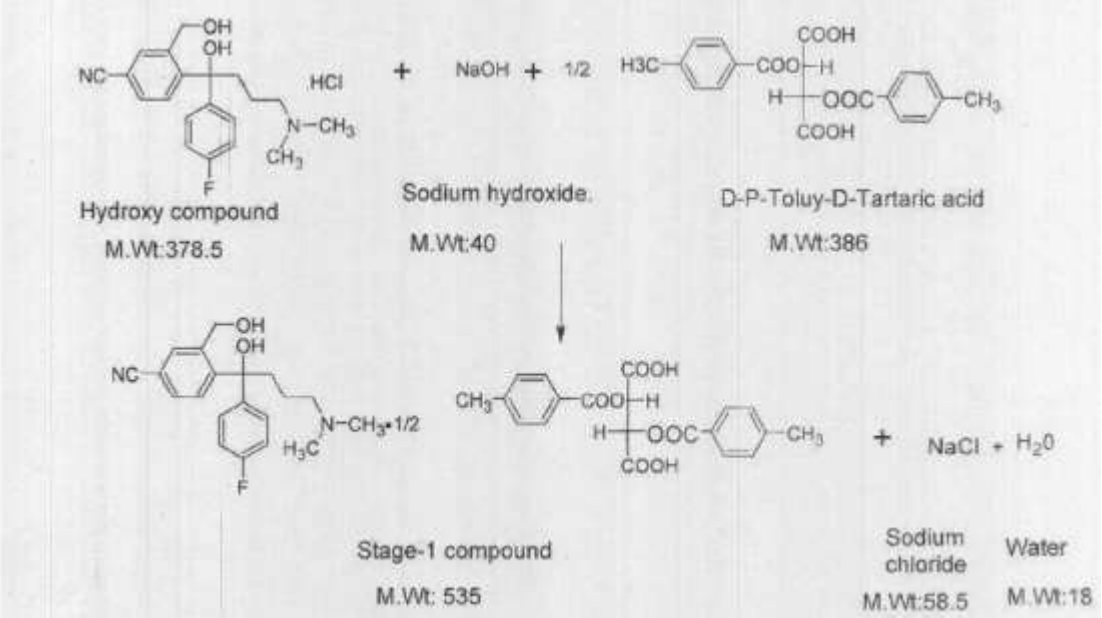
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	2000.00	2203.80	0.00	900.00	10.00	55.60	115.00	117.65	82.20	80.00	0.00	0.00
2	100.00	0.00	0.00	0.00	595.00	5.00	0.00	0.00	0.00	30.00	50.00	0.00	0.00
Pollution Load per Day													
1	0.00	6666.60	7345.93	0.00	2999.97	33.33	185.33	383.33	392.16	274.00	266.66	0.00	0.00
2	333.33	0.00	0.00	0.00	1983.31	16.67	0.00	0.00	0.00	100.00	166.67	0.00	0.00
Total	**333.33**	**6666.60**	**7345.93**	**0.00**	**4983.28**	**50.00**	**185.33**	**383.33**	**392.16**	**374.00**	**433.33**	**0.00**	**0.00**

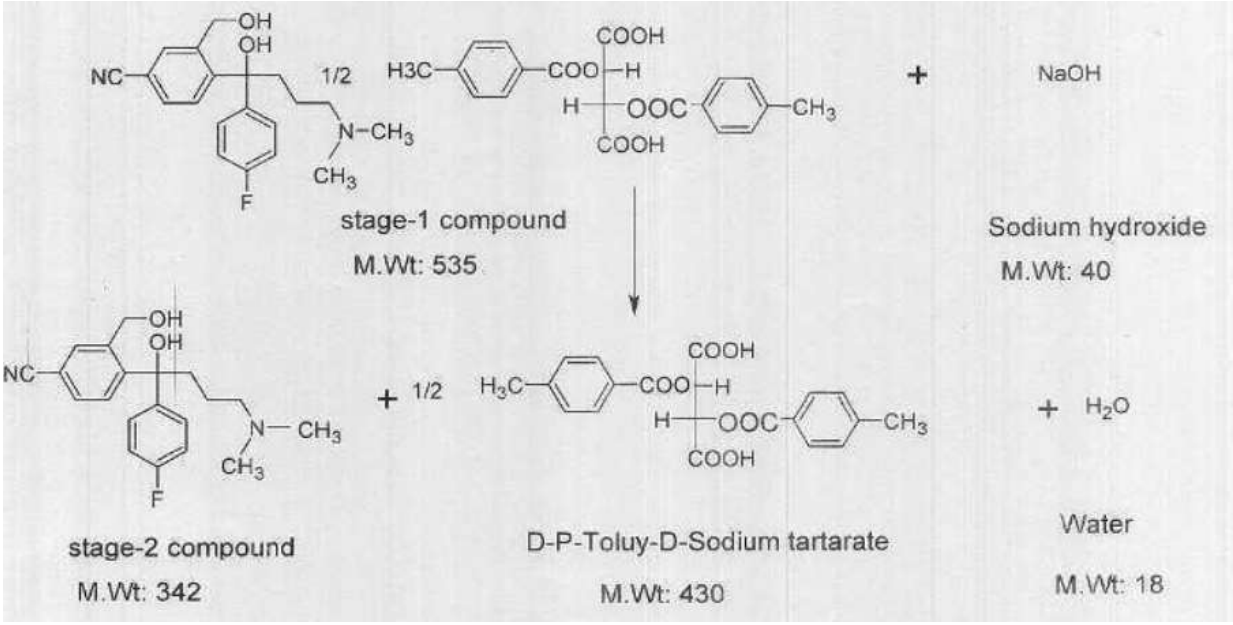
5. Escitalopram Oxalate

Process Description with Route of Synthesis

Stage-I: Hydroxy compound is reacted with Sodium hydroxide and D-P-Toluyl, D-Tartaric acid in Methylene Chloride and Isopropyl alcohol to produce stage-I compound.

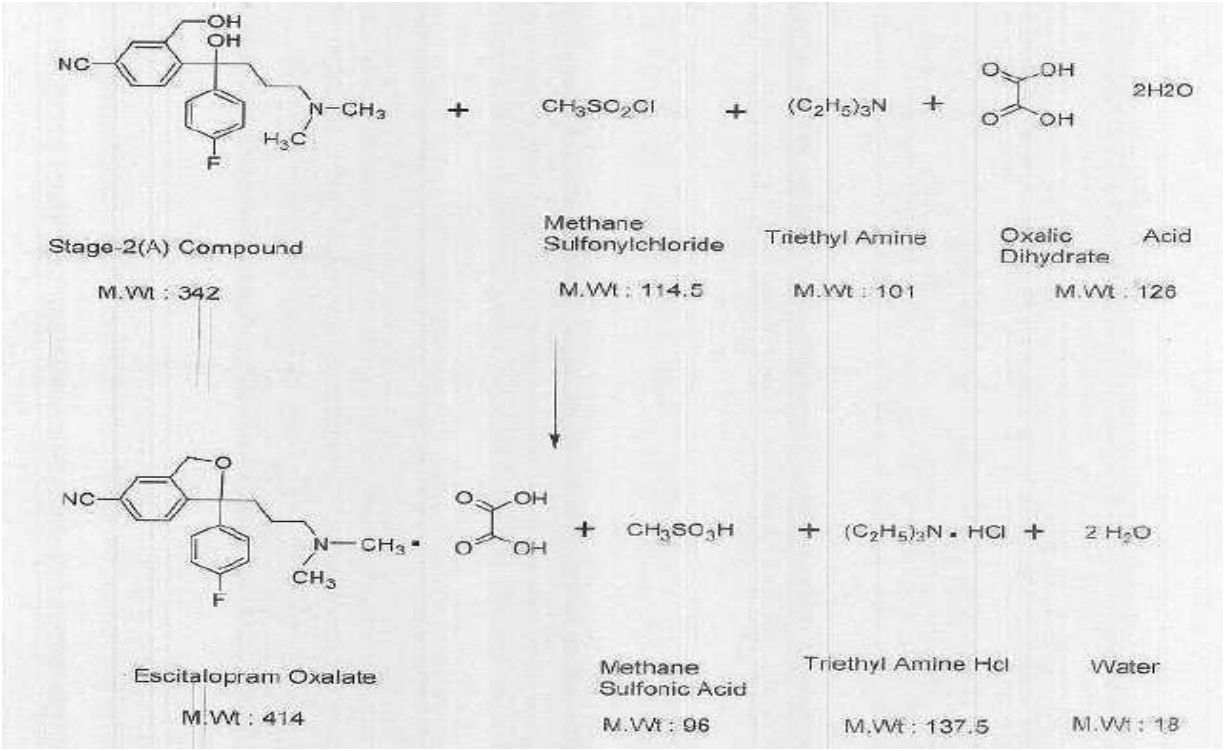


Stage-II: Stage-I compound is reacted with Sodium hydroxide in presence of Toluene and Acetone to produce stage-II compound.

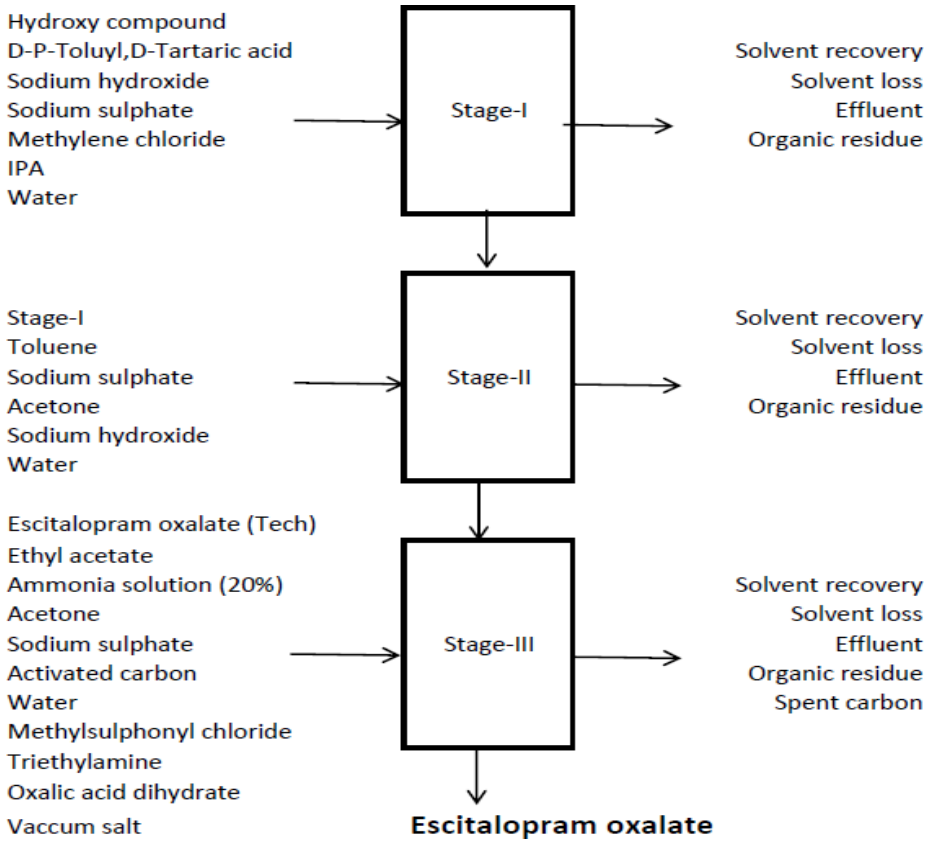


Stage-III: Stage-II compound is reacted with Methane sulphonyl chloride, Triethyl amine and Oxalic acid dehydrate to produce Escitalopram oxalate Tech

and this is purified in Ethyl acetate and Acetone to get Escitalopram oxalate.



Process Flow Diagram



Material Balance

Stage-I			
Raw materials	**kg/batch**	**Output**	**kg/batch**
Hydroxy compound	170.00	Stage-I	180
D-P-Toluyl,D-Tartaric acid	80.00	**Recovery**	
Sodium hydroxide	40.50	Methylene chloride	930.00
Sodium sulphate	20.00	Methylene chloride loss	70.00
Methylene chloride	1000.00	IPA	500.00
IPA	600.00	IPA loss	40.00
Water	4000.00	**Effluent**	
		Water	4000.00
		NaOH	26.500
		NaCl	20.00
		Gen. water	6.00
		IPA	60.00
		Inorganic residue	
		Sodium sulphate	20.00
		Organic residue	
		D-P-Toluyl,D-Tartaric acid	15.00
		Hydroxy compound	43.00
Total input	**5910.50**	**Total output**	**5910.50**
Stage-II			
Raw materials	**kg/batch**	**Output**	**kg/batch**
Stage-I	180.00	Escitalopram oxalate (Tech)	110.00
Toluene	2000.00	**Recovery**	
Sodium sulphate	20.00	Toluene	1990.00
Acetone	1000.00	Toluene loss	10.00
Sodium hydroxide	34.00	Acetone	850.00
Water	4000.00	Acetone loss	30.00
		Effluent	
		Water	4000.00
		NaOH	21.00
		Gen. water	6.00
		Acetone	120.00
		Inorganic residue	
		Sodium sulphate	20.00
		Organic residue	
		D-P-Toluyl,D-Sodium Tartarate	69.00
		Stage-I	8.00
Total input	**7234.00**	**Total output**	**7234.00**

Stage-III			
Raw materials	**kg/batch**	**Output**	**kg/batch**
Escitalopram oxalate (Tech)	110.00	Escitalopram oxalate (API)	100.00
Ethyl acetate	550.00	**Recovery**	
Ammonia solution (20%)	100.00	Ethyl acetate	540.00
Acetone	500.00	Ethyl acetate loss	5.00
Sodium sulphate	20.00	Acetone	450.00
Activated carbon	25.00	Acetone loss	12.00

Water	2500.00	**Effluent**	
Methylsulphonyl chloride	40.00	Water	2500.00
Triethylamine	34.00	Triethylamine	14.60
Oxalic acid dihydrate	44.00	Oxalic acid dihydrate	13.60
Vaccum salt	20.00	Methane sulphonic acid	23.20
		Gen. water	8.60
		Ammonia solution (20%)	100.00
		Vaccum salt	20.00
		Acetone	38.00
		Ethyl acetate	5.00
		Spent carbon	**25.00**
		Inorganic residue	
		Sodium sulphate	20.00
		Organic residue	
		Methylsulphonyl chloride	7.00
		Escitalopram oxalate (Tech)	27.40
		Triethylamine HCl	33.20
Total input	**3943.00**	**Total output**	**3942.60**

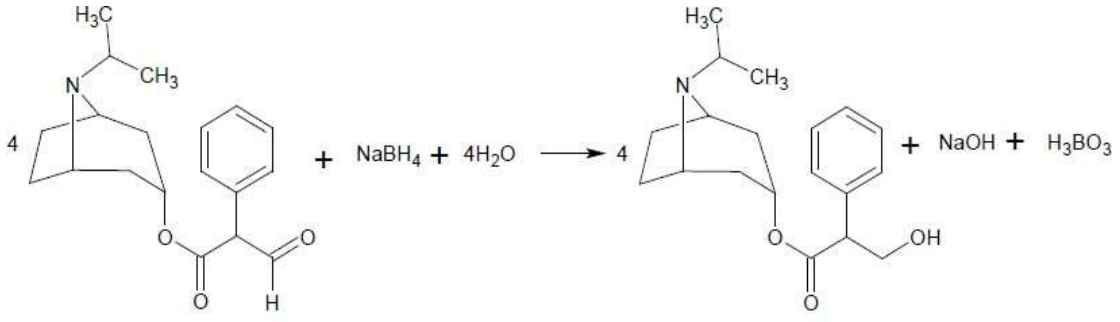
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	4000.00	4112.50	0.00	1430.00	110.00	60.00	46.50	144.00	58.00	0.00	0.00	20.00
2	0.00	4000.00	0.00	4147.00	2840.00	40.00	120.00	21.00	265.20	77.00	0.00	0.00	20.00
3	100.00	2500.00	2723.00	0.00	990.00	17.00	43.00	40.00	148.74	67.60	25.00	0.00	20.00
Pollution Load per Day													
1	0.00	1333.20	1370.70	0.00	476.62	36.66	20.00	15.50	48.00	19.33	0.00	0.00	6.67
2	0.00	1333.20	0.00	1382.20	946.57	13.33	40.00	7.00	88.39	25.66	0.00	0.00	6.67
3	33.33	833.25	907.58	0.00	329.97	5.67	14.33	13.33	49.57	22.53	8.33	0.00	6.67
Total	**33.33**	**3499.65**	**2278.27**	**1382.20**	**1753.16**	**55.66**	**74.33**	**35.83**	**185.96**	**67.53**	**8.33**	**0.00**	**20.00**

6. Ipratropium Bromide Monohydrate

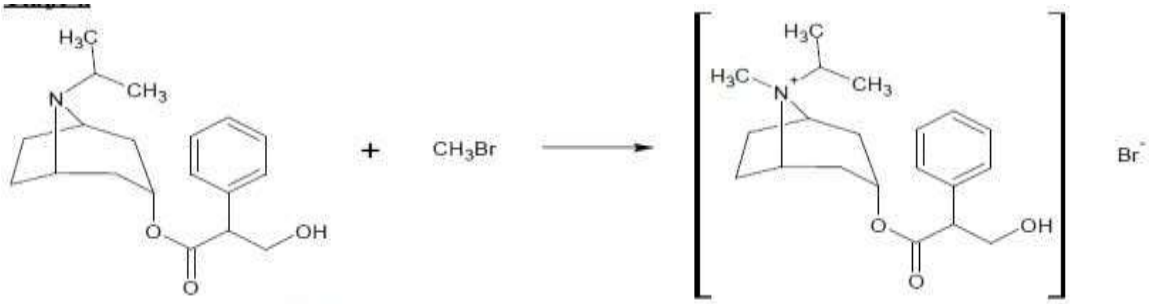
Process Description with Route of Synthesis

Stage-I: Ipratropium condensation product is reacted with Sodium boro hydride and Water in presence of Methanol, Acetone and Methylene chloride to produce stage-I compound.



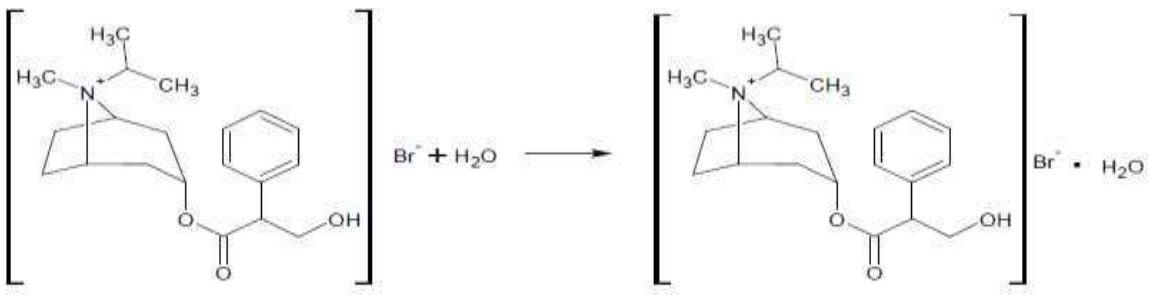
Ipratropium Condensation Product (M Wt: 315) | Sodium Borohydride (M Wt: 38) | Water (M Wt: 18) | Isopropyl Noratropine (M Wt : 317) | Sodium Hydroxide (M Wt 40) | Boric Acid (M Wt: 62)

Stage-II: Stage-I compound is reacted with Methyl bromide in presence of Toluene and Chloroform to produce Stage-II compound.



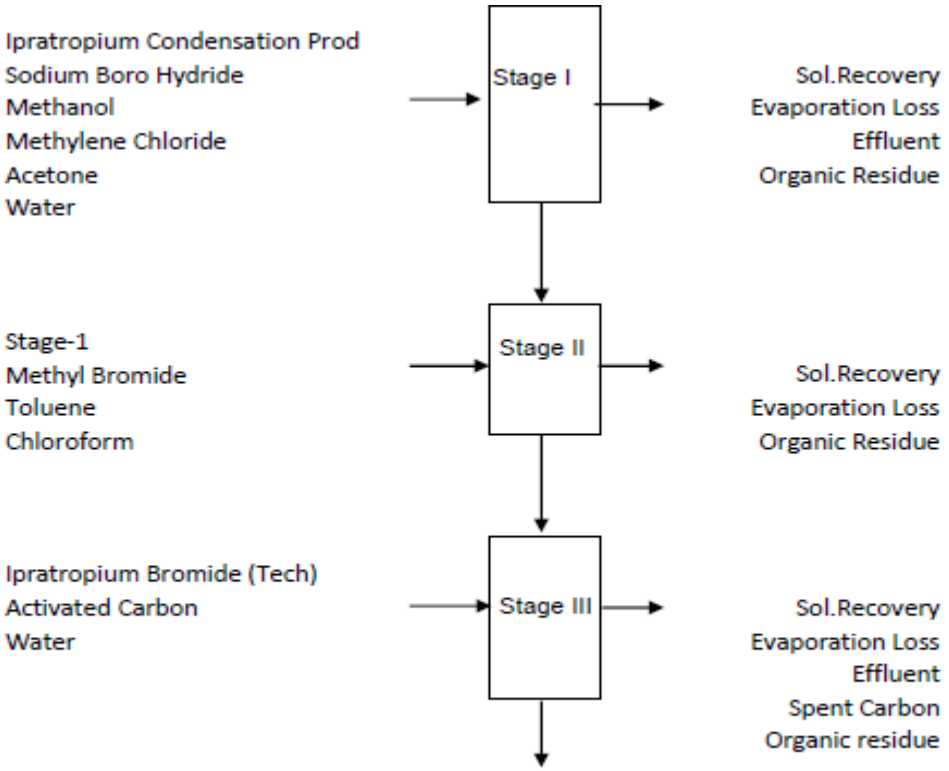
Isopropyl Noratropine (M Wt : 317) | Methyl Bromide (M Wt: 95) | Ipratropium Bromide (M Wt: 412)

Stage-III: Formed stage-II compound is reacted with Water in presence of Isopropyl alcohol to get Ipratropium bromide monohydrate.



Ipratropium Bromide (M Wt :412) | Water (M Wt: 18) | Ipratropium Bromide Monohydrate (M Wt: 430)

Process Flow Diagram



Ipratropium Bromide Monohydrate

Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Ipratropium Condensation Prod	120.00	**Product**	
Sodium Boro Hydride	45.00	Stage-I	100.00
Methanol	450.00	**Recovery**	
Methylene Chloride	1460.00	Methanol	400.00
Acetone	500.00	Methanol loss	5.00
Water	4500.00	Methylene Chloride	1420.00
		Methylene Chloride loss	40.00
		Acetone	480.00
		Acetone loss	20.00
		Effluent	
		Water	4494.00
		Sodium Borohydride	42.00
		Methanol	45.00
		Sodium hydroxide	3.00
		Boric acid	5.00
		Organic residue	
		Ipratropium	21.00
Total	**7075.00**	**Total**	**7075.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-I	100.00	**Product**	
Methyl Bromide	40.00	Ipratropium Bromide (Tech)	114.00
Toluene	440.00	**Recovery**	
Chloroform	2900.00	Toluene	418.00
		Toluene	22.00
		Chloroform	2750.00
		Chloroform	150.00
		Organic residue	
		Stage-1	12.30
		Methyl Bromide	13.70
Total	**3480.00**	**Total**	**3480.00**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Ipratropium Bromide (Tech)	110.00	**Product**	
Isopropyl Alcohol	850.00	Ipratropium Bromide pure	100.00
Activated Carbon	30.00	**Recovery**	
Water	5500.00	Isopropyl Alcohol	750.00
		Isopropyl Alcohol loss	10.00
		Effluent	
		Water	5491.80
		Isopropyl Alcohol	90.00
		Organic residue	
		Ipratropium Bromide (Tech)	18.20
		Spent carbon	**30.00**
Total	**6490.00**	**Total**	**6490.00**

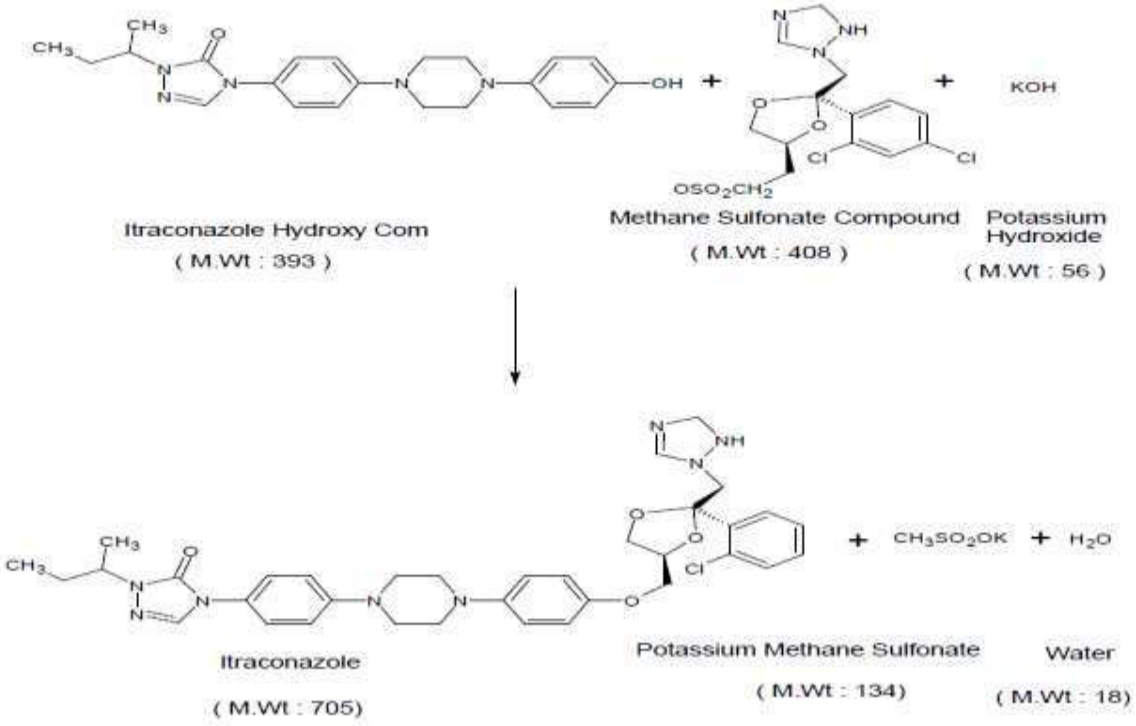
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	4500.00	4589.00		2300.00	65.00	45.00	50.00	67.50	21.00	0.00	0.00	0.00
2	0.00	0.00	0.00	0.00	3168.00	172.00	0.00	0.00	0.00	26.00	0.00	0.00	0.00
3	100.00	5500.00	0.00	5581.80	750.00	10.00	90.00	0.00	216.00	18.20	30.00	0.00	0.00
Pollution Load per Day													
1	0.00	750.15	764.99	0.00	383.41	10.84	7.50	8.34	11.25	3.50	0.00	0.00	0.00
2	0.00	0.00	0.00	0.00	528.11	28.67	0.00	0.00	0.00	4.33	0.00	0.00	0.00
3	16.67	916.85	0.00	930.49	125.03	1.67	15.00	0.00	36.01	3.03	5.00	0.00	0.00
Total	**16.67**	**1667.00**	**764.99**	**930.49**	**1036.54**	**41.17**	**22.50**	**8.34**	**47.26**	**10.87**	**5.00**	**0.00**	**0.00**

7. Itraconazole

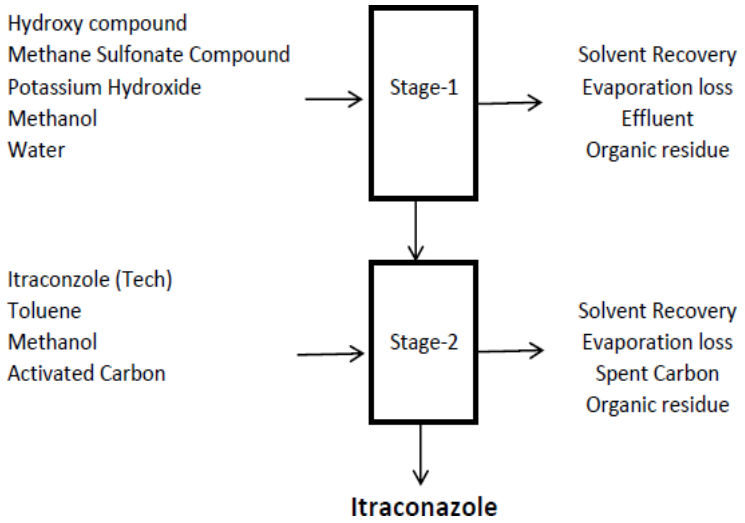
Process Description with Route of Synthesis

Stage-I: Itraconazole hydroxy compound is reacted with Methane sulfonate compound and Potassium hydroxide in presence of Itraconazole (Tech) product



Stage-II: Itraconazole (Tech) product is purified with Methanol and Toluene to get Itraconazole (Pharma) product.

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Hydroxy compound	70.00	**Product**	
Methane Sulfonate Compound	80.00	Itraconzole (Tech)	110.00
Potassium Hydroxide	24.50	**Recovery**	
Methanol	280.00	Methanol	200.00
Water	3200.00	Methanol loss	30.00
Sodium chloride	86.00	**Effluent**	
		Water	3200.00
		Generated water	2.70
		Potassium Hydroxide	15.80
		Potassium methane sulphonate	21.00
		Methanol	50.00
		Sodium chloride	86.00
		Organic residue	
		Hydroxy compound	8.70
		Methane Sulfonate	16.30
Total	**3740.50**	**Total**	**3740.50**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Itraconzole (Tech)	110.00	**Product**	
Toluene	502.00	Itraconzole (Pharma)	100.00
Methanol	1420.00	**Recovery**	
Activated Carbon	30.00	Methanol	1400.00
		Methanol loss	20.00
		Toluene	500.00
		Toluene loss	2.00
		Organic residue	
		Itraconzole (Tech)	10.00
		Spent carbon	**30.00**
Total	**2062.00**	**Total**	**2062.00**

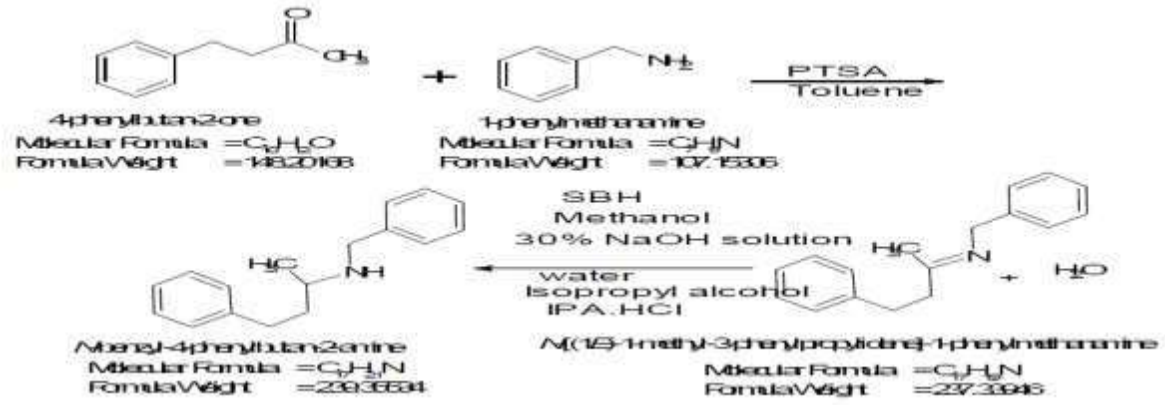
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	3200.00	3375.50	0.00	200.00	30.00	50.00	122.80	82.56	25.00	0.00	0.00	0.00
2	100.00	0.00	0.00	0.00	1900.00	22.00	0.00	0.00	0.00	10.00	30.00	0.00	0.00
Pollution Load per Day													
1	0.00	10666.56	11251.55	0.00	666.66	100.00	166.67	409.33	275.20	83.33	0.00	0.00	0.00
2	333.33	0.00	0.00	0.00	6333.27	73.33	0.00	0.00	0.00	33.33	100.00	0.00	0.00
Total	**333.33**	**10666.56**	**11251.55**	**0.00**	**6999.93**	**173.33**	**166.67**	**409.33**	**275.20**	**116.67**	**100.00**	**0.00**	**0.00**

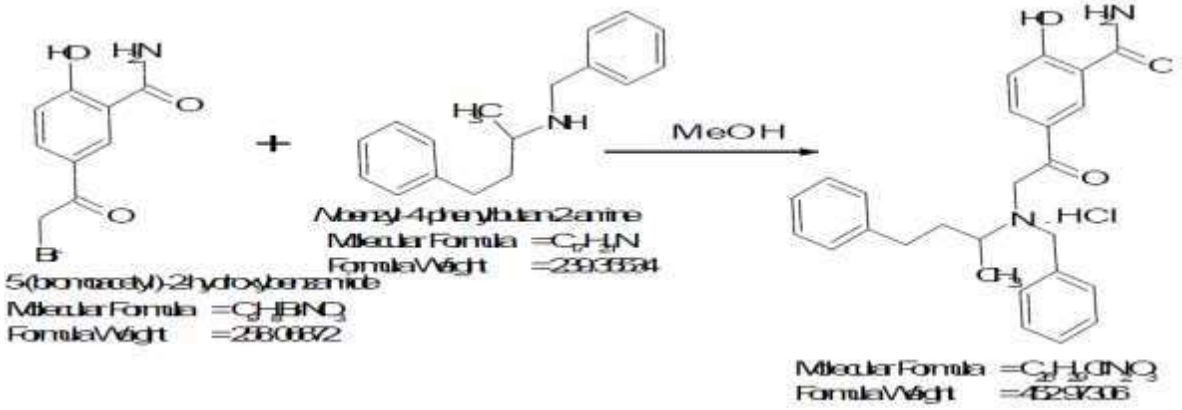
8. Labetalol Hydrochloride

Process Description with Route of Synthesis

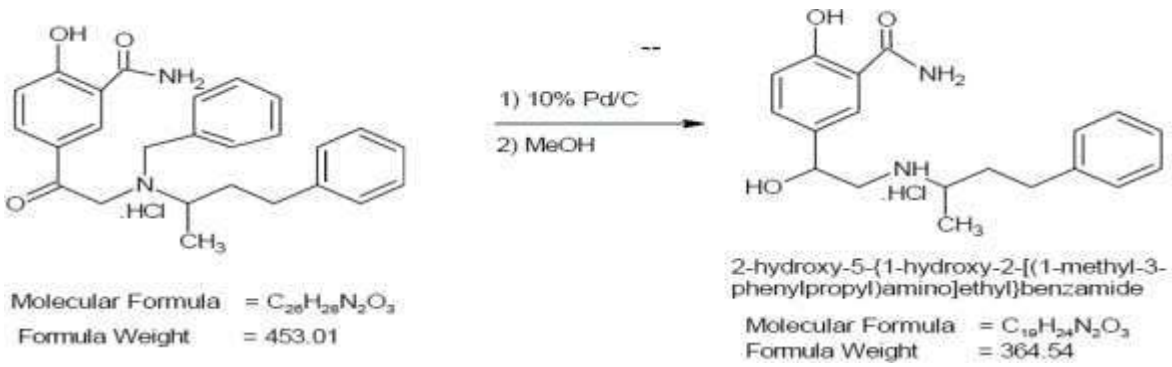
Stage-I: Benzyl acetone is reacted with Benzyl amine in presence Methanol, Toluene and Isopropyl alcohol to get stage-I compound.



Stage-II: Stage-I compound is reacted with LH-Bromide and Hydrochloric acid in presence of Methanol to get stage-II compound.



Stage-III: Stage-II compound is reacted with Hydrogen in presence of Methanol to get Labetalol hydrochloride.

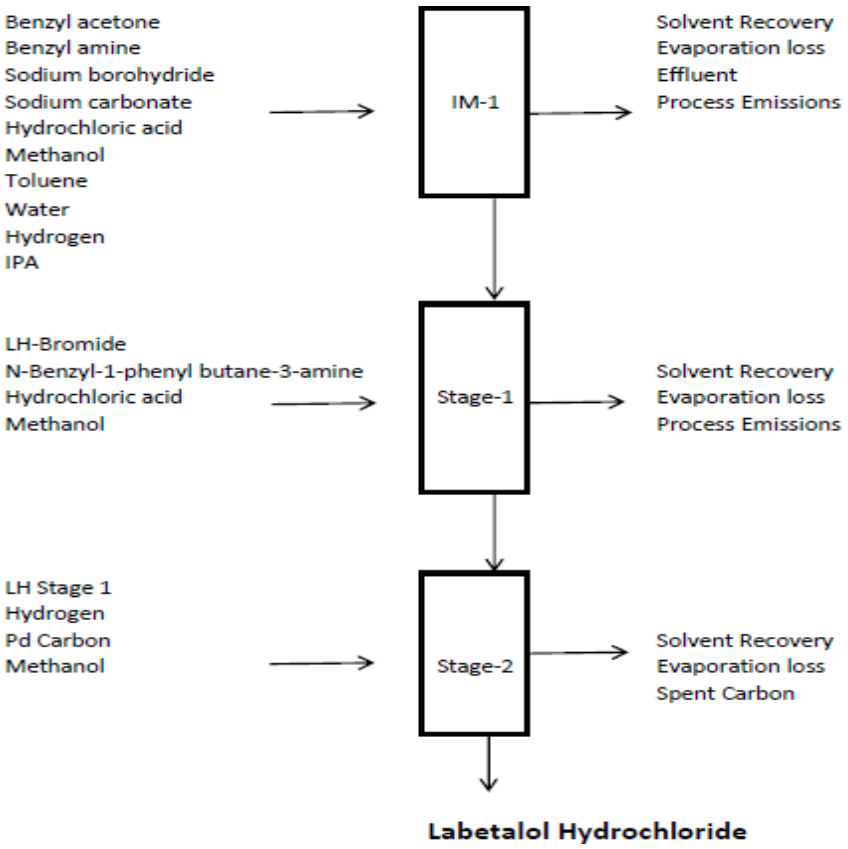


Molecular Formula = $C_{26}H_{28}N_2O_3$
Formula Weight = 453.01

2-hydroxy-5-{1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl}benzamide

Molecular Formula = $C_{19}H_{24}N_2O_3$
Formula Weight = 364.54

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Benzyl acetone	35.29	**Product**	
Benzyl amine	25.52	N-Benzyl-4-phenylbutane-2-amine	57.00
Sodium borohydride	85.00	**Solvent recovery**	
Sodium carbonate	12.62	Methanol	125.00
Hydrochloric acid	49.66	Methanol loss	3.50
Methanol	141.00	Toluene	637.50
Toluene	638.00	Toluene loss	0.50
Water	305.00	IPA	315.00
Hydrogen	0.46	IPA loss	2.00
IPA	317.00	**Effluent**	
Activated carbon	20.00	Water	305.00
		Hydrochloric acid	8.85
		Sodium borohydride	85.00
		Water from HCl	32.28
		Sodium chloride	14.00
		Generated water	6.18
		Methanol	12.50
		Spent carbon	**20.00**

		Emissions	
		Carbon dioxide	5.24
Total	**1629.55**	**Total**	**1629.55**
Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
LH-Bromide	57.00	**Product**	
N-Benzyl-1-phenyl butane-3-amine	52.83	Stage-II	100.00
Hydrochloric acid	8.10	**Solvent recovery**	
Methanol	882.00	Methanol	867.00
		Methanol loss	15.00
		Hydrobromic acid	17.93
Total	**999.93**	**Total**	**999.93**

Stage-2			
Input	**kg/batch**	**Output**	**kg/batch**
LH Stage 1	100.00	**Product**	
Hydrogen	0.89	Labetalol. HCl	80.55
Pd Carbon	23.50	**Solvent recovery**	
Methanol	450.00	Methanol	445.00
		Methanol loss	5.00
		Toluene	20.34
		Spent carbon	**23.50**
Total	**574.39**	**Total**	**574.39**

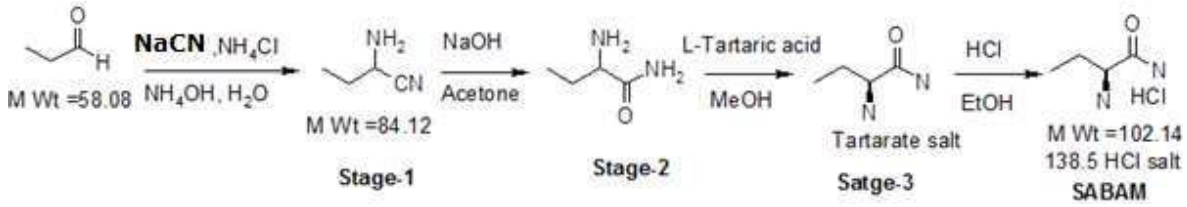
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	305	463.81	0.00	1077.50	6.00	12.50	107.85	18.75	0.00	20.00	5.24	0.00
2	0.00	0.00	0.00	0.00	867.00	15.00	0.00	0.00	0.00	0.00	0.00		0.00
3	80.55	0.00	0.00	0.00	445.00	5.00	0.00	0.00	0.00	0.00	23.50	0.00	0.00
Pollution Load per Day													
1	0.00	631.09	959.69	0.00	2229.51	12.41	25.86	223.16	38.80	0.00	41.38	10.84	0.00
2	0.00	0.00	0.00	0.00	1793.95	31.04	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3	166.67	0.00	0.00	0.00	920.77	10.35	0.00	0.00	0.00	0.00	48.63	0.00	0.00
Total	**166.67**	**631.09**	**959.69**	**0.00**	**4944.23**	**53.80**	**25.86**	**223.16**	**38.80**	**0.00**	**90.01**	**47.94**	**0.00**

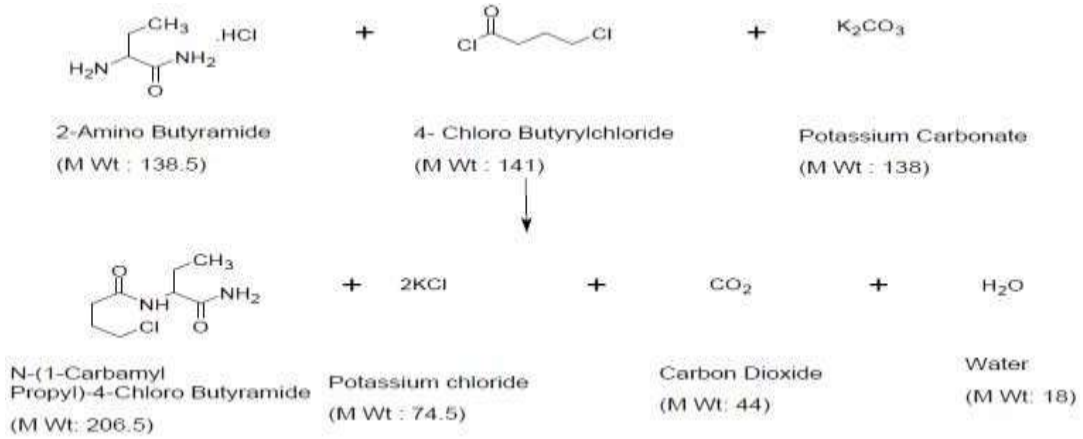
9. Levetiracetam

Process Description with Route of Synthesis

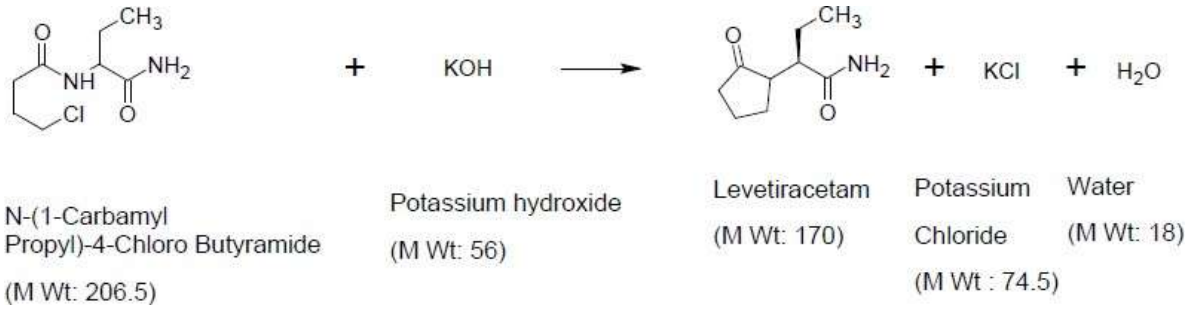
Stage-1: Propionaldehyde is reacted with Ammonium chloride, Sodium cyanide, Ammonium hydroxide, L-Tartaric acid and Hydrochloric acid in presence of Acetone, Methanol and Ethanol/IMS to get stage-I compound.



Stage-II: Stage-I compound is reacted with 2-Amino butyramide, 4-Chloro butyrylchloride and Potassium carbonate in presence of Acetonitrile and Di isopropyl ether to get stage-II compound.

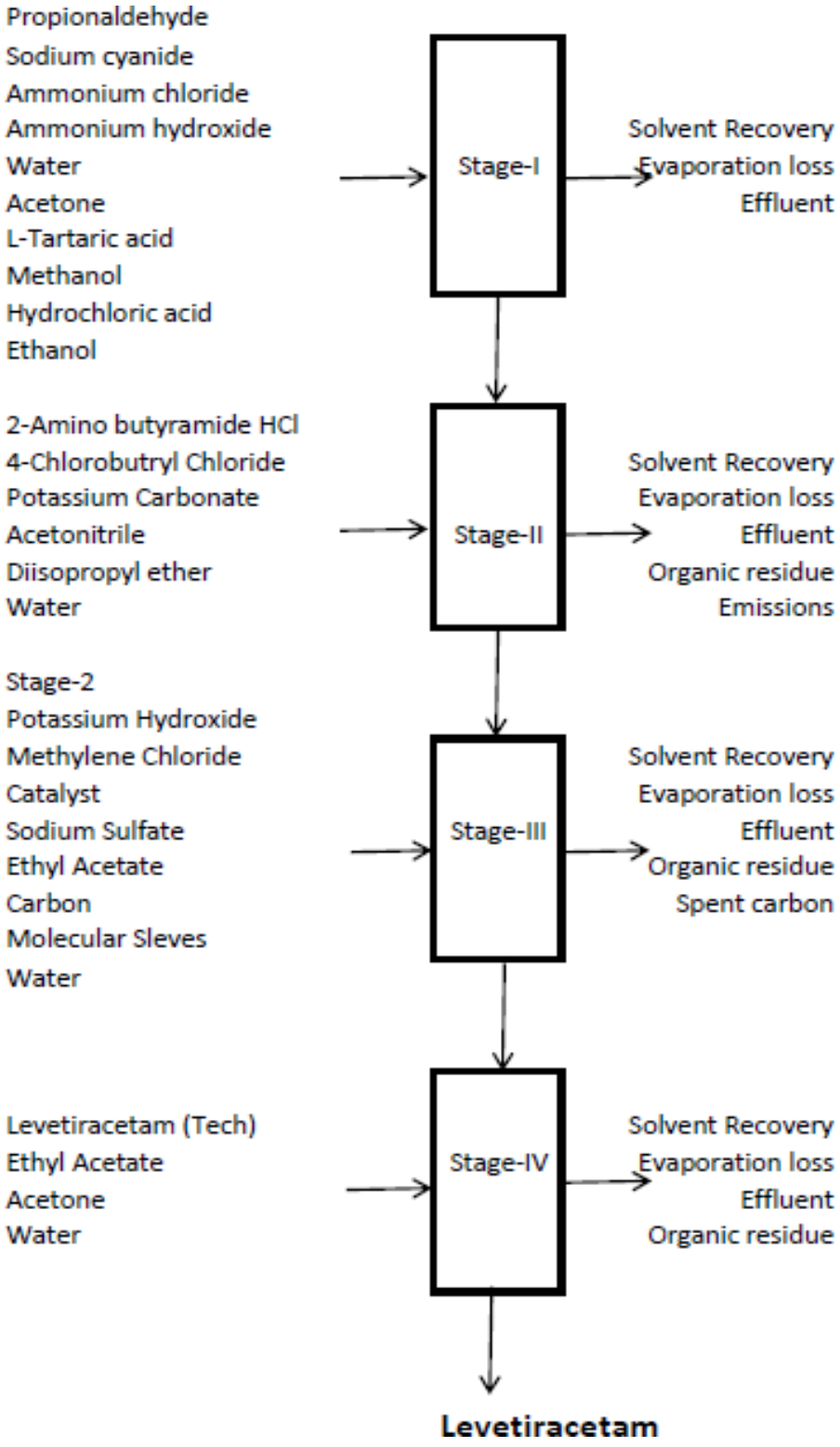


Stage-III: Stage-II compound is reacted with Potassium hydroxide in presence of Methylene chloride and Ethyl acetate to get Levetiracetam (Tech) product.



Stage-IV: Levetiracetum (Tech) product is purified with Ethyl acetate and Acetone to get Levetiracetam (Pharma) product.

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Propionaldehyde	50.40	2-Amino butyramide HCl (SABAM)	**120.00**
Sodium cyanide	42.00	**Solvent recovery**	
Ammonium chloride	30.00	Acetone	87.00
Ammonium hydroxide	30.00	Acetone loss	4.00
Water	150.00	Methanol	70.00
Acetone	90.00	Methanol loss	3.00
L-Tartaric acid	1.00	Ethanol	79.00
Methanol	80.00	Ethanol loss	1.00
Hydrochloric acid	180.00	**Effluent**	
Ethanol	80.00	Water	150.00
		Sodium chloride	50.00
		Gen. water	16.40
		L-Tartaric acid	1.00
		Methanol	7.00
		Ammonium chloride	28.00
		Water from HCl	117.00
Total	**733.40**	**Total**	**733.40**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
2-Amino butyramide HCl	120.00	**Product**	
4-Chlorobutryl Chloride	164.00	Stage-II	160.00
Potassium Carbonate	106.90	**Recovery**	
Acetonitrile	100.00	Acetonitrile	82.00
Diisopropyl ether	100.00	Acetonitrile loss	1.00
Water	450.00	Diisopropyl ether	90.00
Sodium chloride	70.00	Diisopropyl ether loss	3.00
		Effluent	
		Water	450.00
		Generated water	14.10
		Acetonitrile	17.00
		Potassium chloride	116.00
		Sodium chloride	70.00
		Organic residue	
		2-Amino butyramide HCl	12.00
		4-Chlorobutryl Chloride	54.70
		Diisopropyl ether	7.00
		Emissions	
		CO2	34.10
Total	**1110.90**	**Total**	**1110.90**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-II	160.00	**Product**	
Potassium Hydroxide	35.50	Levetiracetam (Tech)	108.00
Methylene Chloride	150.00	**Recovery**	

Catalyst	6.00	Methylene Chloride	147.00
Sodium Sulfate	15.00	Methylene Chloride loss	3.00
Ethyl Acetate	200.00	Ethyl Acetate	199.00
Carbon	30.00	Ethyl Acetate loss	1.00
Molecular Sleves	45.00	**Effluent**	
Water	750.00	Water	750.00
		Generated water	12.00
		Potassium chloride	47.30
		Organic residue	
		Organic compound	28.20
		Inorganic residue	
		Catalyst	6.00
		Molecular Sleves	45.00
		Sodium Sulfate	15.00
		Spent carbon	**30.00**
Total	**1391.50**	**Total**	**1391.50**

Stage-IV			
Input	**kg/batch**	**Output**	**kg/batch**
Levetiracetam (Tech)	108.00	**Product**	
Ethyl Acetate	200.00	Levetiracetam (Pharma)	100.00
Acetone	240.00	**Recovery**	
Water	350.00	Ethyl Acetate	199.00
		Ethyl Acetate loss	1.00
		Acetone	237.00
		Acetone loss	3.00
		Effluent	
		Water	350.00
		Organic residue	
		Levetiracetam (Tech)	8.00
Total	**898.00**	**Total**	**898.00**

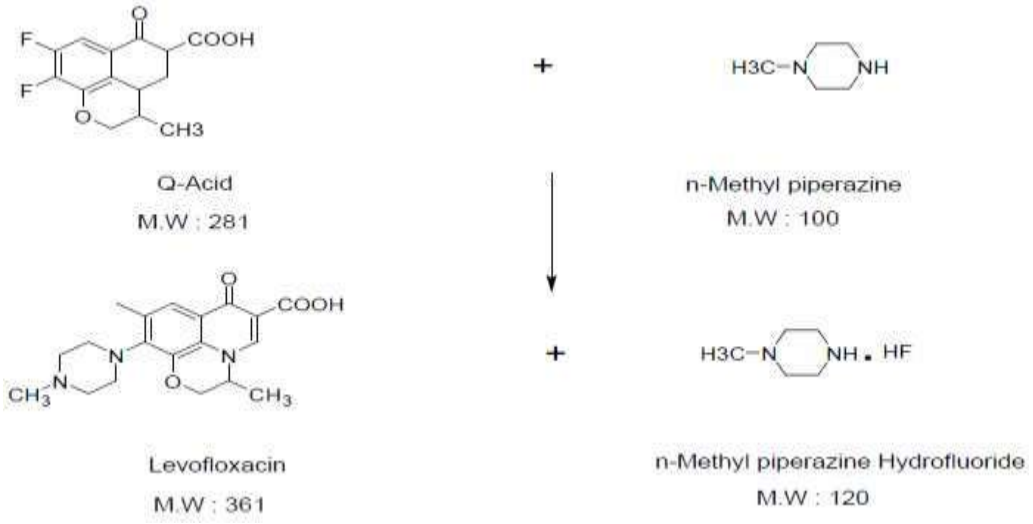
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	150.00	369.40	0.00	236.00	8.00	7.00	78.00	10.50	0.00	0.00	0.00	0.00
2	0.00	450.00	667.10	0.00	172.00	4.00	17.00	186.00	9.52	73.70	0.00	34.10	0.00
3	0.00	750.00	809.30	0.00	346.00	4.00	0.00	47.30	0.00	28.20	30.00	0.00	66.00
4	100.00	350.00	0.00	350.00	436.00	4.00	0.00	0.00	0.00	8.00	0.00	0.00	0.00
Pollution Load per Day													
1	0.00	1500.00	3694.00	0.00	2360.00	80.00	70.00	780.00	105.00	0.00	0.00	0.00	0.00
2	0.00	4500.00	6671.00	0.00	1720.00	40.00	170.00	1860.00	95.20	737.00	0.00	341.00	0.00
3	0.00	7500.00	8093.00	0.00	3460.00	40.00	0.00	473.00	0.00	282.00	300.00	0.00	660.00
4	1000.00	3500.00	0.00	3500.00	4360.00	40.00	0.00	0.00	0.00	80.00	0.00	0.00	0.00
Total	**1000.00**	**17000.00**	**18458.00**	**3500.00**	**11900.00**	**200.00**	**240.00**	**3113.00**	**200.20**	**1099.00**	**300.00**	**341.00**	**660.00**

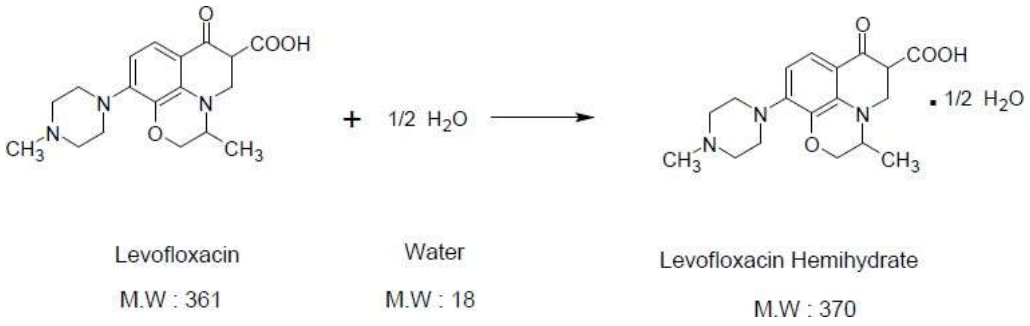
10. Levofloxacin Hemihydrate

Process Description with Route of Synthesis

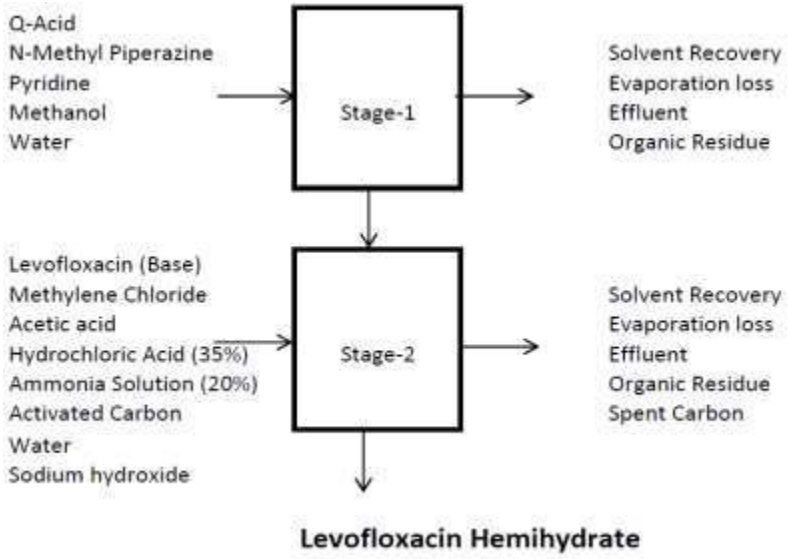
Stage-I: Q-acid is reacted with n-Methyl piperazine in presence of Pyridine and Methanol to get stage-I compound.



Stage-II: Stage-I compound is reacted with water in presence of Methylene chloride to get Levofloxacin hemihydrate.



Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Q-Acid	100.00	**Product**	
n-Methyl Piperazine	110.00	Levofloxacin (Base)	115.00
Pyridine	592.00	**Solvent recovery**	
Methanol	435.00	Methanol	400.00
Water	700.00	Methanol loss	3.00
		Pyridine	591.00
		Pyridine loss	1.00
		Effluent	
		Water	700.00
		Methanol	32.00
		Organic residue	
		Q-Acid	10.50
		N-Methyl Piperazine	46.30
		N-Methyl Piperazine. HF	38.20
Total	**1937.00**	**Total**	**1937.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Levofloxacin (Base)	115.00	**Product**	
Methylene Chloride	4250.00	Levofloxacin Hemihydrate	100.00
Acetic acid	20.00	**Solvent recovery**	
Hydrochloric Acid (35%)	40.00	Methylene Chloride	4240.00
Ammonia Solution (20%)	20.00	Methylene Chloride loss	10.00
Activated Carbon	33.00	**Effluent**	
Water	3600.00	Water	3598.00
Sodium hydroxide	135.00	Acetic acid	20.00

		Sodium hydroxide	120.00
		Sodium chloride	22.00
		Generated water	7.00
		Ammonia	4.00
		Water from HCl	26.00
		Water from NH4OH	16.00
		Organic residue	
		Levofloxacin (Base)	17.00
		Spent Carbon	**33.00**
Total	**8213.00**	**Total**	**8213.00**

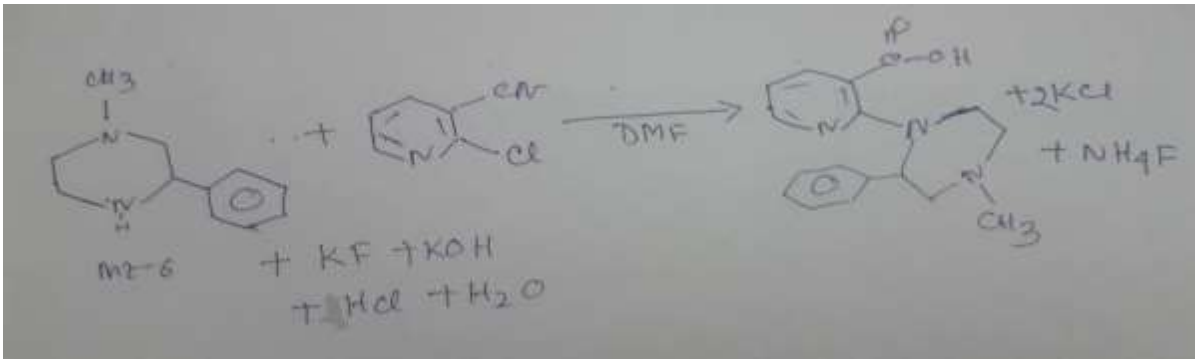
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	700.00	0.00	732.00	991.00	4.00	32.00	0.00	48.00	95.00	0.00	0.00	0.00
2	100.00	3600.00	3813.00	0.00	4240.00	10.00	20.00	146.00	21.40	17.00	33.00	0.00	0.00
Pollution Load per Day													
1	0.00	1166.69	0.00	1220.02	1651.70	6.67	53.33	0.00	80.00	158.34	0.00	0.00	0.00
2	166.67	6000.12	6355.13	0.00	7066.81	16.67	33.33	243.34	35.67	28.33	55.00	0.00	0.00
Total	**166.67**	**7166.81**	**6355.13**	**1220.02**	**8718.51**	**23.33**	**86.67**	**243.34**	**115.67**	**186.67**	**55.00**	**0.00**	**0.00**

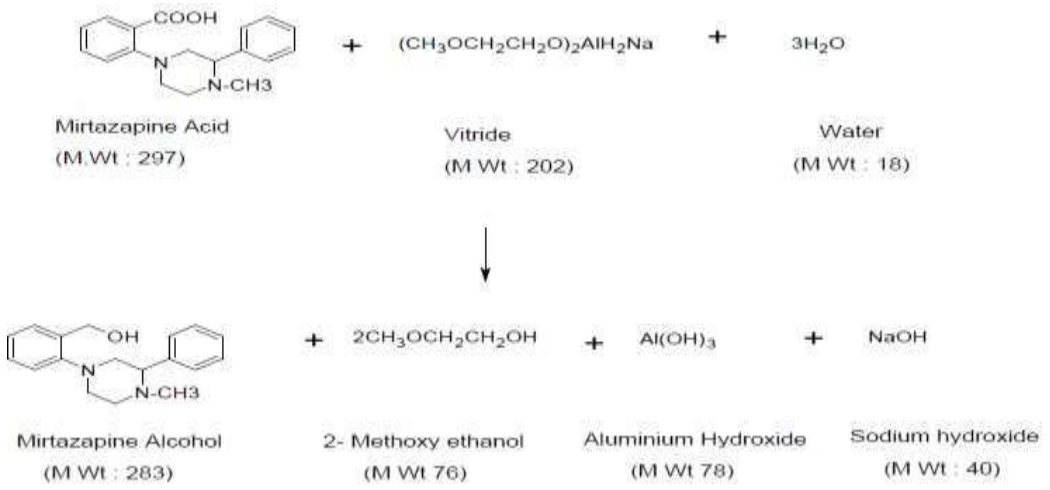
11. Miratazapine

Process Description with Route of Synthesis

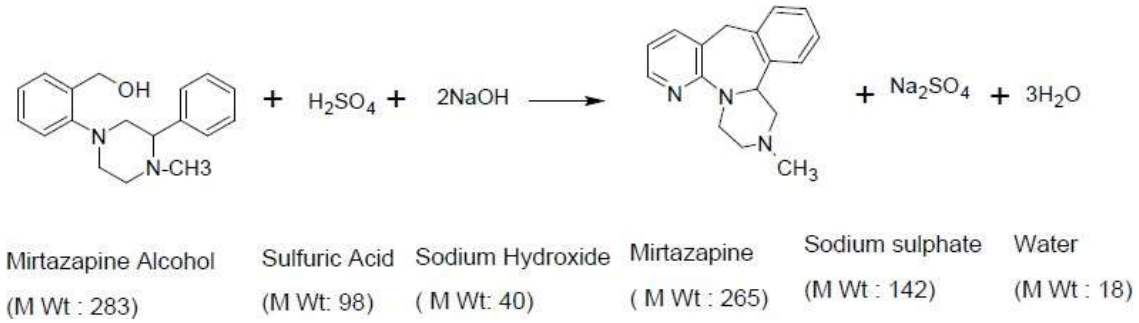
Stage-I: 2-Chloronicotinontrile (MZ-6) is reacted with 1-Methyl-3-phenyl piperazine, Potassium fluoride, Potassium hydroxide , Hydrogen chloride and Water in presence of Dimethyl formamide, Ethyl acetate, IMS, Toluene and Chloroform to get stage-I compound.



Stage-II: Stage-I compound is reacted with Vitride and Water in presence of Toluene and Ethyl acetate to get stage-II compound.

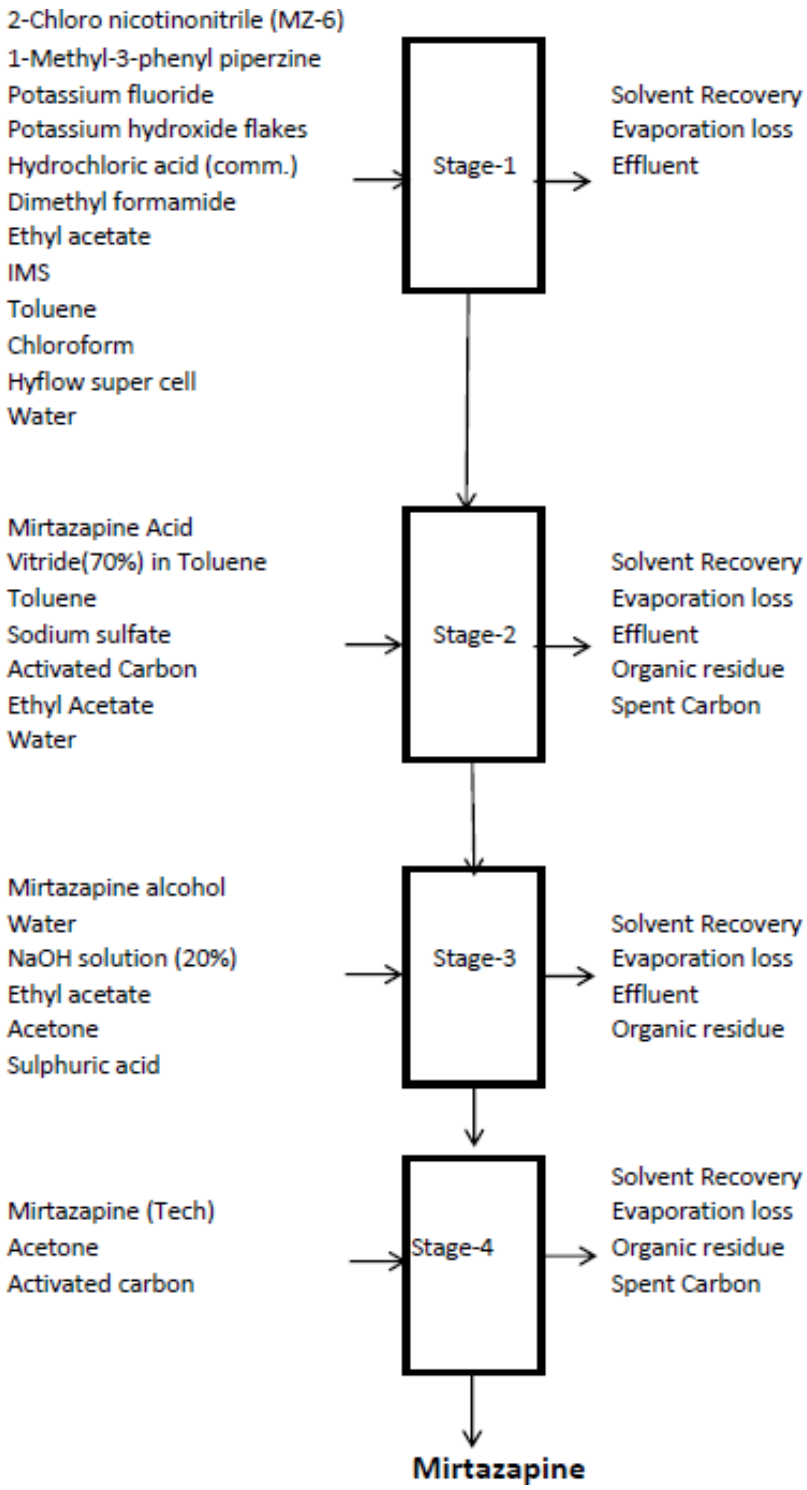


Stage-III: Stage-II compound is reacted with Sulfuric acid and Sodium hydroxide in presence of Ethyl acetate and Acetone to get stage-III compound.



Stage-IV: Mirtazapine (Tech) product is purified with Acetone and activated carbon to get Mirtazapine (Pharma) product.

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
2-Chloro nicotinonitrile (MZ-6)	84.00	**Product**	
1-Methyl-3-phenyl piperzine	95.00	Mirtazapine acid	160.00
Potassium fluoride	31.00	**Solvent recovery**	
Potassium hydroxide flakes	153.20	Dimethyl formamide	89.00
Sodium chloride	50.00	Dimethyl formamide loss	1.00
Hydrochloric acid	285.80	Ethyl acetate	100.00
Dimethyl formamide	90.00	Ethyl acetate loss	5.00
Ethyl acetate	105.00	IMS	255.00
IMS	270.00	IMS loss	3.00
Toluene	120.00	Toluene	117.00
Chloroform	200.00	Toluene loss	3.00
Hyflow super cell	38.50	Chloroform	192.00
Water	200.00	Chloroform loss	8.00
		Effluent	
		Water	190.00
		Gen. water	40.00
		Ammonium fluoride	20.00
		Sodium chloride	50.00
		Water from HCl	185.77
		IMS	12.00
		Inorganic residue	
		Hyflow super cell	38.50
		Potassium chloride	243.23
		Organic residue	
		MZ-6	10.00
Total	**1722.50**	**Total**	**1722.50**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Mirtazapine Acid	160.00	**Mirtazapine alcohol**	**135.00**
Vitride(70%) in Toluene	160.00	**Solvent recovery**	
Toluene	600.00	Toluene	642.80
Sodium sulfate	45.00	Toluene loss	2.00
Activated Carbon	18.00	Ethyl acetate	491.00
Ethyl Acetate	500.00	Ethyl acetate loss	9.00
Water	3000.00	**Effluent**	
Sodium chloride	22.00	Water	2974.20
Hyflow super cell	40.00	Aluminium hydroxide	37.30
		Sodium hydroxide	19.00
		2-Mehoxy ethanol	72.50
		Sodium chloride	22.00
		Organic residue	
		Mirtazapine Acid	18.00
		Vitride	19.20
		Inorganic residue	
		Sodium sulphate	45.00
		Hyflow super cell	40.00
		Spent carbon	**18.00**
Total	**4545.00**	**Total**	**4545.00**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Mirtazapine alcohol	135.00	**Mirtazapine (Tech)**	**120.00**
Water	1000.00	**Solvent recovery**	
NaOH solution (20%)	180.00	Ethyl acetate	240.00
Ethyl acetate	250.00	Ethyl acetate loss	2.00
Acetone	190.00	Acetone	170.00
Sulphuric acid	44.00	Acetone loss	6.00
Hyflow super cell	25.60	**Effluent**	
Sodium hydroxide flakes	30.00	Ethyl acetate	8.00
		Acetone	14.00
		Water	1000.00
		Water from NaOH	144.00
		Generated water	24.00
		NaOH	30.00
		Inorganic residue	
		Sodium sulphate	64.00
		Hyflow super cell	25.60
		Organic residue	
		Mirtazapine alcohol	7.00
Total	**1854.60**	**Total**	**1854.60**

Stage-IV

Input	**kg/batch**	**Output**	**kg/batch**
Mirtazapine (Tech)	120.00	**Product**	**100.00**
Acetone	480.00	**Solvent Recovery**	
Activated carbon	25.00	Acetone	470.00
		Acetone loss	10.00
		Organic residue	
		Mirtazapine (Tech)	20.00
		Spent carbon	**25.00**
Total	**625.00**	**Total**	**625.00**

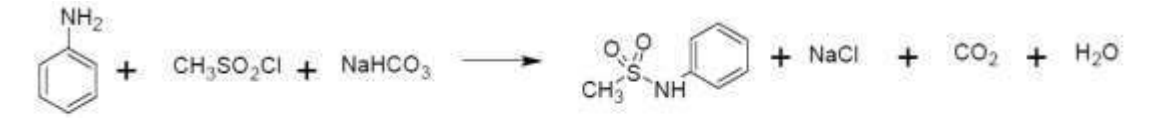
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	200.00	497.77	0.00	753.00	20.00	12.00	70.00	24.96	10.00	0.00	0.00	281.73
2	0.00	3000.00	3125.00	0.00	1133.80	11.00	0.00	78.30	49.30	37.20	18.00	0.00	85.00
3	0.00	1000.00	1220.00	0.00	410.00	8.00	22.00	30.00	45.50	7.00	0.00	0.00	89.60
4	100.00	0.00	0.00	0.00	470.00	10.00	0.00	0.00	0.00	20.00	25.00	0.00	0.00
Pollution Load per Day													
1	0.00	333.34	829.63	0.00	1255.03	33.33	20.00	116.67	41.60	16.67	0.00	0.00	469.56
2	0.00	5000.10	5208.44	0.00	1889.70	18.33	0.00	130.50	82.17	62.00	30.00	0.00	141.67
3	0.00	1666.70	2033.37	0.00	683.35	13.33	36.67	50.00	75.83	11.67	0.00	0.00	149.34
4	166.67	0.00	0.00	0.00	783.35	16.67	0.00	0.00	0.00	33.33	41.67	0.00	0.00
Total	**166.67**	**7000.14**	**8071.44**	**0.00**	**4611.43**	**81.67**	**56.67**	**297.17**	**199.60**	**123.67**	**71.67**	**0.00**	**760.57**

12. Sotalol Hydrochloride

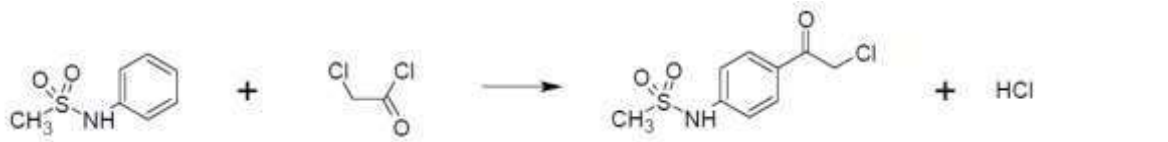
Process Description with Route of Synthesis

Stage-I: Aniline is reacted with Methane sulfonyl chloride and Sodium bicarbonate in presence of Toluene to get Stage-I compound.



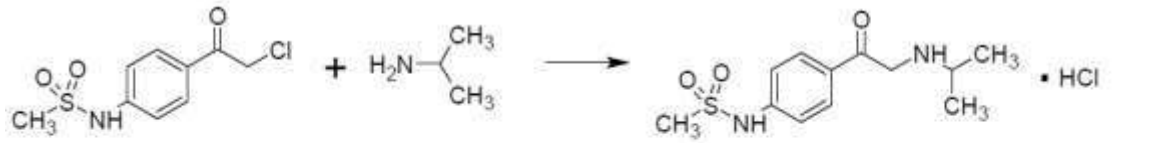
Aniline	Methane Sulfonyl Chloride	Sodium Bicarbonate	Methane Sulfonanilide	Sodium Chloride	Carbon Dioxide	Water
M Wt : 93	M Wt : 114.5	M Wt : 84	M Wt : 171	M Wt : 58.5	M Wt : 44	M Wt : 18

Stage-II: Stage-II compound is reacted with Chloro acetyl chloride in presence of Methylene dichloride and Acetone to get Stage-II compound.



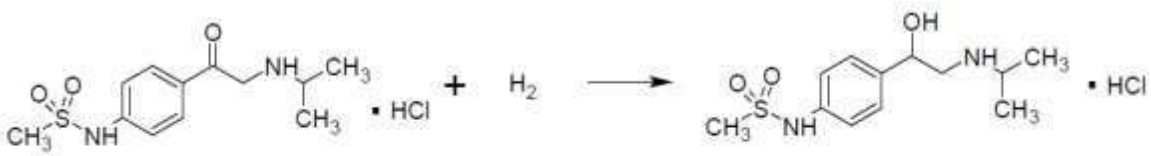
Methane Sulfonanilide	Chloroacetyl Chloride	4-(2-Chloro acetyl) Methane Sulfonanilide	Hydrochloric acid
M Wt :171	M Wt : 113	M Wt : 247.5	M Wt : 36.5

Stage-III: Stage-II compound is reacted with Isopropyl amine in presence of Methanol to get Stage-III compound.



4-(2-Chloro acetyl) Methane Sulfonanilide	Isopropyl Amine	4-(2-Isopropyl amino acetyl) Methane Sulfonanilide Hydrochloride
M Wt : 247.5	M Wt: 59	M Wt : 306.5

Stage-IV: Stage-III compound is reacted with Hydrogen in presence Isopropyl alcohol, Methanol and IMS to get Sotalol hydrochloride.



4-(2-Isopropyl amino acetyl) Methane Sulfonanilide Hydrochloride

M Wt : 306.5

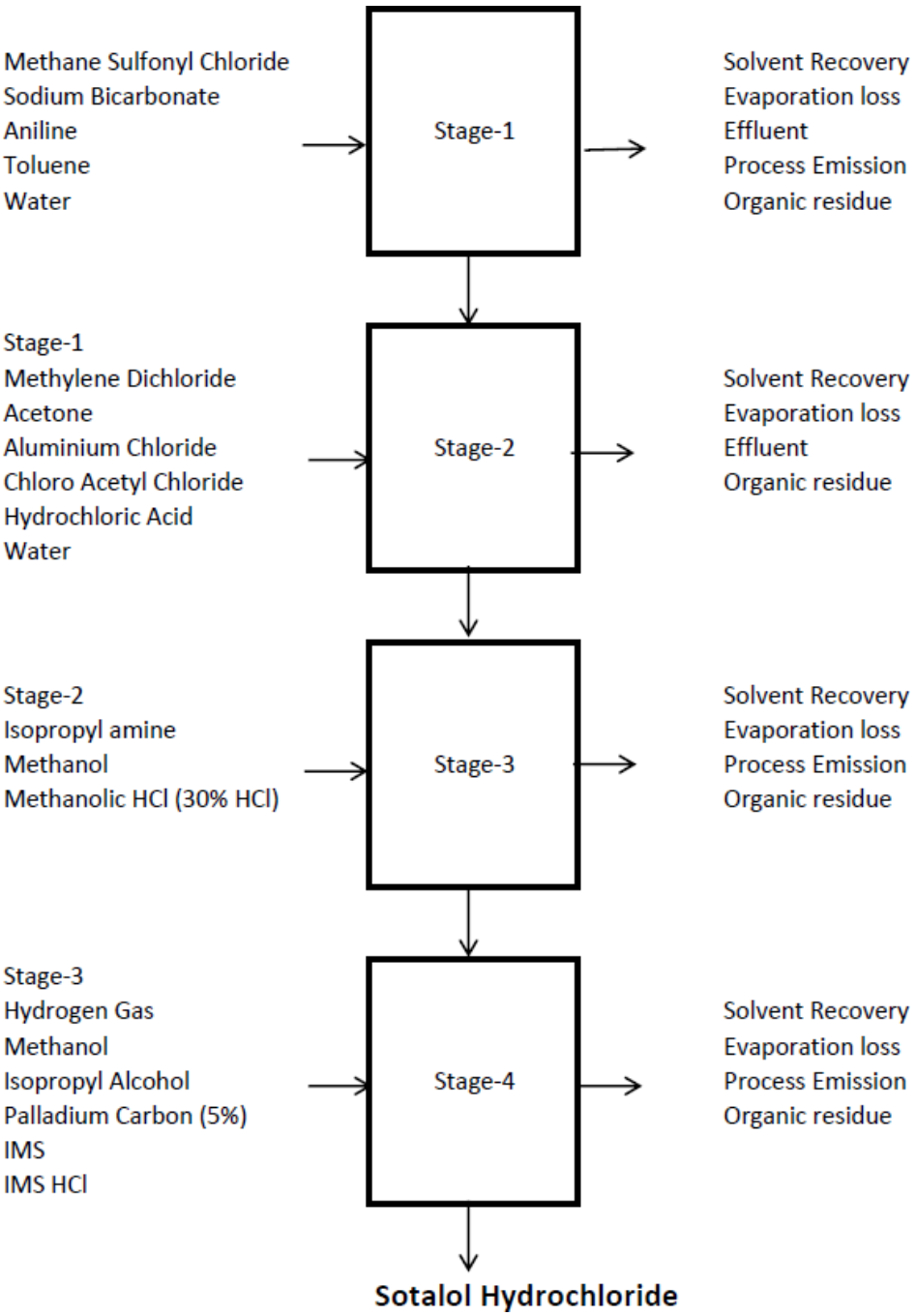
Hydrogen

M Wt : 2

Sotalol HCl.

M Wt : 308.5

Process Flow Diagram



Material Balance

Stage-I			
Input	**kg/batch**	**Output**	**kg/batch**
Methane Sulfonyl Chloride	60.00	**Product**	
Sodium Bicarbonate	150.00	Stage-I	80.00
Aniline	52.00	**Recovery**	
Toluene	200.00	Toluene	180.00
Water	1200.00	Toluene loss	20.00
		Effluent	
		Water	1200.00
		Sodium Bicarbonate	110.70
		Sodium chloride	27.40
		Generated water	8.40
		Aniline	8.50
		Organic residue	
		Methane Sulfonyl Chloride	6.40
		Emissions	
		Carbon dioxide	20.60
Total	**1662.00**	**Total**	**1662.00**

Stage-II			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-I	80.00	**Product**	
Methylene Dichloride	200.00	Stage-II	104.00
Acetone	200.00	**Recovery**	
Aluminium Chloride	54.00	Methylene Dichloride	185.00
Chloro Acetyl Chloride	56.00	Methylene Dichloride loss	15.00
Hydrochloric Acid	100.00	Acetone	182.00
Water	150.00	Acetone loss	8.00
		Effluent	
		Water	150.00
		Acetone	10.00
		Aluminium Chloride	54.00
		Hydrochloric Acid	35.00
		Water from HCl	65.00
		Generated water	15.30
		Organic residue	
		Stage-I	8.20
		Chloro Acetyl Chloride	8.50
Total	**840.00**	**Total**	**840.00**

Stage-III			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-II	104.00	**Product**	
Isopropyl alcohol	400.00	Stage-III	112.00
Methanol	400.00	**Recovery**	
Methanolic HCl (30% HCl)	30.00	Isopropyl alcohol	340.00
		Isopropyl alcohol loss	38.00
		Methanol	406.00
		Methanol loss	15.00
		Emission	
		Hydrochloric acid	9.00
		Organic residue	
		Stage-II	14.00
Total	**934.00**	**Total**	**934.00**

Stage-IV			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-III	112.00	**Product**	
Hydrogen Gas	0.60	Sotalol Hydrochloride	100.00
Methanol	720.00	**Recovery**	
Isopropyl Alcohol	400.00	Isopropyl Alcohol	385.00
Palladium Carbon (5%)	28.00	Isopropyl Alcohol loss	15.00
IMS	480.00	Methanol	690.00
IMS HCl	10.00	Methanol loss	30.00
		IMS	475.00
		IMS loss	5.00
		Organic Residue	
		Stage-III	12.60
		IMS HCl	10.00
		Spent carbon	**28.00**
Total	**1750.60**	**Total**	**1750.60**

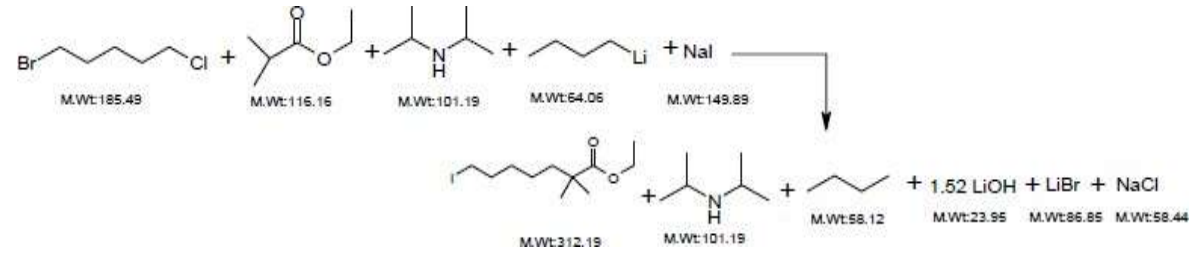
Anticipated Pollution Load

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0.00	1200.00	1355.00	0.00	180.00	20.00	0.00	138.10	20.49	6.40	0.00	20.60	0.00
2	0.00	150.00	329.30	0.00	367.00	23.00	10.00	89.00	22.10	16.70	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00	746.00	53.00	0.00	0.00	0.00	14.00	0.00	9.00	0.00
4	100.00	0.00	0.00	0.00	1550.00	50.00	0.00	0.00	0.00	22.60	28.00	0.00	0.00
Pollution Load per Day													
1	0.00	2000.04	2258.38	0.00	300.01	33.33	0.00	230.17	34.14	10.67	0.00	34.33	0.00
2	0.00	250.01	548.84	0.00	611.68	38.33	16.67	148.34	36.83	27.83	0.00	0.00	0.00
3	0.00	0.00	0.00	0.00	1243.36	88.34	0.00	0.00	0.00	23.33	0.00	15.00	0.00
4	166.67	0.00	0.00	0.00	2583.39	83.34	0.00	0.00	0.00	37.67	46.67	0.00	0.00
Total	**166.67**	**2250.05**	**2807.22**	**0.00**	**4738.43**	**243.34**	**16.67**	**378.51**	**70.98**	**99.50**	**46.67**	**49.33**	**0.00**

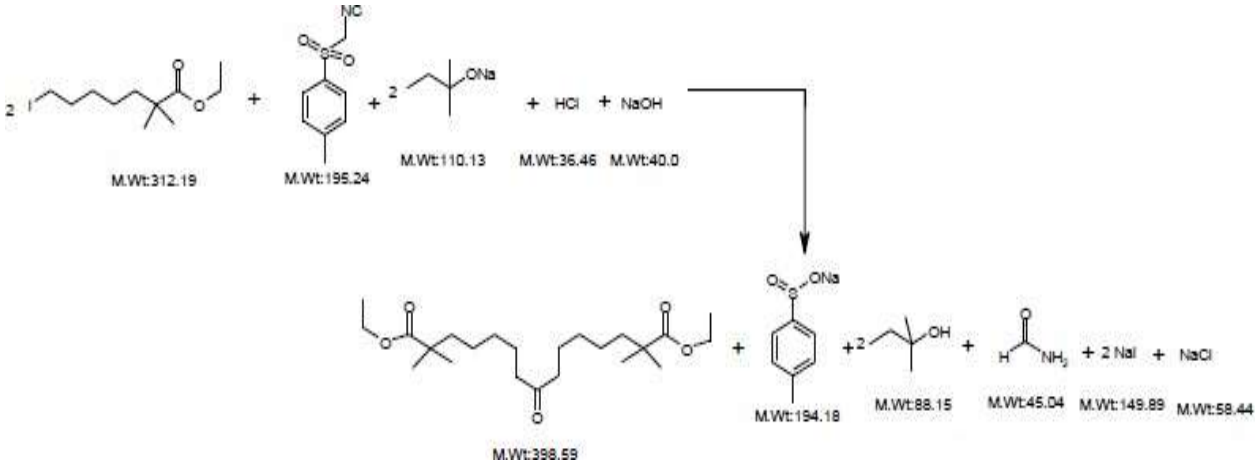
13. Bempodoicacid

Manufacturing Process

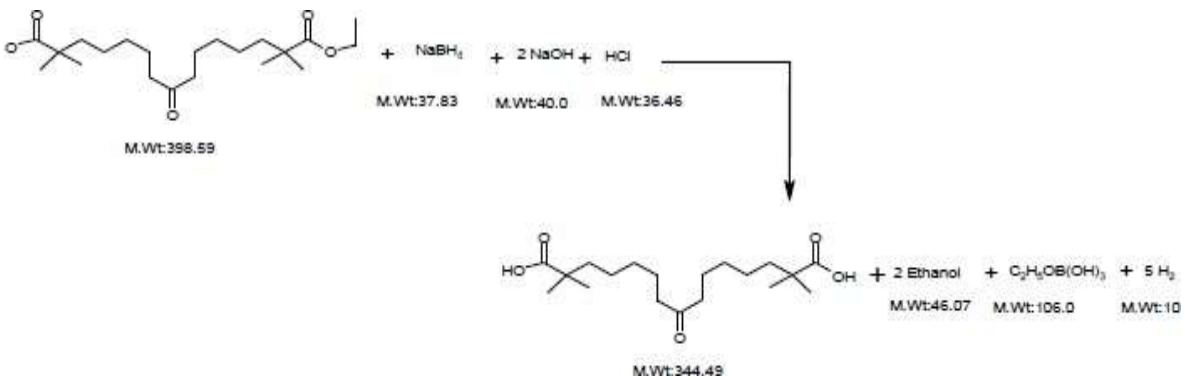
Stage-1: 1-Bromo-5-chloropentane is reacted with Ethyl isobutyrate, Diisopropyl amine, n-Butyl lithium and Sodium iodide in the presence of Tetrahydro furan to get Stage-1.

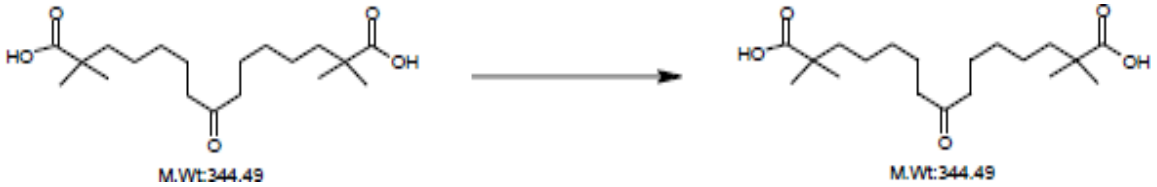


Stage-2: Stage-1 is reacted with Tosmic (IM-2), Sodium tertiary pentoxide, Hydrochloric acid and Sodium hydroxide in the presence of Dimethyl formamide, Isopropyl acetate and n-Heptane to get Stage-2.

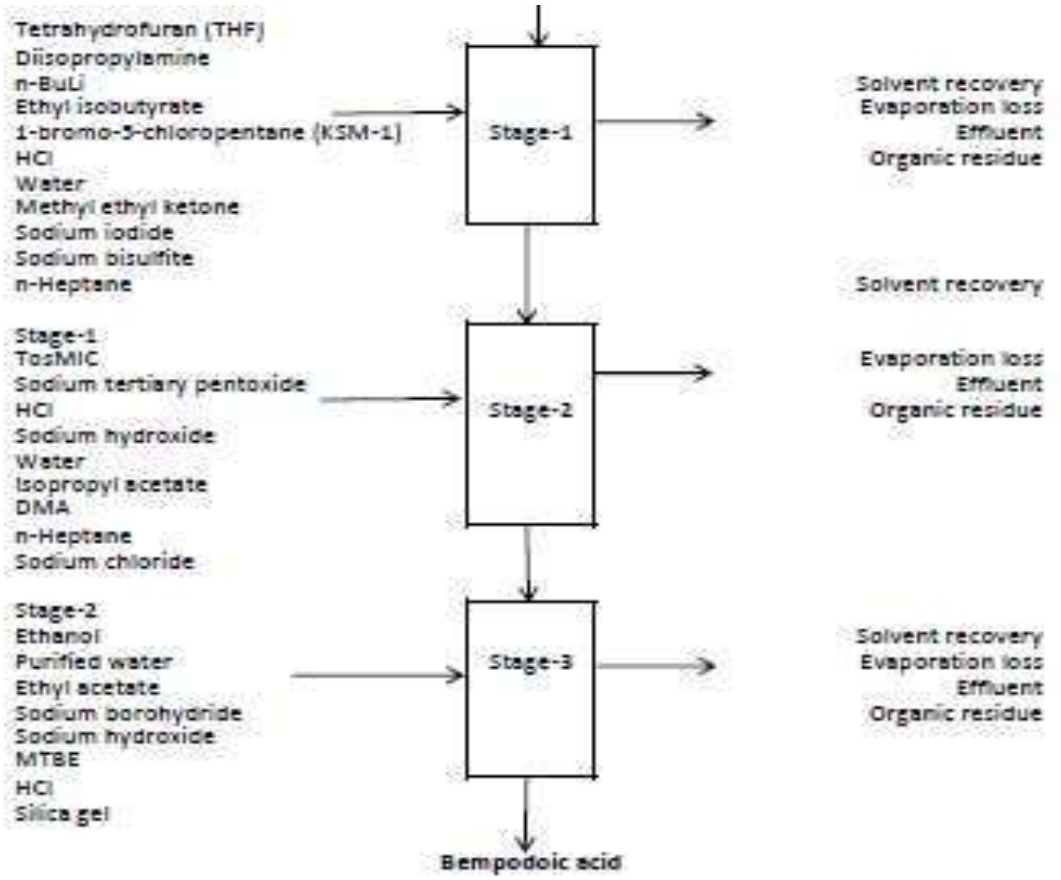


Stage-3 & 4: Stage-2 is reacted with Sodium borohydride, Hydrochloric acid and Sodium hydroxide in the presence of Ethyl acetate, Ethanol and Methyl tert butyl ether to get Stage-3and it is purified to result the finished product.





Process Flow Diagram



Material balance

Stage-1					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
Tetrahydrofuran (THF)	3.0917	222.945	**Stage-1**	0.2532	79.05
Diisopropylamine	0.3424	34.65	Tetrahydrofuran (THF)	2.9990	216.26
n-BuLi	1.1942	76.5	Tetrahydrofuran (THF) loss	0.0928	6.688
Ethyl isobutyrate	0.2583	30	Diisopropylamine	0.3322	33.611
1-bromo-5-chloropentane	0.2696	50	Diisopropylamine loss	0.0103	1.040
HCl	0.3333	6	n-Heptane	1.3193	132.211
Water	6.6667	120	n-Heptane loss	0.0408	4.089
Methyl ethyl ketone	2.7167	195.9	**Effluent**		
Sodium iodide	0.2535	38	Water	6.6667	120
Sodium bisulfite	0.0058	0.6	Sodium bisulfite	0.0058	0.6
n-Heptane	1.3601	136.3	Sodium iodide	0.0003	0.05
			Sodium chloride	0.2533	14.80
			Lithium bromide	0.2533	22
			Butane	0.2533	14.72
			Water from HCl	0.2133	3.84
			HCl	0.1200	2.16
			Organic residue		
			1-bromo-5-chloropentane	0.0163	3.03
			Methyl ethyl ketone	2.7167	195.9
			n-BuLi	0.9407	60.26
			Ethyl isobutyrate	0.0051	0.59
Total input	**16.4923**	**910.895**	**Total output**	**16.4922**	**910.895**

Stage-2					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
Stage-1	0.2563	80	**Stage-2**	0.1269	50.6
TosMIC	0.1280	25	**Solvent recovery**		
Sodium tertiary pentoxide	0.2542	28	Isopropyl acetate	0.4653	47.520
HCl	0.4681	13.1	Isopropyl acetate loss	0.0194	1.980
Sodium hydroxide	0.3000	12	DMA	3.6941	321.832
Water	33.3333	600	DMA loss	0.0754	6.568
Isopropyl acetate	0.4847	49.5	n-Heptane	2.2341	223.876
DMA	3.7695	328.4	n-Heptane loss	0.0691	6.924
n-Heptane	2.3032	230.8	**Effluent**		
Sodium chloride	0.0171	1	Water	33.3333	600
			Sodium chloride	0.1441	8.42
			Water from HCl	0.4658	8.38
			Sodium hydroxide	0.0460	1.84
			HCl	0.0023	0.085
			Formamide	0.1270	5.72
			Sodium iodide	0.2539	38.06
			2-Isobutanol	0.2539	22.38
			Organic residue		
			Stage-1	0.0024	0.74
			TosMIC	0.0011	0.22
			Sodium tertiary pentoxide	0.0002	0.04

			Sodium p-toluene sulfinate	0.1270	22.62
Total input	**41.3144**	**1367.8**	**Total output**	**41.3143**	**1367.8**

Stage-3					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
Stage-2	0.1004	40	**Stage-3**	0.0584	20
Ethanol	0.2055	9.468	**Solvent recovery**		
Purified water	3.8889	70	Ethanol	0.1973	9.089
Ethyl acetate	0.0276	2.43	Ethanol loss	0.0082	0.379
Sodium borohydride	0.0027	0.1	Ethyl acetate	0.0268	2.357
Sodium hydroxide	0.1175	4.7	Ethyl acetate loss	0.0008	0.073
MTBE	0.2090	18.426	MTBE	0.2028	17.873
HCl	0.5374	11.83	MTBE loss	0.0063	0.553
Silica gel	0	0.5	**Effluent**		
			Water	3.8889	70
			Water from HCl	0.4206	7.57
			NaCl	0.1168	6.83
			Sodium borohydride	0.0027	0.1
			Silica gel	0	0.5
			Ethanol	0.1168	5.38
			Sodium hydroxide	0.0008	0.03
			Organic residue		
			Stage-2	0.0420	16.724
Total input	**5.0890**	**157.454**	**Total output**	**5.0890**	**157.454**

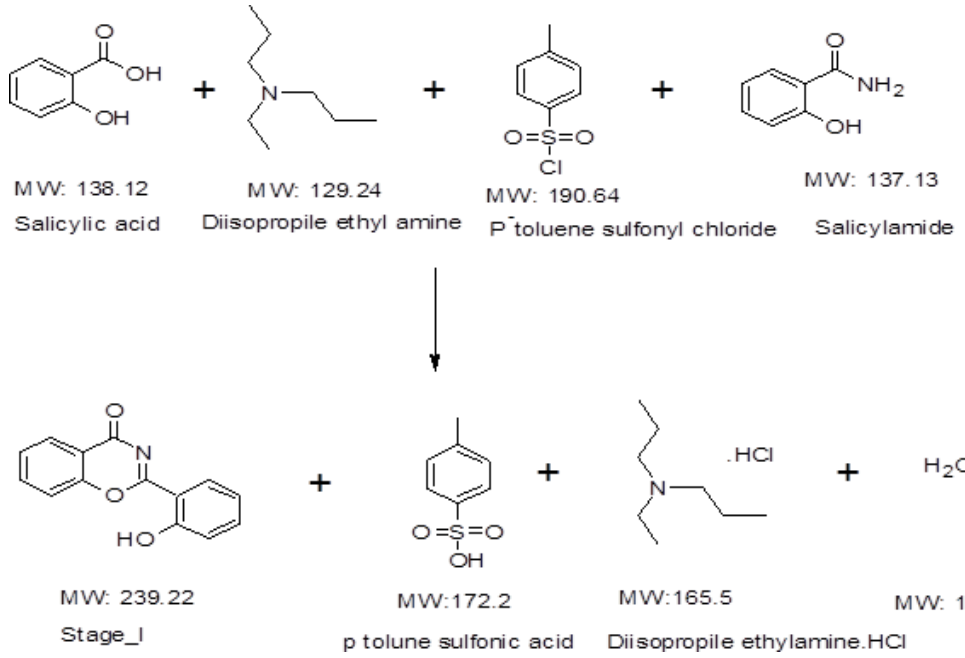
Pollution load

Stages	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	TDS (mg/L)	COD (mg/L)	Input solvent (kg)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Per batch															
1	0	79.05	120	178.17	0	98558	0	393.9	382.08	11.82	0	21.18	0	0	0
2	0	50.6	600	684.89	0	15105	2903	608.7	589.94	18.76	0	10.39	0	0	1.99
3	20	0	70	90.41	0	82461	62097	30.32	29.32	1	7.46	0	0	0	5.61
Per Day															
1	0	1317.48	1999.98	2969.47	0	1642616.9	0	6564.93	6367.93	196.99	0	352.99	0	0	0
2	0	843.32	9999.9	11414.71	0	251747.48	48382.84	10144.89	9832.23	312.66	0	173.15	0	0	33.16
3	333.33	0	1166.6	1506.81	0	1374336.3	1034939.7	505.32	488.66	16.66	124.33	0	0	0	93.49
Total	**333.33**	**2160.8**	**13166.48**	**15890.99**	**0**	**1089566.9**	**361107.49**	**17215.14**	**16688.82**	**526.31**	**124.33**	**526.14**	**0**	**0**	**126.65**

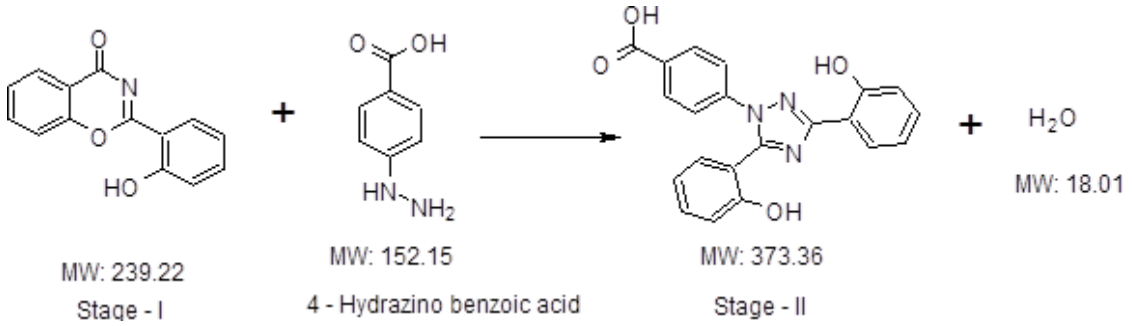
14. Diferasirox

Manufacturing Process

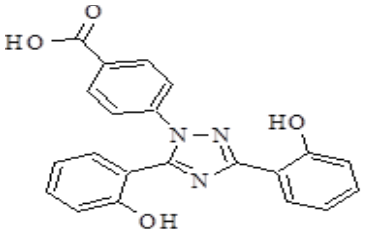
Stage-1: Salicyclic Acid is reacted with Para toluene Sulfonyl chloride and Salicylamide in the presence of Ethanol, Toluene and MDC to obtain Stage-1.



Stage-2: Stage-1 is reacted with 4-Hydrazino Benzoic acid in the presence of Methanol and MDC to obtain Stage-2.

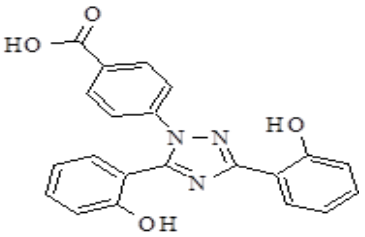


Stage-3: It is a purification process.



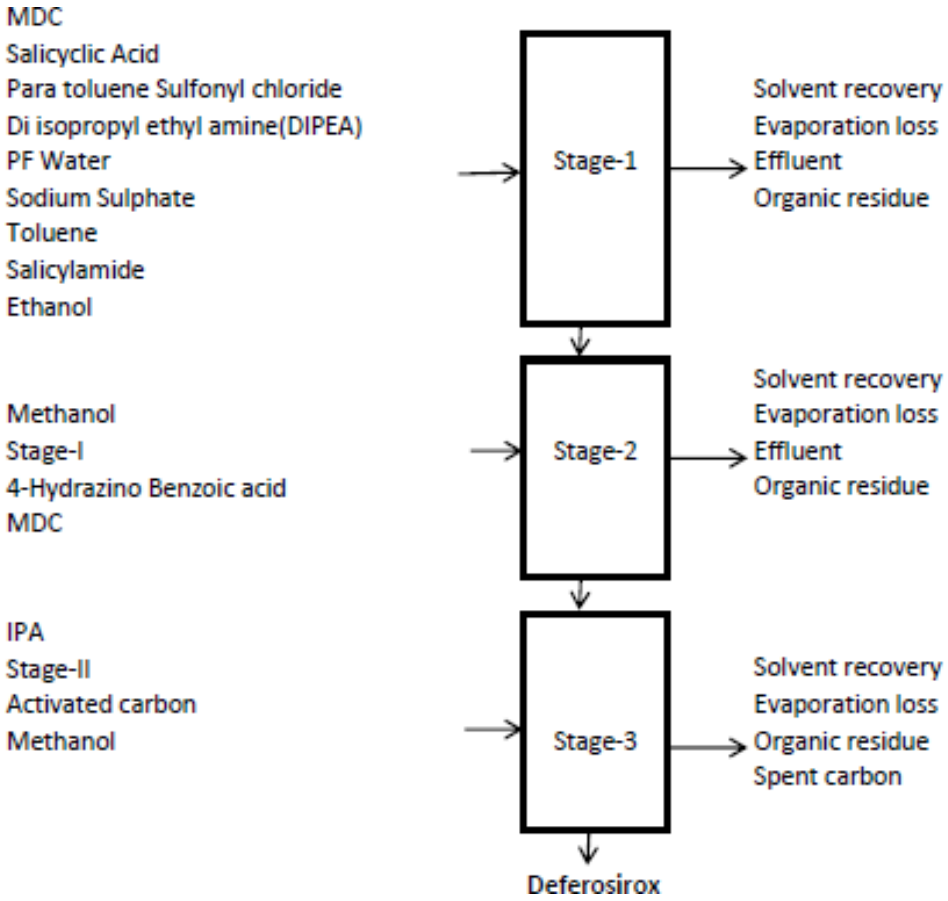
Stage - II
Daferasirox (Crude)
M.F: $C_{21}H_{15}N_3O_4$
M.Wt: 373.36

Isopropyl alcohol
Methanol



Stage - III
Daferasirox
M.F: $C_{21}H_{15}N_3O_4$
M.Wt: 373.36

Process Flow Diagram



Material balance

Stage 1					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
MDC	14.4855	1230.25	**Stage 1**	0.4679	**111.93**
Salicyclic Acid	0.5285	73	**Solvent recovery**		
Para toluene Sulfonyl chloride	0.5523	105.3	MDC	13.9060	1181.040
Di isopropyl ethyl amine(DIPEA)	0.6314	81.6106	MDC loss	0.4346	36.908
PF Water	82.2222	1480	Toluene	6.6846	615.917
Sodium Sulphate	0.1302	18.5	Toluene loss	0.2089	19.247
Toluene	6.9631	641.58	Ethanol	13.7776	634.735
Salicylamide	0.5244	71.89	Ethanol loss	0.4306	19.835
Ethanol	14.3517	661.182	**Effluent**		
			MDC	0.1449	12.303
			Toluene	0.0696	6.416
			Ethanol	0.1435	6.612
			PF Water	82.2222	1480
			Water from reaction	0.4676	8.417
			Sodium Sulphate	0.1302	18.5
			Organic residue		
			Salicyclic Acid	0.0606	8.374
			Di isopropylethyl amine(DIPEA)	0.1636	21.15
			Para toluene Sulfonyl chloride	0.0844	16.1
			Salicylamide	0.0564	7.73
			p toluene sulphonic acid	0.4678	80.56
			DPA HCl	0.4680	77.54
Total	**120.3893**	**4363.313**	**Total**	**120.3891**	**4363.313**

Stage 2					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
Methanol	44.2966	1419.264	**Stage 2**	0.3375	**126**
Stage-I	0.4682	112	**Solvent recovery**		
4-Hydrazino Benzoic acid	0.3858	59	Methanol	42.5228	1362.43
MDC	14.0313	1191.68	Methanol loss	1.3289	42.58
			MDC	13.4701	1144.01
			MDC loss	0.4209	35.75
			Effluent		
			Methanol	0.4449	14.25
			MDC	0.1403	11.92
			Water	0.3372	6.07
			Organic residue		
			4-Hydrazino Benzoic acid	0.0503	7.6536
			Stage-I	0.1307	31.27
Total	**59.1819**	**2781.94**	**Total**	**59.1819**	**2781.94**

Stage 3					
Input	**Moles**	**kg/batch**	**Output**	**Moles**	**kg/batch**
IPA	23.7067	1424.775	**Product**	**0.1289**	**48.125**
Stage-II	0.1473	55	**Solvent recovery**		
Activated carbon	0	6	IPA	22.7585	1367.78
Methanol	6.7978	217.8	IPA loss	0.9483	56.99
			Methanol	6.5258	209.09
			Methanol loss	0.2720	8.71
			Organic residue		
			Carbon residue	0	6
			Stage-II	0.0184	6.875
Total	**30.6518**	**1703.58**	**Total**	**30.6519**	**1703.58**

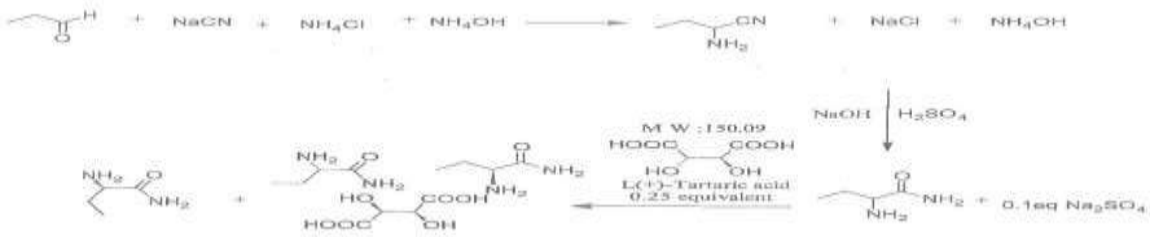
Pollution load

Stages	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	TDS (mg/L)	COD (mg/L)	Input solvent (kg)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Per batch														
1	0	111.93	1480	1532.25	12074	25176	2533.01	2431.69	75.990	18.5	211.45	0	0	38.58
2	0	126	0	32.24	0	803621	2610.94	2506.44	78.33	0	38.924	0	0	25.91
3	48.125	0	0	0	0	0	1642.58	1576.87	65.71	0	6.875	6	0	0
Per Day														
1	0	77.52	1025.0	1061.2	8362.11	17436.18	1754.29	1684.12	52.63	12.81	146.44	0	0	26.72
2	0	87.3	0	22.33	0	556564.9	1808.26	1735.9	54.25	0	26.96	0	0	17.94
3	33.33	0	0	0	0	0	1137.60	1092.10	45.51	0	4.76	6	0	0
Total	**33.33**	**164.78**	**1025.0**	**1083.5**	**8362.11**	**191333**	**4700.16**	**4512.10**	**152.39**	**12.81**	**178.16**	**6.00**	**0.00**	**44.66**

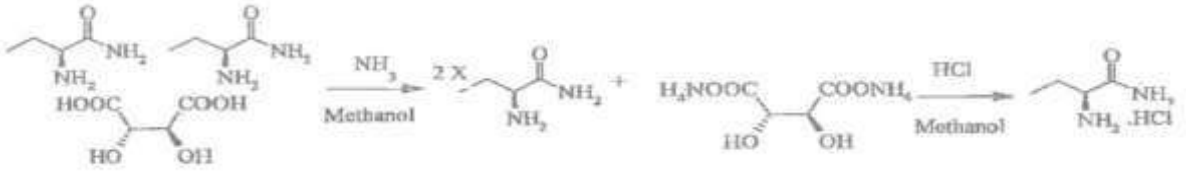
15. Sabam Hydrochloride

Manufacturing Process

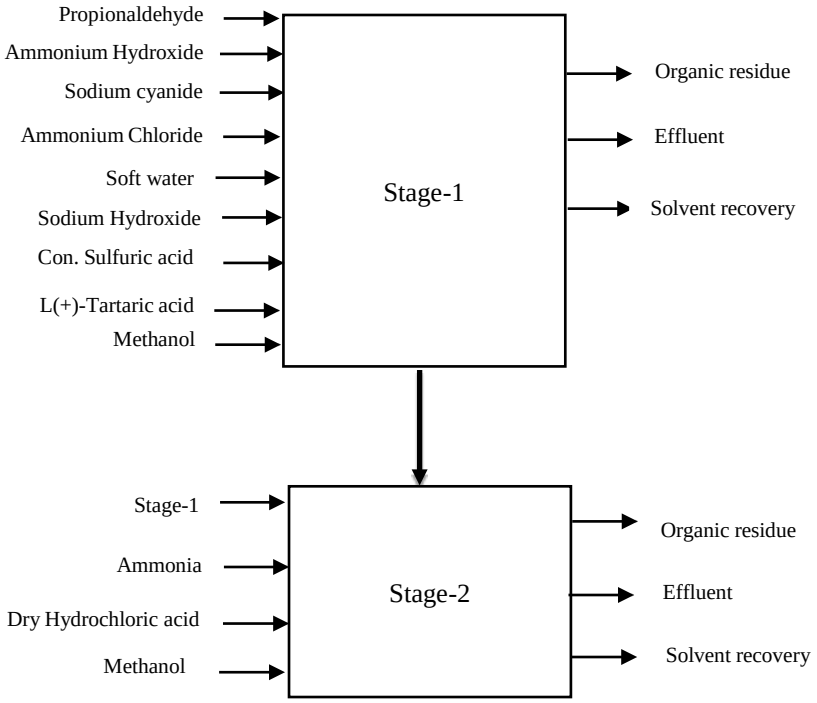
Stage-1: Propionaldehyde reacts with sodium cyanide in a solution of ammonium hydroxide and ammonium chloride to form an amino nitrile, which further hydrolyses using sodium hydroxide, gives the desired amide and then reacts with L (+)-Tartaric acid results in Stage-1.



Stage-2: Stage-1 reacts with ammonia in presence of methanol gives free base, then by passing dry HCl gas yields Stage-2



Process Flow Diagram



Material Balance

Stage 1:

Input	kg/batch	Output	kg/batch
Propionaldehyde	500	**Stage-1**	440
Sodium Cyanide	400	**Solvent recovery**	
Ammonium Chloride	507	Methanol	2495
Ammonium Hydroxide	1004	Methanol vapor loss	277
Soft water	1760	Water distillate	67.05
Sodium Hydroxide	149	Aqueous effluent water	1760
Methanol	2772	Propionaldehyde	283.654
Sulfuric acid	182.522	Sodium Cyanide	217.453
L (+)-Tartaric acid	207	Ammonium Chloride	307.75
		Ammonium Hydroxide	1004
		L (+)-Tartaric acid	20.644
		Sodium Chloride	217.686
		R – Ismev	126.822
		Sodium Sulphate	264.471
Total input	**7481.52**	**Total Output**	**7481.52**

Stage-2

Input	kg/batch	Output	kg/batch
Stage-1	580	Stage-2	290
Methanol	3234	**Solvent recovery**	
Ammonia	111.5	Methanol	2749
HCL gas	125.3	**Stage -1**	**209.243**
		Evaporation loss	258
		Ammonium tartrate salt	192.60
		Ammonia	75.927
		Hydrochloric acid	49.028
		Methanol Mls	227
Total Input	**4050.8**	**Total Output**	**4050.8**

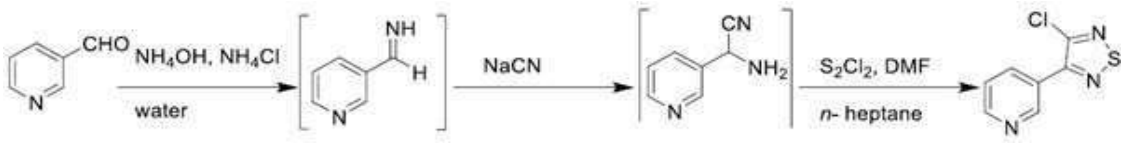
Pollution load

Stages	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	440	1760	3720.32	67.05	2495	277	245.12	956.32	46.25	0	0	0	0
2	290	0	0	0	2749	258	232.18	0	0	495.527	0	0	0
Pollution load Per Day													
1	0	1213.8	2565.7	46.24	1720.7	191.03	169.04	659.53	31.89	0	0	0	0
2	200	0	0	0	1895.9	177.93	160.1	0	0	341.74	0	0	0
Total	**200**	**1213.8**	**2565.7**	**46.24**	**3616.5**	**368.96**	**329.14**	**659.53**	**31.89**	**341.74**	**0**	**0**	**0**

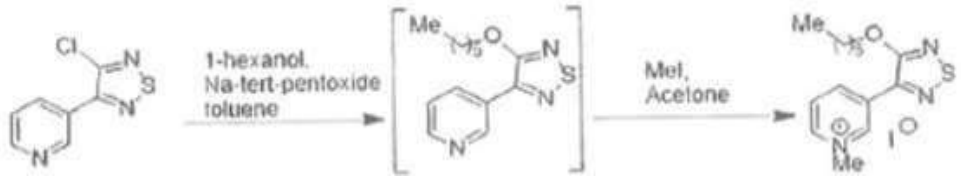
16. Xanomeline Tartrate

Manufacturing Process:

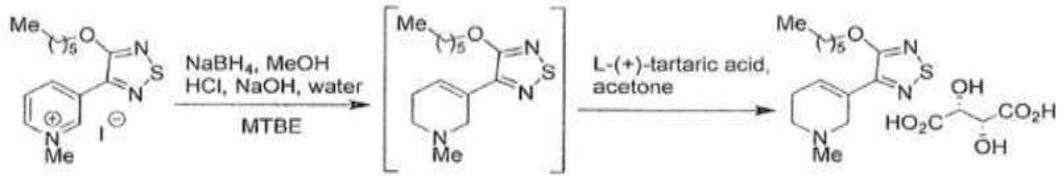
Stage-1: Nicotinaldehyde in presence of ammonium hydroxide and ammonium chloride in aqueous media results aldimine intermediate which is treated with Sodium cyanide to form cyanohydrin compound and it was further cyclized with Sulphur monochloride to form Stage-1.



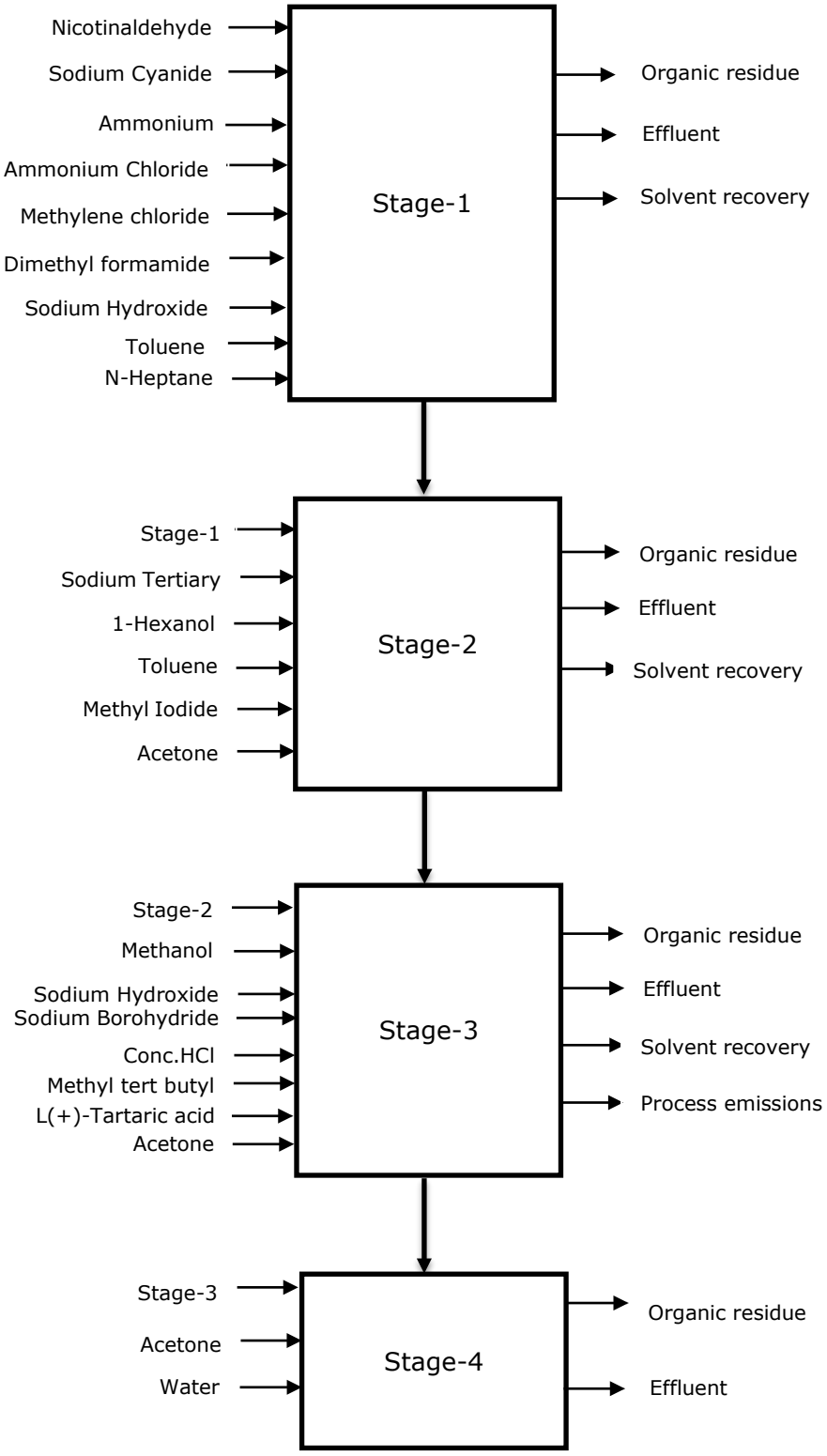
Stage-2: Stage-1 in presence of sodium tert-pentoxide and toluene reacts with 1-hexanol to form O-alkylated product. i.e., Intermediate, which further reacts with Methyl iodide to form quaternary ammonium salt.i.e., Stage-2.



Stage-3: Stage-2 in presence of methanol and reacts with sodium boro hydride to form free base, which further reacts with L (+) -Tartaric acid to form Stage-3.



Process Flow Diagram



Material balance

Stage-1			
Input	**kg/batch**	**Output**	**kg/batch**
Nicotinaldehyde	140	**Organic residue**	
Ammonium Hydroxide	172.2	Stage-1	155
Ammonium Chloride	105	**Solvent recovery**	
Sodium Cyanide	70	MDC	4240.65
Water	4314	MDC vapor loss	748.35
Methylene dichloride	4989.6	Toluene	1753.95
Sulfur Monochloride	353	Toluene vapor loss	194.88
Sodium Hydroxide	238	N-heptane	1212.73
Dimethyl formamide	608.26	N-heptane vapor loss	303.18
N-Heptane	1515.91	**Effluent**	
Toluene	1948.8	Aqueous layer	
		Nicotinaldehyde	56
		DMF	608.26
		Ammonium Hydroxide	144.72
		Ammonium Chloride	105
		Sodium Cyanide	31.56
		Sulphur monochloride	141.189
		Water	4371.235
		Sodium Hydroxide	175.26
		Sodium Chloride	137.518
		Sulphur	75.288
Total Input	**14454.7**	**Total Output**	**14454.7**

Stage-2			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-1	240	Stage-2	440
1-Hexanol	196.08	**Solvent recovery**	
Sodium Tert-pentoxide	192.48	Toluene	3932.72
Acetone	379.2	Toluene vapor loss	436.96
Methyl Iodide	210.24	Acetone	356.44
Toluene	4369.68	Acetone vapor loss	22.76
Soft water	1920	**Effluent**	
		Hexanol	85.157
		Sodium Tert-pentoxide	72.92
		n-pentanol	95.69
		Sodium hydroxide	43.238
		HCl	39.57
		Water	1900.628
		Methyl iodide	56.15
		Stage 1	25.443
Total Input	**7507.6**	**Total output**	**7507.6**

Stage-3			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-2	300	Stage-3	237
Sodium Hydroxide	55.6	**Solvent recovery**	

Sodium Borohydride	42.2	MTBE	1887
Con.HCl	141.6	MTBE vapor loss	333
Methanol	1090.2	Acetone	1706.4
L (+)-Tartaric acid	122.2	Acetone vapor loss	426.6
Water	3869	Water	3868.92
Acetone	2133	**Process Emission**	

Sodium Sulphate	75	Hydrogen gas	1.098
Sodium chloride	15	**Effluent**	
Methyl tert butyl ether	2220	Sodium Hydroxide	55.6
		Sodium Borohydride	0.65
		HCl	81.55
		Methanol	1090.2
		L (+)-Tartaric acid	39.83
		Borane	15.19
		Iodine monochloride	89.167
		Stage -2	77.39
		Sodium Chloride	79.205
		Sodium Sulphate	75
Total Input	**10063.8**	**Total Output**	**10063.8**

Stage-4			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-3	685	**Stage-4**	605.5
Acetone	6130	Acetone	6130
Water	205.5	Water	205.5
		Stage -3	79.5
Total Input	**7020.5**	**Total Output**	**7020.5**

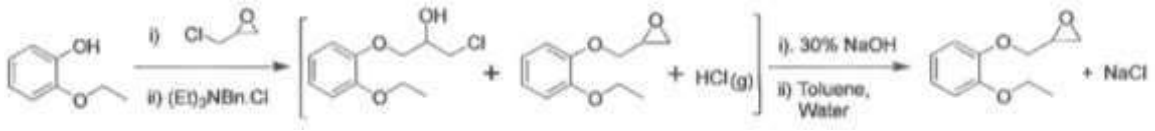
Pollution load

Stages	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	0	4314	5846.03	0	7207.33	1246.41	428	1474.8	701.52	818.41	0	0	0
2	0	1920	2318.8	0	4289.16	459.72	132.5	695.63	371	327.22	0	0	0
3	0	3869	1603.78	0	3593.4	759.6	251.8	400.945	240.56	507.8	0	1.098	0
4	605.5	205.5	285	0	6130	0	0	28.5	25.65	0	0	0	0
Pollution load Per Day													
1	0	949.93	1287.28	0	1587	274.45	94.24	324.74	154.47	180.21	0	0	0
2	0	422.78	510.59	0	944.46	101.22	29.17	153.17	81.69	72.05	0	0	0
3	0	851.94	353.14	0	791.26	167.26	55.37	88.28	52.97	111.81	0	0.24	0
4	133.33	45.25	62.75	0	1349.81	0	0	6.27	5.64	0	0	0	0
Total	**133.33**	**2269.9**	**2213.76**	**0**	**4672.53**	**542.93**	**178.78**	**572.46**	**294.77**	**364.07**	**0**	**0.24**	**0**

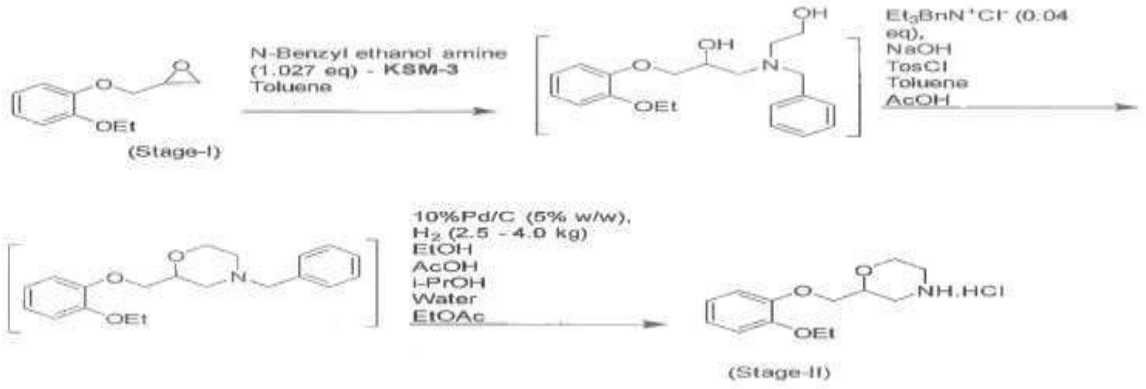
17. Viloxazine Hydrochloride

Manufacturing Process:

Stage-1: Stage-1 is formed by the reaction of 2-ethoxy phenol with epichlorohydrin. The initially formed intermediate then cyclized to give Stage-1.

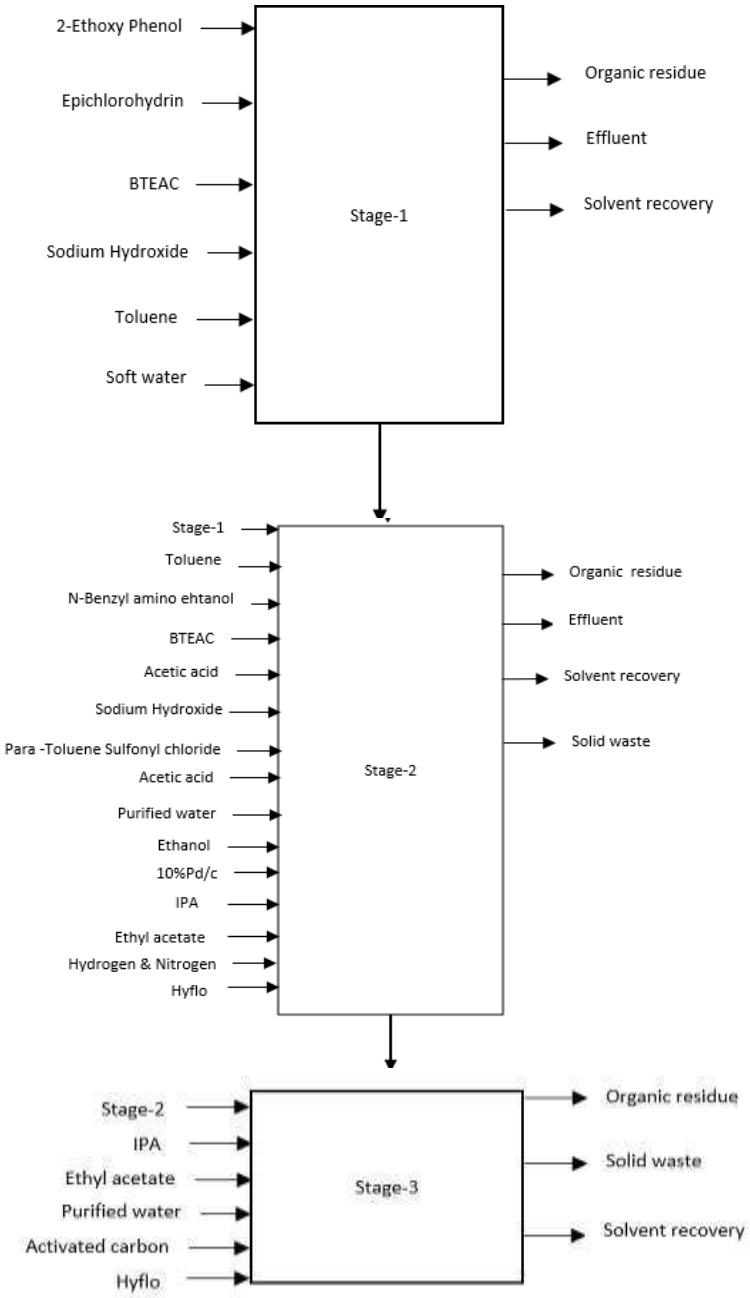


Stage-2: 2-Benzyl amino ethanol reacts with Stage-1 to form intermediate Viloxazine diol. The cyclization of Viloxazine diol to Viloxazine Benz involves the treatment of Viloxazine diol with p-toluene sulfonyl chloride in presence of Sodium Hydroxide and BTEAC . After cyclization, toluene layer will be concentrated in presence of 10%Pd/C catalyst. Further process involves pH adjustment and isolation in ethyl acetate gives Stage-2.



Stage-3: Stage-2 further purified with Isopropyl alcohol & water mixture gives Stage-3.

Process Flow Diagram



Material balance

Stage-1			
Input	**kg/batch**	**Output**	**kg/batch**
2-Ethoxy phenol	300	**Stage-1**	411.9
Racemic Epichlorohydrin	1206	Recovered Epichlorohydrin	908.82
BTEAC	49.8	Epichlorohydrin Vapor loss	100.985
Sodium Hydroxide	113.1	Water	1471.57
		BTEAC	49.8
		Sodium Hydroxide	28.277
		Sodium Chloride	123.926
		Stage -1	**7.02**
Toluene	879.3	Recovered Toluene	670.2
Water	1433.4	Toluene vapor loss	209.1
Total Input	**3981.6**	**Total Output**	**3981.6**

Stage-2			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-1	406	Stage-2	348
N-Benzyl ethanol amine	324.8	Tosyl Hydroxide	218.914
BTEAC	19.1	Toluene	117.1355
Sodium Hydroxide	410.1	Sodium chloride	429.75
		Sodium Acetate	237.8
Tosyl Chloride	420.6	Water	184.545
Toluene	2735	Recovered Toluene	2693.9
Acetic acid	5388.4	Distillate (Acetic acid +Toluene+ water+Ethanol)	7258
		Ethyl acetate recovery	2197
Ethanol	556.2	Ethyl acetate Vapor loss	732.7
		Isopropyl Alcohol recovery	1248
		Isopropyl Alcohol Vapor loss	220.1
10% Pd on Carbon	20.3	Inorganic waste	20.3
Hydrochloric acid	268	Aqueous layer (BTEAC)	19.1
		Aqueous Effluent water	3624.6
Isopropyl alcohol	1468.1	Stage -1	159.067
Ethyl acetate	2929.7	N-Benzyle etanoladehyde	132.57
Water	5070.9	Tosyl Chloride	178.36
Hydrogen	2.6		
Total Input	**20019.8**	**Total output**	**20019.8**

Stage-3			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-2	700	Stage-3	621
Isopropyl alcohol	2145.5	**Solvent recovery**	
Ethyl acetate	4294.5	(IPA+EA recovery)	5474
		Evaporation loss	966
Charcoal	35	Spent carbon + high flow	70
Hyflo	35	Stage-2 Residue	79
Total Input	**7210**	**Total Output**	**7210**

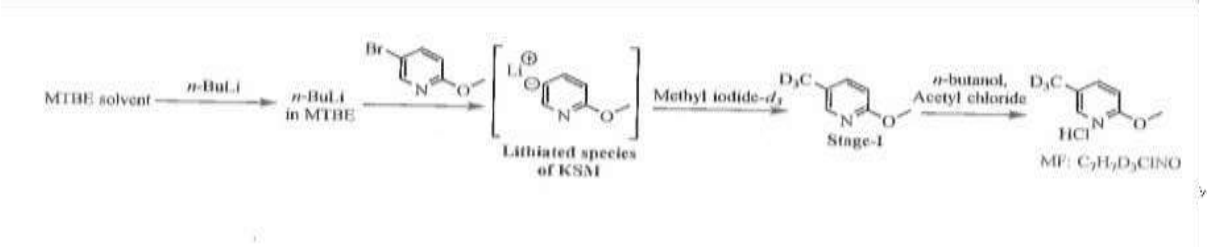
Pollution load

Stages	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	0	1433.4	1680.59	600	1579.02	209.1	200	201.67	80.86	20.5	0	0	0.00
2	0	5070.9	4965.792	600	12266	952.8	870	571.06	21.4	30	0	0	39.40
3	621	0	0	0	5474	966	940	0	0	79	70	0	0.00
Pollution load Per Day													
1	0	307.75	360.83	128.82	339.02	44.89	42.94	43.30	17.36	4.40	0	0	0.00
2	0	1088.73	1066.17	128.82	2633.54	204.57	186.79	122.61	4.59	6.44	0	0	8.46
3	133.33	0	0	0	1175.28	207.40	101.82	0	0	16.96	15.03	0	0.00
Total	**133.33**	**1396.49**	**1426.99**	**257.64**	**4147.83**	**456.86**	**331.55**	**165.91**	**21.95**	**27.80**	**15.03**	**0**	**8.46**

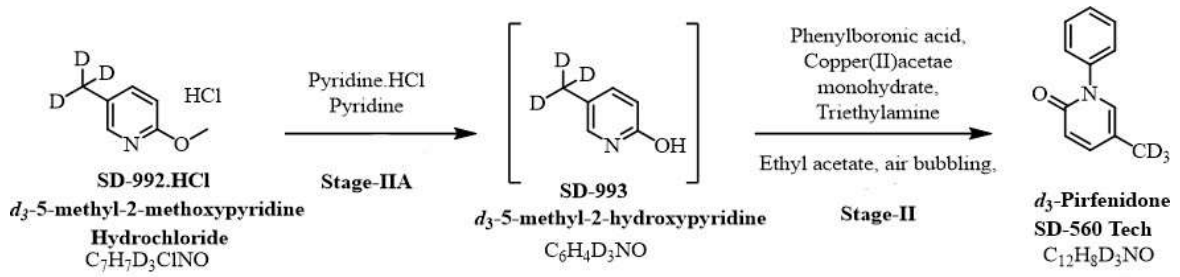
18. LYT 100

Manufacturing Process:

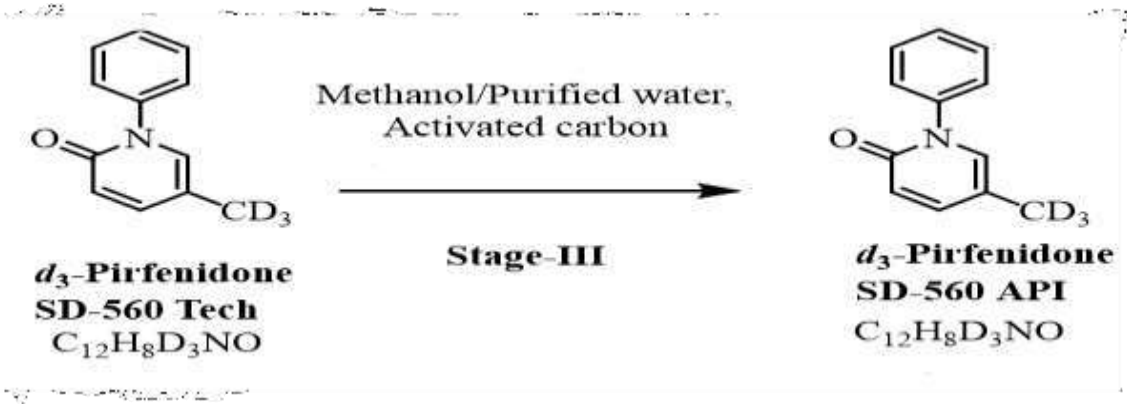
Stage-1: n- BuLi is added to 5-Bromo 2-methoxypyridine and n-hexane to form lithiated species in MTBE medium. Water present in MTBE will be scavenged by n-BuLi to decrease formation of 2-methoxypyridine impurity and then reacted with n-butanol and acetyl chloride to form Stage-1.



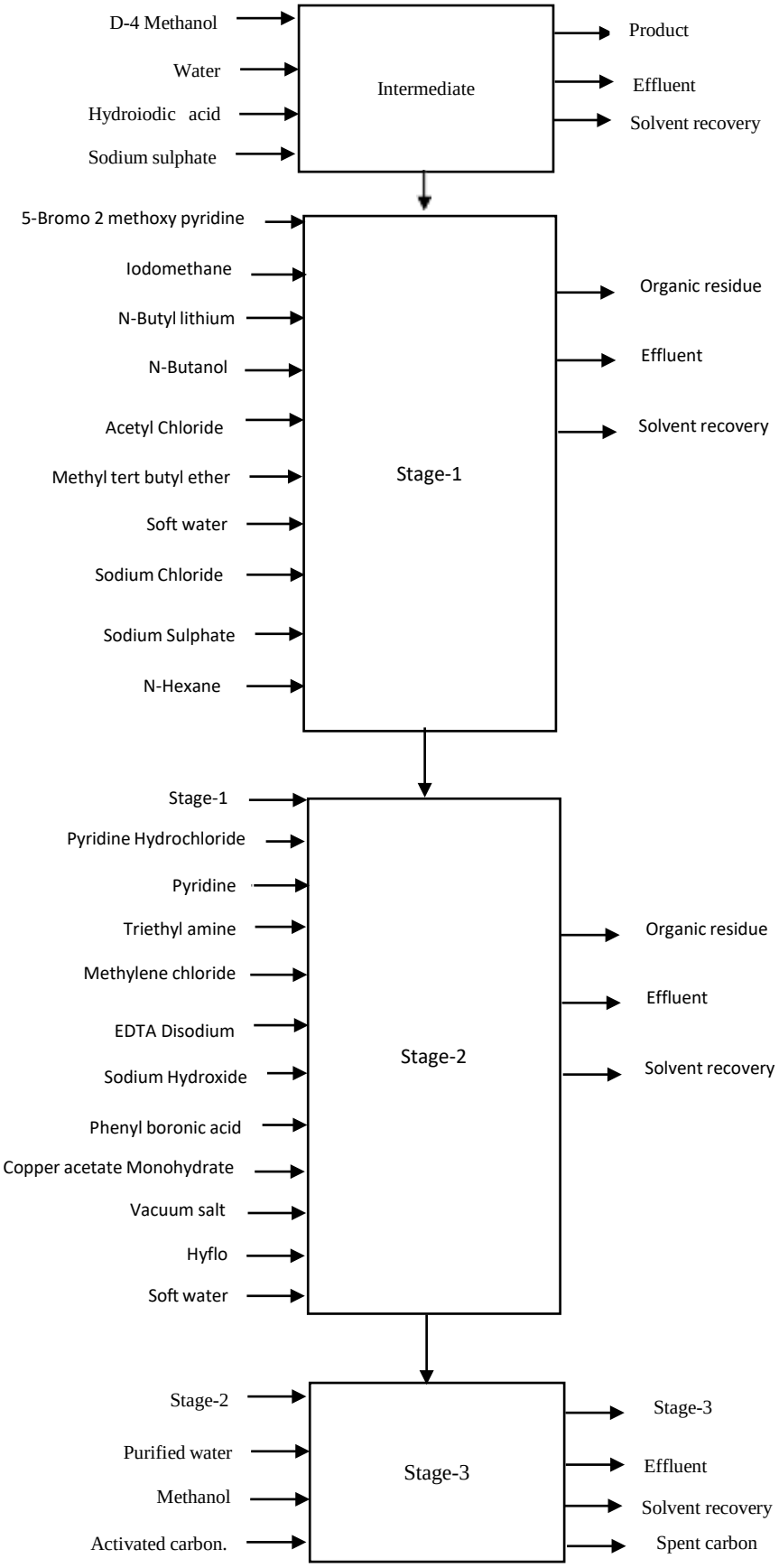
Stage-2: Stage-1 is reacted with Pyridine hydrochloride in pyridine medium to form d3-5-methyl-2-methoxypyridineand further reacted with Phenylboronic acid, Copper (II) acetate monohydrate and triethylamine under air bubbling in Ethyl acetate medium to form d3-pirfenidone(stage-2).Workouts are done with EDTA solution to remove the copper(II) acetate content and with NaOH solution to remove phenylboronic acid content.



Stage-3: Stage-2 further purified with Purified water and methanol results in Stage-3.



Process Flow Diagram



Material balance

Intermediate:

Input	kg/batch	Output	kg/batch
D-4 Methanol	65	Product	196
Water	65	**Effluent**	
Hydroiodic acid	628.55	**D-4 Methanol**	16.22
Water	195	**Hydrochloric acid**	455.53
Sodium sulfite	19.5	**Sodium sulphate**	19.5
		Water	260
		D-water	25.8
Total Input	**973.05**	**Total output**	**973.05**

Stage-1

Input	kg/batch	Output	kg/batch
5-Bromo 2-methoxy pyridine	150.16	Stage-1 HCL	129.74
D3-MI	115.72	Lithium Iodide	106.98
N-butyl Lithium	51.16	1-Bromo butane	109.43
N-butanol	59.1	N-butyl Acetate	92.64
Acetyl Chloride	63	MTBE	767
		Solvent recovery	
		Evaporation loss	134.875
		n-Hexane recovery	60
		Evaporation loss	39
MTBE	901.875	**Effluent**	
Soft water	1200	Sodium Chloride	105
		Sodium sulphate	30
		Water	1200
Sodium Chloride	105	Excess D3-MI	34.28
Sodium sulphate	30	Excess N-butyl Lithium	196.34
N-Hexane	99	Excess Acetyl Chloride	0.35
Total Input	**3005.635**	**Total output**	**3005.635**

Stage 2

Input Details	Qty in Kg	Output Details	Qty in Kg
Stage-1	**120**	Stage-2	94
Pyridine hydrochloride	**128**	**Solvent recovery**	
Pyridine	**235.7**	MDC recovery	2788
Triethyl amine	306.0		
Methylene dichloride	3484.8	Vapor Loss	**696.8**
EDTA Sodium	144.0		
Sodium Hydroxide	240.0	**Effluent**	
Phenyl boronic acid	**116.9**	**Stage-2**	**38.775**
Copper acetate monohydrate	99.82	**Pyridine hydrochloride**	**70.27**
Vacuum salt	180.0	Pyridine	**196.2**
Hyflo	12	Triethyl amine	**306**
Soft water	6720	EDTA Sodium	**144**

		Sodium Hydroxide	**240**
		Phenyl boronic acid	**55.935**
		Vacuum salt	**180**
		Boric acid	**30.91**
		Hyflo	**12**
		Pyridine hydrochloride	**57.73**
		Copper	**31.825**
		Acetic acid	**60**
		Pyridine	**64.725**
		Water	**6720**
Total Input	**11787.22**	**Total output**	**11787.22**

Stage 3

Input Details	**Qty in Kg**	**Output Details**	**Qty in Kg**
Stage-2	150	Stage-3	120
Methanol	237.6	Methanol	202
Soft water	1350	**Effluent**	
		Water	1350
		Stage -2	30
		Methanol	35.6
Activated carbon	15	Spent carbon	15
Total Input	**1752.6**	**Total output**	**1752.6**

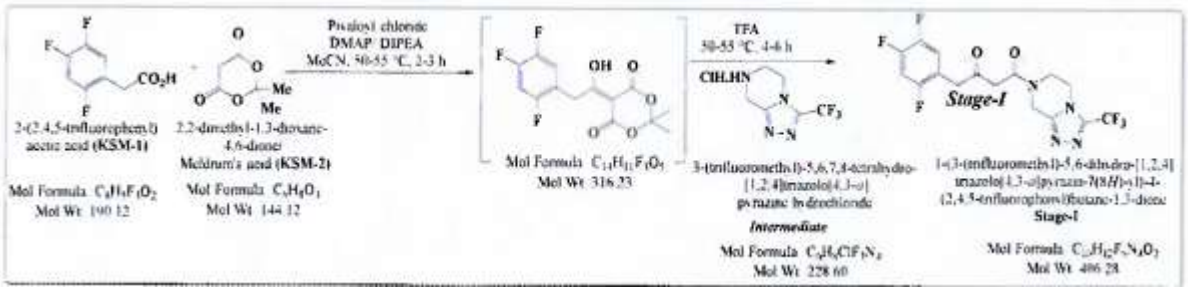
Pollution load

Stages	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
Int	0	260	777.05	0	0	0	0	19.5	116.56	0	0	0	0
1	0	1200	1565.97	0	767	173.875	150.81	135.00	187.92	540.02	0	0	0.00
2	0	6720	8208.37	0	2788	696.8	343	109.05	820.84	1171.125	12	0	0.00
3	120	1350	1415.6	0	202	0	0	0	212.34	0	15	0	0.00
Pollution load Per Day													
Int	0	21.67	64.75	0	0	0	0	1.625	9.71	0	0	0	0
1	0	100.00	130.50	0.00	63.92	14.49	12.57	11.25	15.66	45.00	0	0	0.00
2	0	560.00	684.03	0.00	232.33	58.07	28.58	9.09	68.40	97.59	0	0	0.00
3	10	112.5	117.97	0	16.83	0.00	0.00	0	17.70	0.00	1.25	0	0.00
Total	**10**	**794.17**	**997.25**	**0.00**	**313.08**	**72.56**	**41.15**	**21.96**	**111.47**	**142.60**	**1.25**	**0**	**0.00**

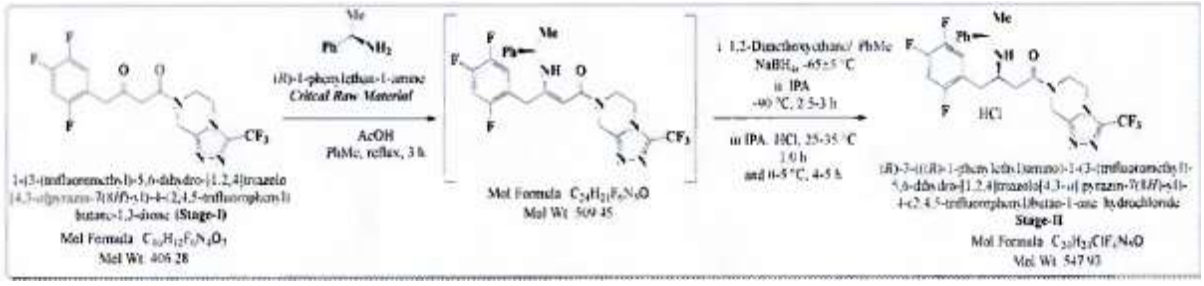
Sitagliptin Phosphate Monohydrate

Manufacturing Process:

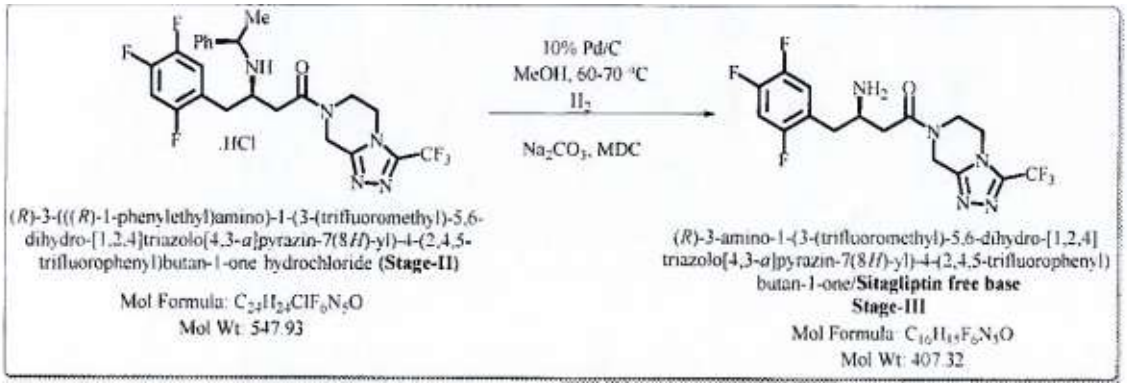
Stage-1: Sitagliptin phosphate monohydrate starts from the coupling reaction between Triflurophenyl acetic acid and Meldrum's acid via an acid-chloride intermediate using pivaloyl chloride in the presence of diisopropylethylamine and dimethyl aminopyridine which is treated with purified water and 5% sodium bicarbonate solution to form Stage-1.



Stage-2: The obtained stage-1 up on condensation in presence of R-(+)-1-phenylethylamine and acetic acid to form amine followed by reduction in presence of 1,2-dimethoxyethane and sodium borohydride reacts with methane sulfonic acid, and which further reacts with IPA.HCl to form salt formation leads to Stage-2 intermediate.



Stage-3: Stage-3 is a N-debenzylation reaction of stage-2 with 10% Pd/C in presence of methanol under hydrogen pressure, further which is treated with purified water and 5% sodium bicarbonate solution followed by dichloromethane to form Stage-3 free base.

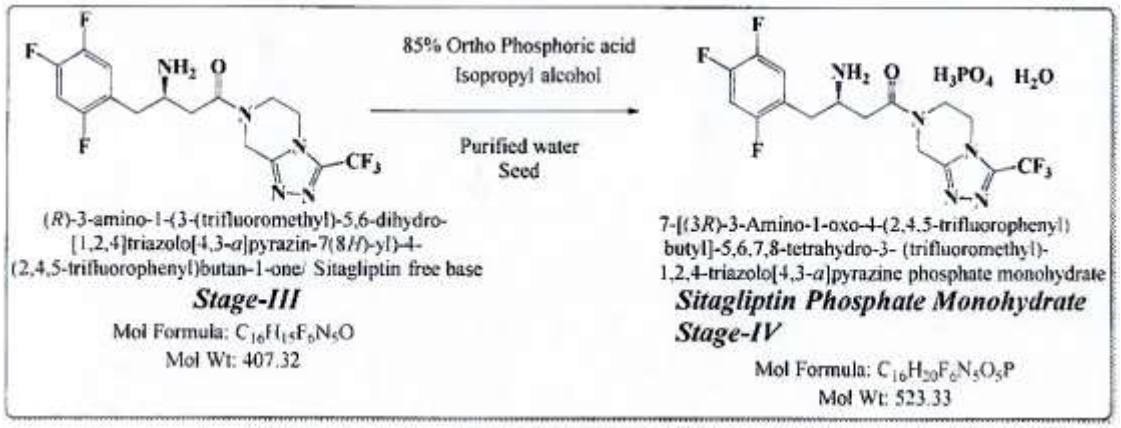


(*R*)-3-(((*R*)-1-phenylethyl)amino)-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl)-4-(2,4,5-trifluorophenyl)butan-1-one hydrochloride **(Stage-II)**

Mol Formula: $C_{24}H_{24}ClF_6N_5O$
Mol Wt: 547.93

(*R*)-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/**Sitagliptin free base**
Stage-III
Mol Formula: $C_{16}H_{15}F_6N_5O$
Mol Wt: 407.32

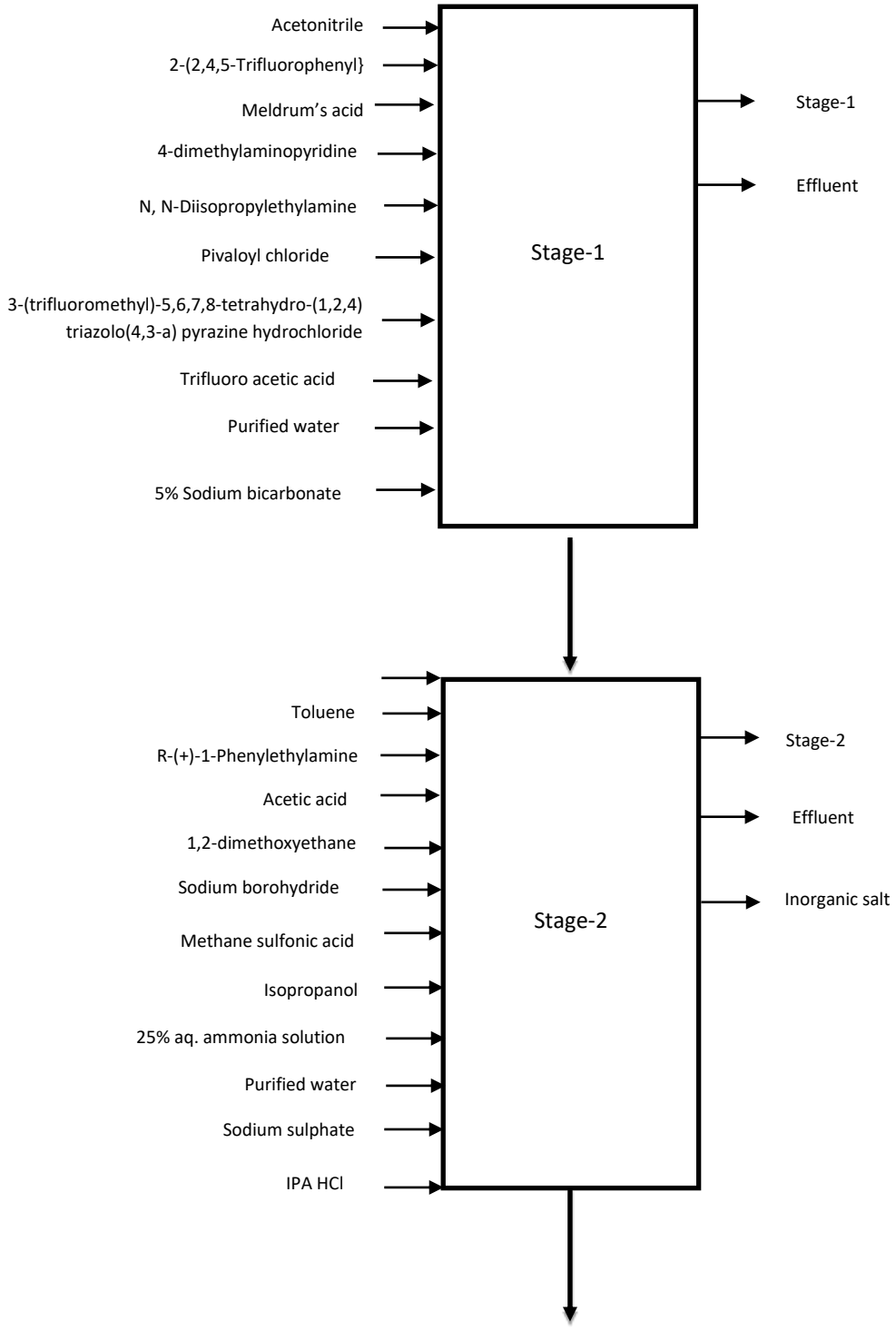
Stage-4: Stage-3 in presence of Purified water and isopropyl alcohol reacts with 85% ortho phosphoric acid to form Stage-4.

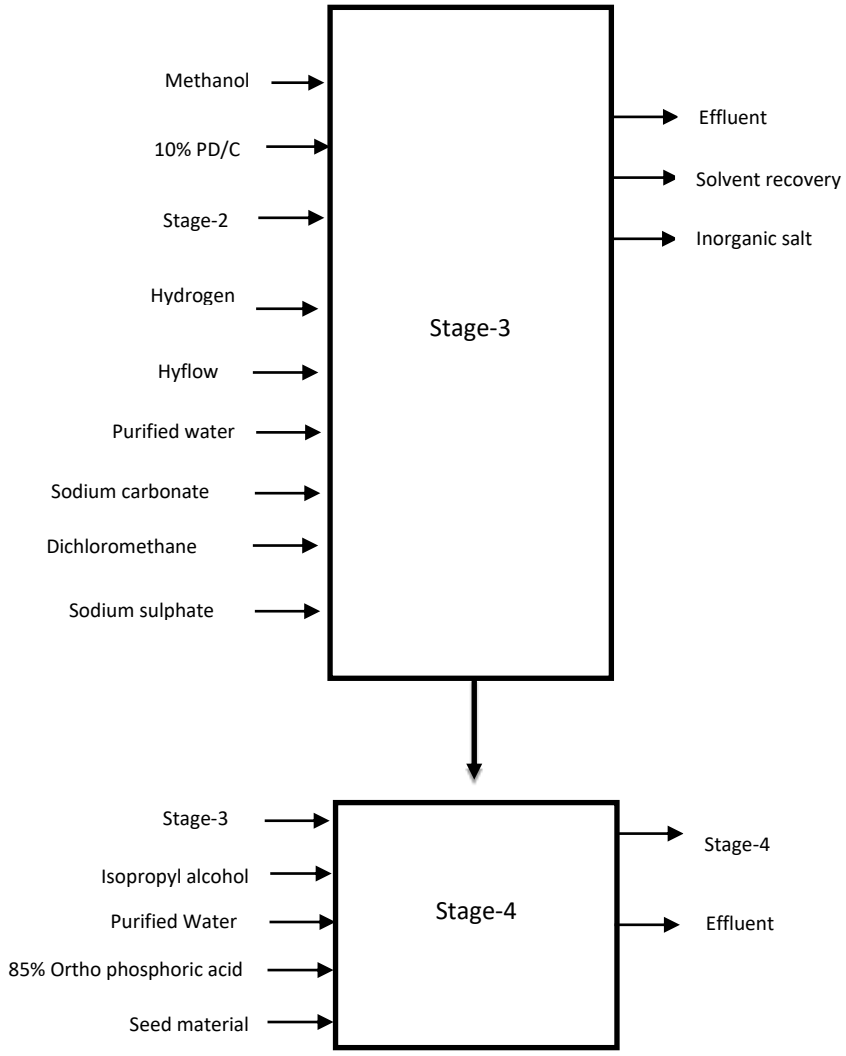


(*R*)-3-amino-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3-*a*]pyrazin-7(8*H*)-yl)-4-(2,4,5-trifluorophenyl)butan-1-one/ Sitagliptin free base
Stage-III
Mol Formula: $C_{16}H_{15}F_6N_5O$
Mol Wt: 407.32

7-[(3*R*)-3-Amino-1-oxo-4-(2,4,5-trifluorophenyl) butyl]-5,6,7,8-tetrahydro-3- (trifluoromethyl)-1,2,4-triazolo[4,3-*a*]pyrazine phosphate monohydrate
Sitagliptin Phosphate Monohydrate
Stage-IV
Mol Formula: $C_{16}H_{20}F_6N_5O_5P$
Mol Wt: 523.33

Process Flow Diagram





Material balance

Stage-1			
Input	**kg/batch**	**Output**	**kg/batch**
2-(2,4,5-Trifluorophenyl) acetic acid	148.53	Stage-1	258.44
Acetonitrile	408.60	**Effluent**	
Meldrum's acid	123.87	Aqueous Liquor	
4-dimethylaminopyridine	7.63	Water	2079.42
N, N-Diisopropylethylamine	200.99	2-(2,4,5-Trifluorophenyl) acetic acid	27.5922
Pivaloyl chloride	102.72	Acetonitrile	408.60
3-(trifluoromethyl)-5,6,7,8-tetrahydro -(1,2,4) triazolo(4,3-a) pyrazine hydrochloride	178.53	Meldrum's acid	32.1871
Trifluoro acetic acid	26.99	4-dimethylaminopyridine	7.63
Purified water	2079.42	N, N-Diisopropylethylamine	200.99
Sodium bicarbonate	44.5	Pivaloyl chloride	26.0175
		Carbondioxide	27.9889
		Acetone	36.8945
		Pivalic Acid	64.9662

		Hydrochloric Acid	46.4362
		3-(trifluoromethyl)-5,6,7,8-tetrahydro -(1,2,4) triazolo(4,3-a) pyrazine hydrochloride	33.1146
		Trifluoro acetic acid	26.99
		Sodium bicarbonate	44.5
Total Input	**3321.78**	**Total Output**	**3321.76**

Stage-2			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-1	147.68	Stage-2	145.91
Toluene	1342.85	**Solvent Recovery**	
R-(+)-1-phenylethylamine	48.43	Toluene	1275.70
Acetic acid	23.98	Toluene Loss	67.15
1,2 dimethoxymethane	897.30	Aqueous Layer	
Sodium borohydride	34.36	Water	1329.12
Methane sulfonic acid	194.30	Stage -2	39.4905
Isopropanol	202.02	R-(+)-1-phenylethylamine	16.1607
Purified water	1329.12	**Acetic Acid**	23.98
25% aq. ammonia solution	129.95	1,2 dimethoxymethane	897.30
IPA HCl	58.03	Sodium borohydride	24.2862
Sodium sulphate	29.53	Methane sulfonic acid	194.30
		Isopropanol	202.02
		ammonia solution	129.95
		IPA HCl	48.3237
		Sodium sulphate	29.53
		Borane	3.6828
		Sodium hydroxide	10.6517
Total Input	**4437.55**	**Total output**	**4437.55**
Stage-3			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-2	255.34	Stage-3	177.46
Methanol	1413.8	**Solvent recovery**	
10% PD/C	12.77	Methanol	1300
Hyflow	51.06	Methanol vapor loss	113.8
Purified water	817	Dichloromethane	2700
Sodium carbonate	61.2	Dichloromethane vapor loss	333.4
Dichloromethane	3033.4	**Effluent Aqueous Layer**	
Anhydrous Sodium Sulphate	25.5	Water	817
Hydrogen	0.8713	Sodium sulphate	25.5
		Spent PD/C	12.77
		Hyflow	51.06
		Stage-2	16.6195
		Sodium Carbonate	38.1092
		Ethyl Benzene	46.2514
		Sodium Chloride	25.4609

		Carbondioxide	9.5871
		Water	3.9211
Total Input	**5670.9413**	**Total Output**	**5670.9392**

Stage-4			
Input	**kg/batch**	**Output**	**kg/batch**
Stage-3	177.46	**Stage-4**	200
Isopropyl alcohol	1354	Aqueous Layer	
Purified Water	299.91	Water	293.031
85% Ortho phosphoric acid	57.87	Isopropyl alcohol	1354
Pharma Seed material	1.77	Ortho phosphoric acid	20.4176
		Stage -3	23.5614
Total Input	**1891.01**	**Total Output**	**1891.01**

Pollution load

Stages	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	TDS (mg/L)	COD (mg/L)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Per Batch														
1	0	258.44	2079.42	3035.34	0	201483	115483	0	0	0	0	0	27.99	0
2	0	145.91	1329.12	2827.22	0	189768	98432	0	67.15	64.47	0	3.68	0	0
3	0	177.46	817	0	101.23	4102	12798	4000	447.2	89.07	16.62	12.77	9.59	0
4	200	0	293.03	0	0	0	0	1354	0	20.42	23.56	0	0	0
Per day														
1	0	43.06	346.53	505.83	0	201483	115483	0	0	0	0	0	4.66	0
2	0	24.31	221.49	471.15	0	189768	98432	0	11.19	10.74	0	0.6	0	0
3	0	29.52	136.15	0	16.86	4102	12798	666.6	74.52	14.84	2.76	2.12	1.59	0
4	33.33	0	48.83	0	0	0	0	225.64	0	3.4	3.92	0	0	0
Total	**33.33**	**96.89**	**753**	**976.98**	**16.86**	**98838.25**	**56678.25**	**892.24**	**85.71**	**28.98**	**6.68**	**2.72**	**6.25**	**0**

Stage wise pollution load for the proposed change of product mix

1. Ciprofloxacin Hydrochloride

No. of stages proposed	Product (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissions (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	382.5	6289	6786	0	6038	36.98	33.31	326.8	151.58	74.7	80	0	50
Pollution Load per Day													
Total	**1300**	**21374**	**23063**	**0**	**20522**	**124.7**	**113.2**	**1111**	**515.17**	**253.9**	**271.9**	**0**	**169.9**

2. Dorzolamide Hydrochloride

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	4200	4571	0	800	18	142	235	142	0	20	0	0
2	0	5000	0	5075	750	45	15	0	45.12	5	0	0	0
3	0	0	0	0	950	35	0	0	0	17	0	0	0
4	0	2400	2470	0	0	0	0	57	0	3	0	0	0
5	0	3200	0	3225	2350	50	0	15.25	0	6	0	0	0
6	0	1000	1056	0	0	0	0	30	0	109	0	0	0
7	0	0	0	0	2320	109	0	0	0	6	32	1	0
8	100	2600	0	2600	0	0	0	0	0	10	35	0	0
Pollution Load per Day													
1	0	700.14	761.99	0	133.36	3	23.67	39.17	23.67	0	3.33	0	0
2	0	833.5	0	846	125.03	7.5	2.5	0	7.52	0.83	0	0	0
3	0	0	0	0	158.37	5.83	0	0	0	2.83	0	0	0
4	0	400.08	411.75	0	0	0	0	9.5	0	0.5	0	0	0
5	0	533.44	0	537.61	391.75	8.34	0	2.54	0	1	0	0	0
6	0	166.7	176.04	0	0	0	0	5	0	18.17	0	0	0
7	0	0	0	0	386.74	18.17	0	0	0	1	5.33	0.17	0
8	16.67	433.42	0	433.42	0	0	0	0	0	1.67	5.83	0	0
Total	**16.67**	**3067.28**	**1349.77**	**1817.03**	**1195.24**	**42.84**	**26.17**	**56.22**	**31.19**	**26.01**	**14.5**	**0.17**	**0**

3. Enalapril Maleate

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	500	640	0	297	16	26	93	81.12	0	18	21	0
2	0	550	649.8	0	600	22	0	91.4	0	8.2	0	0	0
3	100	2100	2266.3	0	610	60	20	108.6	91.01	18.7	0	0	0
Pollution Load per Day													
1	0	333.35	426.69	0	198.01	10.67	17.33	62	54.08	0	12	14	0
2	0	366.69	433.22	0	400.02	14.67	0	60.94	0	5.47	0	0	0
3	66.67	1400.07	1510.94	0	406.69	40	13.33	72.4	60.68	12.47	0	0	0
Total	**66.67**	**2100.11**	**2370.85**	**0**	**1004.72**	**65.34**	**30.67**	**195.34**	**114.76**	**17.93**	**12**	**14**	**0**

4. Entacapone

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	2000	2203.8	0	900	10	55.6	115	117.65	82.2	80	0	0
2	100	0	0	0	595	5	0	0	0	30	50	0	0
Pollution Load per Day													
1	0	6666.6	7345.93	0	2999.97	33.33	185.33	383.33	392.16	274	266.66	0	0
2	333.33	0	0	0	1983.31	16.67	0	0	0	100	166.67	0	0
Total	**333.33**	**6666.6**	**7345.93**	**0**	**4983.28**	**50**	**185.33**	**383.33**	**392.16**	**374**	**433.33**	**0**	**0**

5. Escitalopram Oxalate

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	4000	4112.5	0	1430	110	60	46.5	144	58	0	0	20
2	0	4000	0	4147	2840	40	120	21	265.2	77	0	0	20
3	100	2500	2723	0	990	17	43	40	148.74	67.6	25	0	20
Pollution Load per Day													
1	0	1333.2	1370.7	0	476.62	36.66	20	15.5	48	19.33	0	0	6.67
2	0	1333.2	0	1382.2	946.57	13.33	40	7	88.39	25.66	0	0	6.67
3	33.33	833.25	907.58	0	329.97	5.67	14.33	13.33	49.57	22.53	8.33	0	6.67
Total	**33.33**	**3499.65**	**2278.27**	**1382.2**	**1753.16**	**55.66**	**74.33**	**35.83**	**185.96**	**67.53**	**8.33**	**0**	**20**

6. Ipratropium Bromide Monohydrate

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	4500	4589		2300	65	45	50	67.5	21	0	0	0
2	0	0	0	0	3168	172	0	0	0	26	0	0	0
3	100	5500	0	5581.8	750	10	90	0	216	18.2	30	0	0
Pollution Load per Day													
1	0	750.15	764.99	0	383.41	10.84	7.5	8.34	11.25	3.5	0	0	0
2	0	0	0	0	528.11	28.67	0	0	0	4.33	0	0	0
3	16.67	916.85	0	930.49	125.03	1.67	15	0	36.01	3.03	5	0	0
Total	**16.67**	**1667**	**764.99**	**930.49**	**1036.54**	**41.17**	**22.5**	**8.34**	**47.26**	**10.87**	**5**	**0**	**0**

7. Itraconazole

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	3200	3375.5	0	200	30	50	122.8	82.56	25	0	0	0
2	100	0	0	0	1900	22	0	0	0	10	30	0	0
Pollution Load per Day													
1	0	10666.56	11251.55	0	666.66	100	166.67	409.33	275.2	83.33	0	0	0
2	333.33	0	0	0	6333.27	73.33	0	0	0	33.33	100	0	0
Total	**333.33**	**10666.56**	**11251.55**	**0**	**6999.93**	**173.33**	**166.67**	**409.33**	**275.2**	**116.67**	**100**	**0**	**0**

8. Labetalol Hydrochloride

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	305	463.81	0	1077.5	6	12.5	107.85	18.75	0	20	5.24	0
2	0	0	0	0	867	15	0	0	0	0	0	0	0
3	80.55	0	0	0	445	5	0	0	0	0	23.5	0	0
Pollution Load per Day													
1	0	631.09	959.69	0	2229.51	12.41	25.86	223.16	38.8	0	41.38	10.84	0
2	0	0	0	0	1793.95	31.04	0	0	0	0	0	0	0
3	166.67	0	0	0	920.77	10.35	0	0	0	0	48.63	0	0
Total	**166.67**	**631.09**	**959.69**	**0**	**4944.23**	**53.8**	**25.86**	**223.16**	**38.8**	**0**	**90.01**	**47.94**	**0**

9. Levetiracetam

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	150	369.4	0	236	8	7	78	10.5	0	0	0	0
2	0	450	667.1	0	172	4	17	186	9.52	73.7	0	34.1	0
3	0	750	809.3	0	346	4	0	47.3	0	28.2	30	0	66
4	100	350	0	350	436	4	0	0	0	8	0	0	0
Pollution Load per Day													
1	0	1500	3694	0	2360	80	70	780	105	0	0	0	0
2	0	4500	6671	0	1720	40	170	1860	95.2	737	0	341	0
3	0	7500	8093	0	3460	40	0	473	0	282	300	0	660
4	1000	3500	0	3500	4360	40	0	0	0	80	0	0	0
Total	**1000**	**17000**	**18458**	**3500**	**11900**	**200**	**240**	**3113**	**200.2**	**1099**	**300**	**341**	**660**

10. Levofloxacin Hemihydrate

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	700	0	732	991	4	32	0	48	95	0	0	0
2	100	3600	3813	0	4240	10	20	146	21.4	17	33	0	0
Pollution Load per Day													
1	0	1166.69	0	1220.02	1651.7	6.67	53.33	0	80	158.34	0	0	0
2	166.67	6000.12	6355.13	0	7066.81	16.67	33.33	243.34	35.67	28.33	55	0	0
Total	**166.67**	**7166.81**	**6355.13**	**1220.02**	**8718.51**	**23.33**	**86.67**	**243.34**	**115.67**	**186.67**	**55**	**0**	**0**

11. Miratazapine

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	200	497.77	0	753	20	12	70	24.96	10	0	0	281.73
2	0	3000	3125	0	1133.8	11	0	78.3	49.3	37.2	18	0	85
3	0	1000	1220	0	410	8	22	30	45.5	7	0	0	89.6
4	100	0	0	0	470	10	0	0	0	20	25	0	0
Pollution Load per Day													
1	0	333.34	829.63	0	1255.03	33.33	20	116.67	41.6	16.67	0	0	469.56
2	0	5000.1	5208.44	0	1889.7	18.33	0	130.5	82.17	62	30	0	141.67
3	0	1666.7	2033.37	0	683.35	13.33	36.67	50	75.83	11.67	0	0	149.34
4	166.67	0	0	0	783.35	16.67	0	0	0	33.33	41.67	0	0
Total	**166.67**	**7000.14**	**8071.44**	**0**	**4611.43**	**81.67**	**56.67**	**297.17**	**199.6**	**123.67**	**71.67**	**0**	**760.57**

12. Sotalol Hydrochloride

No. of stages proposed	Prod-uct (kg)	Water (LPD)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evapora-tion loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD Load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissi-ons (kg)	Inorganic residue (kg)
Pollution Load per Batch													
1	0	1200	1355	0	180	20	0	138.1	20.49	6.4	0	20.6	0
2	0	150	329.3	0	367	23	10	89	22.1	16.7	0	0	0
3	0	0	0	0	746	53	0	0	0	14	0	9	0
4	100	0	0	0	1550	50	0	0	0	22.6	28	0	0
Pollution Load per Day													
1	0	2000.04	2258.38	0	300.01	33.33	0	230.17	34.14	10.67	0	34.33	0
2	0	250.01	548.84	0	611.68	38.33	16.67	148.34	36.83	27.83	0	0	0
3	0	0	0	0	1243.36	88.34	0	0	0	23.33	0	15	0
4	166.67	0	0	0	2583.39	83.34	0	0	0	37.67	46.67	0	0
Total	**166.67**	**2250.05**	**2807.22**	**0**	**4738.43**	**243.34**	**16.67**	**378.51**	**70.98**	**99.5**	**46.67**	**49.33**	**0**

13. Bempodoic acid

No. of Stages Proposed	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	COD (mg/L)	Input solvent (kg)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Pollution Load per Batch														
1	0	79.05	120	178.17	0	0	393.9	382.08	11.82	0	21.18	0	0	0
2	0	50.6	600	684.89	0	2903	608.7	589.94	18.76	0	10.39	0	0	1.99
3	20	0	70	90.41	0	62097	30.32	29.32	1	7.46	0	0	0	5.61
Pollution Load per Day														
1	0	1317.48	1999.98	2969.47	0	0	6564.93	6367.93	196.99	0	352.99	0	0	0
2	0	843.32	9999.9	11414.71	0	48382.84	10144.89	9832.23	312.66	0	173.15	0	0	33.16
3	333.33	0	1166.6	1506.81	0	1034939.7	505.32	488.66	16.66	124.33	0	0	0	93.49
Total	**333.33**	**2160.8**	**13166.48**	**15890.99**	**0**	**361107.49**	**17215.14**	**16688.82**	**526.31**	**124.33**	**526.14**	**0**	**0**	**126.65**

14. Diferasirox

No. of Stages Proposed	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	TDS (mg/L)	COD (mg/L)	Input solvent (kg)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Pollution load Per batch														
1	0	111.93	1480	1532.25	12074	25176	2533.01	2431.69	75.99	18.5	211.45	0	0	38.58
2	0	126	0	32.24	0	803621	2610.94	2506.44	78.33	0	38.924	0	0	25.91
3	48.125	0	0	0	0	0	1642.58	1576.87	65.71	0	6.875	6	0	0
Pollution load Per Day														
1	0	77.52	1025	1061.2	8362.11	17436.18	1754.29	1684.12	52.63	12.81	146.44	0	0	26.72
2	0	87.3	0	22.33	0	556564.9	1808.26	1735.9	54.25	0	26.96	0	0	17.94
3	33.33	0	0	0	0	0	1137.6	1092.1	45.51	0	4.76	6	0	0
Total	**33.33**	**164.78**	**1025**	**1083.5**	**8362.11**	**191333**	**4700.16**	**4512.1**	**152.39**	**12.81**	**178.16**	**6**	**0**	**44.66**

15. Sabam Hydrochloride

No. of Stages Proposed	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	440	1760	3720.32	67.05	2495	277	245.12	956.32	168.09	0	0	0	0

2	290	0	0	0	2749	258	232.18	0	0	495.527	0	0	0
Pollution load Per Day													
1	0	1213.8	2565.7	46.24	1720.7	191.03	169.04	659.53	115.92	0	0	0	0
2	200	0	0	0	1895.9	177.93	160.1	0	0	341.74	0	0	0
Total	**200**	**1213.8**	**2565.7**	**46.24**	**3616.5**	**368.96**	**329.14**	**659.53**	**115.92**	**341.74**	**0**	**0**	**0**

16. Xanomeline Tartrate

No. of Stages Proposed	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	0	4314	5846.03	0	7207.33	1246.41	428	1474.8	701.52	818.41	0	0	0
2	0	1920	2318.8	0	4289.16	459.72	132.5	695.63	371	327.22	0	0	0
3	0	3869	1603.78	0	3593.4	759.6	251.8	400.945	240.56	507.8	0	1.098	0
4	605.5	205.5	285	0	6130	0	0	28.5	25.65	0	0	0	0
Pollution load Per Day													
1	0	949.93	1287.28	0	1587	274.45	94.24	324.74	154.47	180.21	0	0	0
2	0	422.78	510.59	0	944.46	101.22	29.17	153.17	81.69	72.05	0	0	0
3	0	851.94	353.14	0	791.26	167.26	55.37	88.28	52.97	111.81	0	0.24	0
4	133.33	45.25	62.75	0	1349.81	0	0	6.27	5.64	0	0	0	0
Total	**133.33**	**2269.9**	**2213.76**	**0**	**4672.53**	**542.93**	**178.78**	**572.46**	**294.77**	**364.07**	**0**	**0.24**	**0**

17. Viloxazine Hydrochloride

No. of Stages Proposed	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
1	0	1433.4	1680.59	600	1579.02	209.1	200	201.67	180.86	20.5	0	0	0
2	0	5070.9	4965.792	600	12266	952.8	870	571.06	421.4	30	0	0	39.4
3	621	0	0	0	5474	966	940	0	0	79	70	0	0
Pollution load Per Day													
1	0	307.75	360.83	128.82	339.02	44.89	42.94	43.3	38.83	4.4	0	0	0
2	0	1088.73	1066.17	128.82	2633.54	204.57	186.79	122.61	90.48	6.44	0	0	8.46
3	133.33	0	0	0	1175.28	207.4	101.82	0	0	16.96	15.03	0	0
Total	**133.33**	**1396.49**	**1426.99**	**257.64**	**4147.83**	**456.86**	**331.55**	**165.91**	**129.31**	**27.8**	**15.03**	**0**	**8.46**

18. LYT 100

No. of Stages Proposed	Product (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in effluent (kg)	Forced Evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	Inorganic residue (kg)
Pollution load Per Batch													
Int	0	260	777.05	0	0	0	0	19.5	116.56	0	0	0	0
1	0	1200	1565.97	0	767	173.875	150.81	135	187.92	540.02	0	0	0
2	0	6720	8208.37	0	2788	696.8	343	109.05	820.84	1171.125	12	0	0
3	120	1350	1415.6	0	202	0	0	0	212.34	0	15	0	0
Pollution load Per Day													
Int	0	21.67	64.75	0	0	0	0	1.625	9.71	0	0	0	0
1	0	100	130.5	0	63.92	14.49	12.57	11.25	15.66	45	0	0	0
2	0	560	684.03	0	232.33	58.07	28.58	9.09	68.4	97.59	0	0	0
3	10	112.5	117.97	0	16.83	0	0	0	17.7	0	1.25	0	0
Total	**10**	**794.17**	**997.25**	**0**	**313.08**	**72.56**	**41.15**	**21.96**	**111.47**	**142.6**	**1.25**	**0**	**0**

19. Sitagliptin Phosphate Monohydrate

No. of Stages Proposed	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	Spent/Mixed Solvent (kg)	Evaporation loss (kg)	Inorganic salts (kg)	Organic residue (kg)	Spent Carbon (kg)	Process emissions (kg)	COD load (kg)
Pollution load per Batch												
1	0	258.44	2079.42	3035.34	0	0	0	0	0	0	27.99	0
2	0	145.91	1329.12	2827.22	0	0	67.15	64.47	0	3.68	0	0
3	0	177.46	817	0	101.23	4000	447.2	89.07	16.62	12.77	9.59	0
4	200	0	293.03	0	0	1354	0	20.42	23.56	0	0	0
Pollution load per day												
1	0	43.06	346.53	505.83	0	0	0	0	0	0	4.66	0
2	0	24.31	221.49	471.15	0	0	11.19	10.74	0	0.6	0	0
3	0	29.52	136.15	0	16.86	666.6	74.52	14.84	2.76	2.12	1.59	0
4	33.33	0	48.83	0	0	225.64	0	3.4	3.92	0	0	0
Total	**33.33**	**96.89**	**753**	**976.98**	**16.86**	**892.24**	**85.71**	**28.98**	**6.68**	**2.72**	**6.25**	**0**

తెలంగాణ రాష్ట్రం
Telangana State

TELANGANA STATE POLLUTION CONTROL BOARD
PARYAVARAN BHAVAN, A - 3, INDUSTRIAL ESTATE,
SANATHNAGAR, HYDERABAD - 500 018

Phone: 23887500
Fax: 040 – 23815631
Website: tspcb.cgg.gov.in

CONSENT & HWA ORDER (EXPANSION)
RED CATEGORY

Consent Order No: 230524567404 **Date:15 06.2023**

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof, Operation of the plant under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation / Renewal of Authorisation under Rule 6 of the Hazardous Wastes (Management, Handling & Transboundary, Movement) Rules 2016 & Amendments thereof).

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974, under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof, and Authorisation under the provisions of HW (MH & TM) Rules, 2016 (hereinafter referred to as 'the Acts', `the Rules') and amendments thereof and the rules and orders made there under to **M/s. Neuland Laboratories Limited., Unit-3, (Formerly M/s. Arch Pharma Labs Ltd. / M/s. Sibra Pharmaceuticals Ltd), Sy.No.10, Plot No.3-72, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District** (hereinafter referred to as 'the Applicant /Industry') and the industry is authorized to operate the industrial plant to discharge the Effluents from the outlets and the quantity of Emissions per hour from the chimneys, by operating pollution control equipment, as detailed below,

i) Out lets for discharge of Effluents:

Outlet No.	Description of outlet	Max daily discharge in KLD	Point of Disposal
1.	HTDS effluents (Process effluents – 114 KLD + Washings – 27 KLD + RO/DM plant -8 KLD + Scrubber – 5 KLD)	154 KLD	• Shall be stripped off for organics recovery. • Stripper condensate to distillate for separation of organic compounds followed by disposal to cement plants for co-processing & distilled effluents shall be routed to ETP. • Stripped effluents for forced evaporation in MEE followed by ATFD. • Condensate from MEE & ATFD shall be routed to ETP. • ATFD salts to TSDF.
2.	LTDS effluents (Process – 11 KLD + Washings -8 KLD + Boiler blowdown - 40 KLD + Cooling Bleedoff – 20 KLD + + Domestic effluents – 20 KLD)	99.0 KLD	• Shall be treated in ETP consisting of primary& secondary treatment. • Treated effluents from ETP shall be filtered in the RO Plant. • RO permeate to reuse and RO reject to MEE & ATFD for forced evaporation.
	Total	**253.0 KLD**	

ii) Emissions from chimneys:

Chimney No.	Description of Chimney
1.	Attached to Coal fired boiler of capacity 8.0 TPH
2.	Attached to Coal fired boiler of capacity 3.0 TPH(Standby)
3.	Attached to process emissions
4.	Attached to DG Sets of capacity 1000 KVA, 725 KVA & 2500 KVA

iii) HW Authorisation No. 230524567404 Date :15.06.2023

HAZARDOUS WASTE AUTHORISATION
(FORM – II)
[See Rule 6 (2)]

M/s. Neuland Laboratories Limited., Unit-3, (Formerly M/s. Arch Pharma Labs Ltd. / M/s. Sibra Pharmaceuticals Ltd), Sy.No.10, Plot No.3-72, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

1. **Hazardous wastes with disposal option:**

Sl. No.	Name of the Hazardous waste	Stream	Quantity	Disposal Option
1.	Process organic residue	29.1 of Schedule – I	4.6 TPD	Shall be disposed to Cement Units for Co-processing / AFRF facilities for pre-processing (or) M/s. TSDF, Dundigal for pre-processing, to be sent to Cement units for Co-processing.
2.	Off Specification / Rejected products	-	10 Kg/day	
3.	Spent carbon	28.3 of Schedule-I	1.81 TPD	
4.	Distillation bottom residue	36.4 of Schedule - I	2.1 TPD	
5.	ETP sludge	35.3 of Schedule – I	5.0 TPD	
6.	Process In Organic residue	34.3 of Schedule – I	1.8 TPD	Shall be sent to TSDF for land filling after stabilization
7.	MEE Salts	**35.3 of Schedule -I**	10.15 TPD	

2. **Hazardous wastes with recycling option:**

Sl. No.	Name of the Hazardous waste	Stream	Quantity	Disposal Option
1.	Spent solvents	28.5 of Schedule - I	60 KLD	The industry shall operate Solvent Recovery Plant within the plant premises in case of utilization of Multiple Solvents/ for recovery of Mixed Solvents / Spent Solvents, which cannot be distilled by Simple Distillation. Solvents shall be recovered to the maximum extent possible and shall be reused. The Spent/Mixed Solvents, which cannot be reused in the plant, shall be disposed to the End Users/ Authorized Cement manufacturing units for Co-processing / AFRF facilities for pre-processing / TSDF, Dundigal for incineration. The industry shall not dispose Spent Solvents / Mixed Spent Solvents to the traders/ recyclers.
2.	Mixed Spent Solvents	28.5 of Schedule - I	2.0 KLD	
3.	Used Oil / Waste Lubricating Oil	5.1 of Schedule - I	60 LPD	Authorized Re-processors / Recyclers.
4.	Containers & Container liners of Hazardous Wastes & Chemicals	33.3 of Schedule - I	500 Nos / Month	After complete detoxification, it shall be disposed to the outside agencies.
5.	General Solid	-	160 Kg/day	Shall be disposed as per Solid Waste

	waste			Management Rules, 2016.
6.	Used lead acid batteries	A1160 of Schedule -III	5 Nos / Month	
7.	E-Waste	B1110 of Schedule -III	50 Kg/day	Authorized Re-processors / Recyclers.
8.	Coal Ash (boiler)	-	21.2 TPD	Sold to brick manufactures.

This consent order is valid for manufacturing the following products along with quantities mentioned as per CFE (Expansion) order dt. 20.11.2020.

Sl. No.	Name of the Product	Capacity (TPM)	No. of stages	Starting Raw Material	Quantity (kg/day)
1	Atazanavir	1	1	Trimethyl pyruvic acid	33.33
2	Bilastin	5	3	4-Bromo phenyl acetic acid	166.66
3	Ciprofloxacin HCl	50	1	Q.Acid	1742.92
4	Dorzolamide HCl	1	8	Dihydrothieno thio pyran sulphonamide	16.67
5	Enalapril maleate	2	3	Michael addition product	73.34
6	Entacapone	10	2	3,4-dihydroxy-5-nitrobenzaldehyde	366.66
7	Escitalopram Oxalate	1	3	Hydroxy compound	56.66
8	Ipratropium Bromide	1	3	Ipratropium Condensation Product	20.00
9	Itraconazole	10	2	Itraconazole hydroxy compound	233.33
10	Labetalol HCl	5	3	Benzyl acetone	73.02
11	Lacosamide	2	4	R-Epichlorohydrin	69.45
12	Levetiracetam	30	4	Propionaldehyde (SRM)	504.00
13	Levofloxacin Hemihydrate	5	2	Q-Acid (SRM)	166.67
14	Mirtazapine	5	4	2-Chloro nicotinonitrile	140.00
15	Moxifloxacin HCl Monohydrate	5	2	Moxifloxacin Q.Acid	150.00
16	Olanzapine	1	5	Propionaldehyde	13.33
17	Sevelamer Carbonate	10	1	Polyallylamine	306.44
18	Sotalol HCl	5	4	Methane Sulfonyl Chloride	100.00
19	Ursodeoxycholic acid	4	3	Cholic acid	233.33
20	Developmental Products (R & D)	5	--	--	--
	Total	**157 TPM**			

This order is subject to the provisions of `the Acts' and the Rules' and amendments made thereunder and further subject to the terms and conditions incorporated in the schedule A, B and C enclosed to this order.

This order of Consents and Authorization is valid for a period upto 31st March,2028.

Sd/-
MEMBER SECRETARY

To
M/s. Neuland Laboratories Limited., Unit-3,
(Formerly M/s. Arch Pharma Labs Ltd. /
M/s. Sibra Pharmaceuticals Ltd),
Sy.No.10, Plot No.3-72, Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District

///T.C.F.B.O///

15/6/2023

SENIOR ENVIRONMENTAL ENGINEER
(CFO – UNIT-III)

SCHEDULE-A

1. The applicant shall make applications through online for renewal of Consent (under Water & Air Acts) and Authorisation under HWM Rules at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts for obtaining Consent & HW Authorisation of the Board. The applicant can also apply for Auto Renewal of the CFO atleast 30 days before the expiry of this order as per the procedure and eligibility stipulated in the Board Circular dt.19.11.2015 & 08.12.2015 (available in Board's Website: http://tspcb.cgg.gov.in/Pages/Circulars.aspx).

2. This order is issued in line with Board's CFE (expansion) order dt.20.11.2020. Concealing the factual data or submission of false information/ fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control Acts. The industry shall comply with all the conditions of CFE (expansion) order dt.20.11.2020 is still applicable.

3. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Rules, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of the Water (Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

4. The industry may explore the possibility of tapping the solar energy for their energy requirements.

5. The Board reserves its right to modify above conditions or stipulate any further conditions and to take action including revoke of this order in the interest of protection of public health and environment.

SCHEDULE-B

1. Total fresh Water Consumption shall not exceed 531.0 KLD.

Sl. No.	Purpose	Quantity (KLD)	
		Fresh	Recycled*
1.	Process	110.0	--
2.	Washings	35.0	--
3.	Boiler makeup	40	108
4.	Cooling	--	170
5.	DM Plant regeneration	33	--
6.	Scrubber	--	5.0
7.	Domestic	20.0	--
8.	Gardening	10.0	--
	Total	**248.0 KLD**	**283.0 KLD**
		531.0 KLD	

2. During the maintenance / breakdown of ZLD, the pre-treated effluent sent to CETP for a period of maximum 15 days in calendar year, duly meeting the following inlet standards.

Parameter	Limiting Standards
pH	5.5 – 9.0
Temperature °C	45.0
Total Dissolved Solids (Inorganic)	5,000 mg/l
Oil and Grease	20 mg/l
Phenolic Compounds (as C_6H_5OH)	5 mg/l

Ammonical Nitrogen (as N)	50 mg/l
Cyanide (as CN)	2 mg/l
Chromium Hexavalent (as Cr^{+6})	2 mg/l
Chromium (total) (as Cr)	2 mg/l
Copper (as Cu)	3 mg/l
Lead (as Pb)	1 mg/l
Nickel (as Ni)	3 mg/l
Zinc (as Zn)	15 mg/l
Arsenic (as As)	0.2 mg/l
Mercury (as Hg)	0.01 mg/l
Cadmium (as Cd)	1 mg/l
Selenium (as Se)	0.05 mg/l
Fluoride (as F)	15 mg/l
Boron (as B)	2 mg/l
COD	15,000 mg/l

3. The emissions shall not contain constituents in excess of the prescribed limits mentioned below.

Chimney No.	Description of Chimney	Parameter	Emission standards
1.	Attached to Coal fired boiler of capacity 8.0 TPH	SPM	115 mg/Nm3
		SO_2*	600 mg/Nm^3 At 6% dry O_2, for solid fuel and3% dry O_2 for liquid fuel
		NO_x*	300 mg/Nm^3 At 6% dry O_2, for solid fuel and3% dry O_2 for liquid fuel
2.	Attached to Coal fired boiler of capacity 3.0 TPH (Standby)	SPM	115 mg/Nm3
		SO_2*	600 mg/Nm^3 At 6% dry O_2, for solid fuel and3% dry O_2 for liquid fuel
		NO_x*	300 mg/Nm^3 At 6% dry O_2, for solid fuel and3% dry O_2 for liquid fuel
3.	Attached to Process vents	HCl	35 mg/Nm^3
4.	Attached to DG Sets of capacity 1000 KVA, 725 KVA & 2500 KVA	SPM	115 mg/Nm^3

***As per MOEF&CC Notification No.GSR 96(E), dt. 29.01.2018 published under the Environment (Protection)Rules, 1986.**

4. The industry shall not manufacture any un-consented products and exceeding capacities without obtaining prior Consent for Establishment (CFE) and Consent for Operation (CFO) of the Board.

5. The industry shall comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets more than 800 KW should comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.

6. The industry shall comply with ambient air quality standards of PM_{10}(Particulate Matter size less than 10μm) - 100 μg/ m^3; $PM_{2.5}$(Particulate Matter size less than 2.5 μm) - 60 μg/ m^3; SO_2 - 80 μg/ m^3; NO_x - 80 μg/m^3, outside the factory premises at the periphery of the industry.

Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009

Noise Levels: Day time - (6 AM to 10 PM) - 75 dB (A)
Night time - (10 PM to 6 AM) - 70 dB (A).

7. **The existing CFO & HWA order dt 17.03.2021 (Expansion – Phase – I) valid upto 31.03.2026 stands cancelled.**

8. As per the directions of the Hon'ble NGT order dated 24.10.2017, the industry shall contribute corpus fund of 0.5% on annual turnover of 2016-17,2017-18, 2018-19 till complete restoration of the entire affected area and till the Tribunal passes appropriate orders. Accordingly, the industry has paid 1% corpus fund of Rs. 44,736.72 and 0.5% corpus fund of Rs.22,370.72 on annual turnover for the financial year 2019-20. The industry shall contribute corpus fund for the remaining financial years as per the Hon'ble NGT guidelines till complete restoration of the entire affected area and till the Tribunal passes appropriate orders.

9. The industry has paid CFO fee Rs.24,82,200/- upto 31.03.2026.

10. The industry shall pay balance consent fee annually as per rates notified in G.O.Ms.No.22. The payment of annual consent fee shall be made at the concerned RO for every financial year (i.e., April to March) within the stipulated time period i.e., 1st quarter of every financial year (April to June) is mandatory for the industry / project, failing which, the validity of the Consent Order automatically stands cancelled and operation industry / project without valid consent attracts penal action under the provision of Water Act, Air Act & Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016.

11. The industry either paying annual fee or total fee for Consented period, shall pay the balance fee as per the revised rates as applicable from time to time.

12. The industry shall segregate effluents into LTDS & HTDS effluents separately.

13. The industry shall regularly operate the ZLD system to treat the effluent and 100% recycle of treated effluent.

14. The industry shall maintain digital flow meters with totalisers (RS-485 communication) for recording the quantity of HTDS effluents, RO permeate and also maintain daily records. They shall connect the flow totaliser data to TSPCB & CPCB servers as per CPCB protocol. The industry shall connect the flow meter at LTDS effluent to TSPCB server within one month as committed.

15. The industry is permitted to send HTDS effluents to the MEE system of M/s. JETL, Jeedimetla for a period of maximum 15 days in a calendar year i.e. during maintenance / break down of Stripper, MEE & ATFD system and shall maintain records.

16. The industry shall provide and operate IP Camera with PAN, Zoom, 5x or above focal length, with night vision capability, at main gate entrance & at other gates where there is movement of effluent tankers, Solvent tankers, Chemical tankers, Hazardous Waste carrying vehicles & other material carrying vehicles. These cameras shall be connected to the website of TSPCB, with minimum backup of three months.

17. The industry shall maintain vent condensers for chemical / solvent storage tanks to control fugitive emissions.

18. The industry shall maintain separate water meters for recording water consumption for process, boiler feed, cooling and domestic purposes and also maintain daily records.

19. The industry shall operate multi stage scrubber along with online pH monitoring system for control of process emissions. They shall maintain log book for operation of scrubber for monitoring active scrubbing media.

20. The industry shall monitor VOCs in ambient air with online VOC analyzer & connect the data to TSPCB server.

21. The industry shall maintain elevated platform with leachate/spillages collection pit to store drums containing chemicals & wastes to control spillages / discharges of chemicals / effluents on ground.

22. The industry shall maintain IP camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability at effluent collection system (HTDS & LTDS) and RO permeate as per CPCB norms. They shall connect the data to CPCB & TSPCB server.

23. The industry shall install on line TDS meter for HTDS effluent generation and connect the same to TSPCB server within two months. They shall maintain the records for effluent generation, TDS values, salts generation on daily basis.

24. The industry shall provide and maintain hood with extraction systems to the HTDS collection tanks and connect to the scrubbers to control the odor problem.

25. The industry shall develop greenbelt as per norms.

26. The industry shall maintain records on source of starting raw material / Intermediates for each product-wise and the consolidated records shall be submitted to R.O., R.C. Puram every month along with invoice copies of the starting raw materials outsourced.

27. The industry shall provide adequate closed storage facilities above the ground with proper lining for storage of effluents before its treatment.

28. The industry shall not use effluents in cooling towers under any circumstances.

29. The industry shall not discharge any effluents onland within or outside the plant premises.

30. The industry shall provide storm water drains to avoid mixing of effluent/spillages with run-off water during rains. The industry shall collect contaminated rain water and shall dispose the same to CETP, after conforming to the influent standards of CETP duly maintain separate records.

31. The industry shall provide sufficient storage collection tank to ensure the collection of first run off rain water.

32. The industry shall provide arrangement to by-pass the rain water collection tank of first run off rain water for subsequent water flow.

33. The industry shall take measures to prevent the seepages such as cement concrete flooring with proper collection system to collect contaminants / spillages in the relevant areas in the industry premises and avoid seepages outside the industry premises.

34. The industry shall carry out Leak Detection and Repair Study (LDAR) to access the solvent losses.

35. The industry shall maintain separate energy meters for recording energy consumption for air pollution control equipments and maintain record for daily energy consumption.

36. The evaporation losses in solvents shall be controlled by taking all preventive measures such as circulation of Chilled brine, transfer of solvents by using pumps instead of manual handling, closed centrifuges, providing primary & secondary condensers to all the reactor vents and all the solvent storage tanks and keeping solvent storage in ground storage tanks with closed pipeline to Reactors.

37. The industry shall operate Solvent Recovery Plant in the plant. Solvents shall be recovered to the maximum extent possible and shall be reused. The industry shall submit status of efficiency of Solvent Recovery Plant to the concerned Regional Officer. The industry shall not dispose spent solvents / mixed spent solvents to the traders/ recyclers.

38. The industry shall provide and maintain Stack Monitoring facility as per Emission Regulation part-3 (ERP-3) norms for all the major stacks of the industry.

39. The industry shall ensure that the Port hole and ladder facility for the Stacks is safe to carry out Stack monitoring. In place of monkey ladder, spiral type/scaffold ladder shall be provided to ensure safety of monitoring personnel.

40. The industry shall implement the odour control measures at source of generation and from ETP and shall ensure to maintain the same effectively to control odour problems.

41. The industry shall ensure that there shall not be any change in process technology and scope of working without prior approval from the Board.

42. (a) The industry shall maintain the following records and the same shall be made available to the Board Officials during the inspection.

    i) Daily production details.
    ii) Quantity of Effluents generated and reused.
    iii) Log Books for pollution control systems.
    iv) Daily solid waste generated and disposed

    (b) The industry shall submit consolidated statement of the above on monthly basis to the Concerned Regional Office.

43. As per G.O.Rt.No.286, the industry shall transport the industrial effluents and plying on the roads is allowed between 6 A.M. to 6 P.M. only.

44. The industry shall comply with Task Force directions issued by the Board from time to time.

45. The applicant shall submit Environment statement in Form V to the Regional office before 30th September of every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.

46. The conditions stipulated in this order are without any prejudice to rights and contentions of this Board in any Hon'ble court of Law.

SCHEDULE – C
[see rule 6(2)]

[SPECIAL CONDITIONS OF AUTHORISATION FOR OCCUPIER OR OPERATOR HANDLING HAZARDOUS WASTES]

1. The industry shall give top priority for waste minimization and cleaner production practices.

2. The industry shall not store hazardous waste for more than 90 days as per the Hazardous and other Wastes (Management. Handling and Transboundary Movement) Rules, 2016 and amendments thereof. The industry shall maintain 6 copy manifest system for transportation of waste generated and copies of receipt of Consignee shall be submitted to the Concerned Regional office. The industry shall maintain proper records for Hazardous Wastes stated in Authorisation in FORM-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form- 4 as per Rule 20(2) of the Hazardous and other Wastes (Management, Handling & Transboundary Movement) Rules, 2016 and amendments thereof.

3. The industry shall dispose /sell the Hazardous Waste to only industries/agencies authorized by the State Pollution Control Boards. The industry shall verify the authorization of the Board given to the Party before disposing its waste to the External Party.

4. The industry shall maintain proper records for Hazardous Wastes disposal and its concurrence with authorization. In case of variation in generation, industry shall submit explanation and obtain amendment in Environmental Clearance/ CFE/CFO in this regard.

5. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal. Waste oils shall be disposed to the authorized Reprocessors/ Recyclers and Used Lead Acid Batteries shall be disposed to the manufacturers / dealers on buyback basis. The industry shall take necessary practical steps for prevention of oil spillages and carryover of oil from the premises. The industry shall check the Certificate/ Authorisation/order of MoEF issued to the Re-user/Recycle units while disposing the waste oil.

6. The industry shall dispose of e-waste to the authorized traders/ recyclers only.

7. The industry shall maintain good housekeeping.

8. The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule B & C of this Order on half yearly basis to Board Office, Hyderabad and concerned Regional Office.

Sd/-
MEMBER SECRETARY

To
M/s. Neuland Laboratories Limited., Unit-3,
(Formerly M/s. Arch Pharma Labs Ltd. /
M/s. Sibra Pharmaceuticals Ltd),
Sy.No.10, Plot No.3-72, Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District

///T.C.F.B.O///

M.Pravin 15/6/2023

SENIOR ENVIRONMENTAL ENGINEER
(CFO – UNIT-III)

PRAGATHI LABS & CONSULTANTS PVT. LTD.
LAB RECOGNISED BY MOEF & CC, GOVT. OF INDIA, Valid upto 16-10-2024
Certified by ISO 9001 : 2015 & ISO 45001 : 2018

Date: 04th January 2024

TO WHOM SO EVER IT MAY CONCERN

M/s. Neuland Laboratories Limited, located at Gaddapotharam village, Jinnaram Mandal Sangareddy District, Telangana State. Presently the industry is manufacturing 20 API products. The proponent wants to replace the 7 Existing products.

M/s. Pragathi Labs & Consultants Pvt.Ltd who is registered with TSPCB as an Empanelled Environmental Auditor, studied the proposed product's material balance in detail and concluded that there will not be any increase in pollution loads than at present. The proposed new products are as follows

No.	Name of the Product	Quantity (TPM)
1	Ciprofloxacin Hydrochloride	39
2	Dorzolamide Hydrochloride	1
3	Enalapril Maleate	2
4	Entacapone	10
5	Escitalopram Oxalate	1
6	Ipratropium Bromide	1
7	Itraconazole	10
8	Labetalol Hydrochloride	5
9	Levetiracetam	30
10	Levofloxavin Hemihydrate	5
11	Mirtazapine	5
12	Sotalol HCl	5
13	Bempodoic acid	10
14	Diferasirox	1
15	Sabam HCl	6
16	Xanomeline Tartrate	4
17	Viloxazine HCL	4
18	LYT -100 (Deupirfenidone)	0.3
19	Sitagliptin Phosphate Monohydrate	1
20	Development products	5
Total		**145.3**

Hence it is certified that there will not be any increase in pollution loads in future with the given new products.

For Pragathi Labs & Consultants Pvt.Ltd
(Registered Empanelled Environmental Auditor with TSPCB)

(Dr. M. Ravi Kiran)
Managing Director

Overall Pollution Loads for the Proposed Products (per day)

No.	Product	No. of stages proposed	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	I/p solvent (kg)	Solvent Recovery & Reuse (kg)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissions (kg)	Inorganic residue (kg/day)
1	Ciprofloxacin Hcl	1	1300.00	0.00	21374.37	23062.64	0.00	21035.24	20522.19		124.66	113.21	1110.55	515.17	253.88	271.89	0.00	169.93
2	Dorzolamide	8	16.67	154.20	3067.28	1349.77	1817.03	1260.25		1195.24	42.84	26.17	56.22	31.19	26.01	14.50	0.17	
3	Enalapril Maleate	3	66.67	106.67	2100.11	2370.85	0.00	1083.39		1004.72	65.34	30.67	195.34	114.76	17.93	12.00	14.00	
4	Entacapone	2	333.33	433.33	6666.60	7345.93	0.00	5133.28		4983.28	50.00	185.33	383.33	392.16	374.00	433.33	0.00	
5	Escitalopram	3	33.33	96.66	3499.65	2278.27	1382.20	1883.15		1753.16	55.66	74.33	35.83	185.96	67.53	8.33	0.00	20.00
6	Ipratropium Bromide	3	16.67	35.67	1667.00	764.99	930.49	1100.22		1036.54	41.17	22.50	8.34	47.26	10.87	5.00	0.00	
7	Itraconazole	2	333.33	366.66	10666.56	11251.55	0.00	7339.93	6999.93		173.33	166.67	409.33	275.20	116.67	100.00	0.00	
8	Labetalol	3	166.67	324.86	631.09	959.69	0.00	5023.90	4944.23		53.80	25.86	223.16	38.80	0.00	90.01	10.84	0.00
9	Levetricetum	4	1000.00	3880.00	17000.00	18458.00	3500.00	12400.00		11900.00	200.00	240.00	3113.00	200.20	1099.00	300.00	341.00	660.00
10	Levofloxacin	2	166.67	191.67	7166.81	6355.13	1220.02	8795.18	8718.51		23.33	86.67	243.34	115.67	186.67	55.00	0.00	
11	Mirtazapine	4	166.67	691.68	7000.14	8071.44	0.00	4675.09	4611.43		81.67	56.67	297.17	199.60	123.67	71.67	0.00	760.57
12	Sotalol	4	166.67	493.34	2250.05	2807.22	0.00	5000.10		4738.43	243.34	16.67	378.51	70.98	99.50	46.67	49.33	
13	Bempodoic acid	3	333.33	2160.80	13166.48	15890.99	0.00	17215.14		16688.82	126.31	135.64	765.14	126.65	526.14	0.00	0.00	124.33
14	Diferasirox	1	33.33	164.78	1025.00	1083.50	0.00	4700.16		4512.20	82.39	70.00	113.90	44.66	202.37	6.00	0.00	12.81
15	Sabam HCl	2	200.00	0.00	1213.79	2565.74	46.24	3715.56		3616.56	168.96	229.14	659.53	31.89	341.74	0.00	0.00	0.00
16	Xanomeline Tartrate	4	133.33	0.00	2269.90	2213.76	0.00	4765.44	4672.53		212.93	178.78	572.46	294.77	364.07	0.00	0.24	0.00
17	Viloxazine HCL	3	133.33	0.00	1396.49	1426.99	257.64	4173.14		4147.83	25.31	131.55	165.91	21.95	27.80	15.03	0.00	8.46
18	LYT -100 (Deupirfenidone)	3	10.00	0.00	794.17	997.25	0.00	426.79		313.08	72.56	41.15	21.96	111.47	142.60	1.25	0.00	0.00
19	Sitagliptin Phosphate Monohydrate	4	33.33	96.89	753.00	976.98	16.86	977.95	892.24		85.71	0.00	38.21	0.00	6.68	2.72	6.25	28.98
20	Development products		166.67	262.81	5947.28	3632.92	1397.23	3399.23		3288.39	62.19	44.31	288.91	93.53	135.33	57.65	17.67	0.00
			4810.00	**9460.02**	**109655.76**	**113863.62**	**10567.71**	**114103.12**	**51361.06**	**59178.25**	**1991.51**	**1875.32**	**9080.13**	**2911.87**	**4122.45**	**1491.05**	**439.51**	**1785.07**

Overall Pollution load for Existing Products (per day)

No.	Product	No. of stages proposed	Product (kg)	Intermediate (kg)	Water (L)	HTDS Effluent (L)	LTDS Effluent (L)	I/p solvent (kg)	Solvent Recovery & Reuse (kg)	Spent Solvent (kg)	Evaporation loss (kg)	Loss in Effluent (kg)	Forced evaporation salts (kg)	COD load (kg)	Organic residue (kg)	Spent carbon (kg)	Emissions (kg)	Inorganic residue (kg)
1	Ata zanavir	1	33.33	0.00	576.61	754.67	0.00	1266.54		1241.21	19.66	5.33	69.29	11.06	21.58	0.00	8.27	
2	Bilastin	3	166.67	351.44	4891.24	5506.33	0.00	5176.92		4760.90	101.45	74.27	508.75	162.23	743.70	58.33	36.96	
3	Ciprofloxacin Hcl	1	1666.67	0.00	27403.10	29567.54	0.00	26616.79	26310.55		161.13	145.12	1423.79	660.48	325.49	348.58	0.00	217.87
4	Dorzolamide	8	16.67	154.20	3067.28	1349.77	1817.03	1260.25		1195.24	42.84	26.17	56.22	31.19	26.01	14.50	0.17	
5	Enalapril Maleate	3	66.67	106.67	2100.11	2370.85	0.00	1083.39		1004.72	65.34	30.67	195.34	114.76	17.93	12.00	14.00	
6	Entacapone	2	333.33	433.33	6666.60	7345.93	0.00	5133.28		4983.28	50.00	185.33	383.33	392.16	374.00	433.33	0.00	
7	Escitalopram	3	33.33	96.66	3499.65	2278.27	1382.20	1883.15		1753.16	55.66	74.33	35.83	185.96	67.53	8.33	0.00	20.00
8	Ipratropium Bromide	3	16.67	35.67	1667.00	764.99	930.49	1100.22		1036.54	41.17	22.50	8.34	47.26	10.87	5.00	0.00	
9	Itraconazole	2	333.33	366.66	10666.56	11251.55	0.00	7339.93	6999.93		173.33	166.67	409.33	275.20	116.67	100.00	0.00	
10	Labetalol	3	166.67	324.86	631.09	959.69	0.00	5023.90	4944.23		53.80	25.86	223.16	38.80	0.00	90.01	10.84	0.00
11	Lacosomide	4	66.67	243.07	3224.63	4133.65	0.00	6948.22		6734.45	102.08	83.68	576.29	146.73	586.75	54.72	8.96	
12	Levetricetum	4	1000.00	3880.00	17000.00	18458.00	3500.00	12400.00		11900.00	200.00	240.00	3113.00	200.20	1099.00	300.00	341.00	660.00
13	Levofloxacin	2	166.67	191.67	7166.81	6355.13	1220.02	8795.18	8718.51		23.33	86.67	243.34	115.67	186.67	55.00	0.00	
14	Mirtazapine	4	166.67	691.68	7000.14	8071.44	0.00	4675.09	4611.43		81.67	56.67	297.17	199.60	123.67	71.67	0.00	760.57
15	Moxifloxacin	2	166.67	166.67	833.35	1088.36	0.00	2800.06		2413.38	336.67	50.00	173.34	75.00	153.34	66.67	0.00	0.00
16	Olanzpaine	5	33.33	143.32	4566.21	3369.20	1403.29	956.57		880.91	42.33	33.33	94.86	68.66	27.46	8.33	0.00	38.33
17	Sevelamer carbonate	1	333.33	0.00	1587.29	2028.55	0.00	502.85		476.19	10.79	15.87	317.57	23.81	0.00	79.36	21.52	
18	Sotalol	4	166.67	493.34	2250.05	2807.22	0.00	5000.10		4738.43	243.34	16.67	378.51	70.98	99.50	46.67	49.33	
19	Ursodeoxycholic acid	3	133.33	309.99	1366.63	1987.86	0.00	5373.20		5263.20	86.00	8.00	284.53	23.62	134.52	0.00	0.00	22.67
20	Development products		166.67	262.81	3492.28	3632.92	337.27	3399.23		3288.39	62.19	44.31	288.91	93.53	135.35	57.65	17.67	56.56
	Total		**5233.35**	**8252.04**	**109656.62**	**114081.93**	**10590.30**	**106734.84**	**51584.65**	**51669.99**	**1952.80**	**1391.47**	**9080.88**	**2936.90**	**4250.02**	**1810.17**	**508.72**	**1775.98**