Environmental Management Plan

for Amendment to EC

(Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing unit)

Of

M/s. Covalent Laboratories Pvt. Ltd., Unit-I

Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V), Hatnoor (M),
Sangareddy District (formerly Medak District),
Telangana State

Submitted to

Ministry of Environment, Forest & Climate Change,
Paryavaran Bhavan,
New Delhi

April 2017

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1.0 Introduction

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing facility located at Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A, Gundlamachanoor (V), Hatnoor (M), Sangareddy District (formerly Medak District), Telangana State with an area of 11.85 Ha.

- The industry was originally established in 1989 and obtained its first Environmental Clearance vide J -11011/88/2004-IA II (I) dated 30-11-2004.
- In 2015, industry proposed expansion of the unit and obtained its Environmental Clearance F.No. J-11011/375/2013-IA II (I) dated 30-12-2015 **(Annexure-I)** to manufacture on campaign basis any 20 products at a time out of 65 products with total production capacity of 2400 TPA (200 TPM) along with 3 MW coal based CPP. The Public Hearing for this project was conducted on 04-12-2014.
- Consent for Establishment vide order No. 01/TSPCB/CFE/RO-SR-I/HO/2018-1596 dated 29-09-2016 **(Annexure-II).**
- Consent to Operate vide order no. TSPCB/SRD/HO/CFO/2017-2861 dated 28-01-2017 valid upto 30-09-2021 **(Annexure-III).**

After the unit was put into operation in January 2017, it has come to the knowledge that the overall Steam Requirement was under estimated during the proposal submitted in 2015 for expansion by about 12 TPH. It was also identified that the Captive Power requirement is on the higher side compared to the earlier estimation. Hence, Covalent after thorough understanding of the requirement has proposed to request for Amendment to the Environmental Clearance from the Ministry of Environment, Forests & Climate Change for the installation of an additional boiler of 20 TPH capacity with 2 MW Captive Power generation along with changes in the list of products i.e. dropping 20 products and revise individual production capacity of about 3 products thereby marginally increasing the overall production capacity and pollution load. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

The Gross investment for the proposed project would increase from the originally estimated Rs.212.94 crores to Rs.225 Crores.

1.1 The Details of the proposal are given hereunder:

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, Active Pharmaceutical Ingredients (APIs) & API Intermediates manufacturing facility located at Sy. No. 345, 346, 358, 359, 374, 375, 376, 315/E, 377/A, Gundlamachanoor (V), Hatnoor (M), Sangareddy District (formerly Medak District), Telangana State. This site is at a distance of about 15 km (aerial distance) from Hyderabad ORR, 0.7 km from

Gundlamachanoor village and 8 km from the NH-65 (previously NH-9) (Hyderabad-Mumbai Highway).

General location, Google map showing the Co-ordinates and revised Plant layout of the project showing the proposed facilities are presented at **Annexures- IV, V & VI.**

M/s. Covalent Laboratories Pvt. Ltd., Unit-I, has been permitted to manufacture 20 products at a time from total 65 permitted products with total production capacity of 2400 TPA (200 TPM) along with 3MW Captive Power Plant using 30TPH Coal Fired Boiler.

Covalent Unit-I proposes to request for Amendment to the Environmental Clearance from the Ministry of Environment, Forests & Climate Change for the installation of an additional boiler of 20 TPH capacity with 2 MW Captive Power generation along with permitted 3MW Captive Power Plant using 30 TPH coal fired boiler. The industry has also identified about 20 Products to be dropped out of the permitted 65 products and retain 45 products. The industry proposes to marginally revise the individual production capacities of 3 products out of the 45 products thereby marginally increasing the overall production capacity and pollution load of the industry. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

Industry has identified certain by-products from the permitted products manufactured which were disposed as waste in either effluent or in solid waste, that can be reused within the industry or disposed of as by-product. After thorough R&D on these by-products, industry now proposes to recover them in pure form with better yields. Some of these by-products are either utilized back as raw material or sold as by-product to other parties where it can be reused. The additional capacity of the boiler will be utilized to make up the under estimated 12TPH and balance steam will be used in the process for recovery of by-products from waste streams, purification of by-products by adding additional stage and recovery of additional solvents.

The permitted and proposed products with its production capacities are presented in **Tables 1 & 2** respectively.

Table 1: List and Quantities of the Proposed and retained permitted Products and its status

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
1	**Cefixime Trihydrate**	**2166.7**	780.0	3	Increased
2	**Cefpodoxime Proxetil**	**333.3**	120.0	2	Increased
3	**Cefuroxime Axetil**	**500**	180.0	3	Increased
4	Cefuroxime Sodium	66.7	24.0	1	Retained
5	**Ceftriaxone Sodium**	**500**	180.0	1	Retained
6	Cefpirome Sulfate	33.3	12.0	3	Retained
7	**Cefdinir Monohydrate**	**200**	72.0	4	Retained

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
8	**Cefprozil Monohydrate**	**166.7**	60.0	3	Retained
9	Cefepime Dihydrochloride Monohydrate	33.3	12.0	2	Retained
10	**Cefuroxime Acid**	**100**	36.0	2	Retained
11	Cefditoren Pivoxil	33.3	12.0	3	Retained
12	Ceftibuten Monohydrate	66.7	24.0	2	Retained
13	Cefazoline Sodium	33.3	12.0	3	Retained
14	Cefoperazone Sodium	33.3	12.0	3	Retained
15	Cefoxitin Sodium	16.7	6.0	4	Retained
16	Ceftazidime Pentahydrate	16.7	6.0	6	Retained
17	**Cefotaxime Sodium**	**100**	36.0	2	Retained
18	Ceftizoxime Sodium	33.3	12.0	1	Retained
19	Cephalothin Sodium	33.3	12.0	2	Retained
20	Cefpodoxime Acid	33.3	12.0	1	Retained
21	Cefcapene Pivoxil	26.7	9.6	2	Retained
22	Cefmetazole Sodium	33.3	12.0	3	Retained
23	Cefmetazole	33.3	12.0	2	Retained
24	**Meropenem**	**166.7**	60.0	2	Dropped
25	Imipenem	66.7	24.0	3	Dropped
26	Cilastatin Sodium	66.7	24.0	3	Dropped
27	Ertapenem Sodium	33.3	12.0	2	Dropped
28	**Doripenem Monohydrate**	**166.7**	60.0	3	Dropped
29	Biapenem	33.3	12.0	2	Dropped
30	**Faropenem Sodium**	**100**	36.0	5	Dropped
31	Panipenem	33.3	12.0	2	Dropped
32	Tebipenem Pivoxil	3.3	1.2	2	Dropped
33	Darifenacin Hydrobromide	16.7	6.0	6	Dropped
34	Solifenacin Succinate	16.7	6.0	5	Dropped
35	Tolterodine Tartrate	16.7	6.0	4	Dropped
36	**7-AVNA**	**166.7**	60.0	2	Retained
37	**MEAT (Thio Ester)**	**166.7**	60.0	1	Retained
38	**7-APCA**	**100**	36.0	2	Retained
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12.0	1	Retained
40	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	24.0	1	Retained

Sl. No.	Product name	Permitted Quantity (Kg/day)	Proposed Quantity (TPA)	No. of Stages	Status
41	**Lacosamide**	**333.3**	120.0	1	Dropped
42	Silodosin	66.7	24.0	1	Dropped
43	Fingolimod Hydrochloride	66.7	24.0	1	Dropped
44	**Cinacalcet Hydrochloride**	**333.3**	120.0	1	Dropped
45	**Fexofenadine Hydrochloride**	**333.3**	120.0	1	Dropped
46	Sitagliptin Phosphate	66.7	24.0	1	Decreased
47	Prasugrel Hydrochloride	66.7	24.0	2	Decreased
48	Venlafaxine Hydrochloride	66.7	24.0	1	Dropped
49	Pregabalin	66.7	24.0	1	Decreased
50	Diacerein	66.7	24.0	2	Decreased
51	**Dronedarone Hydrochloride**	**333.3**	120.0	1	Dropped
52	Linezolid	66.7	24.0	1	Decreased
53	Ropinirole Hydrochloride	66.7	24.0	1	Decreased
54	D-Cycloserine	66.7	24.0	1	Decreased
55	Clopidogrel Hydrogen Sulfate	66.7	24.0	1	Decreased
56	Bosentan	66.7	24.0	1	Decreased
57	Candesartan Cilexitil	66.7	24.0	1	Decreased
58	**Deferasirox**	**333.3**	120.0	1	Dropped
59	Febuxostat	66.7	24.0	1	Decreased
60	Azilsartan medoxomil	66.7	24.0	1	Decreased
61	Solifenacin Succinate	66.7	24.0	1	Decreased
62	Darifenacin Hydrobromide	66.7	24.0	1	Decreased
63	Trospium Chloride	66.7	24.0	1	Decreased
64	Tolterodine Tartrate	66.7	24.0	1	Decreased
65	Valsartan	66.7	24.0	1	Decreased

Table 2: List and Quantities of the Proposed Products and Therapeutic Category

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	Therapeutic Category / API Intermediate
1	**Cefixime Trihydrate**	**3055**	**1100**	Antibiotic
2	**Cefpodoxime Proxetil**	**833**	**300**	
3	**Cefuroxime Axetil**	**833**	**300**	
4	Cefuroxime Sodium	**66.7**	**24**	
5	**Ceftriaxone Sodium**	**500**	**180**	
6	Cefpirome Sulfate	33.3	12	
7	**Cefdinir Monohydrate**	**200**	**72**	
8	**Cefprozil Monohydrate**	**166.7**	**60**	
9	Cefepime Dihydrochloride Monohydrate	33.3	12	
10	**Cefuroxime Acid**	**100**	**36**	Anti-Infective
11	Cefditoren Pivoxil	33.3	12	Antibiotic
12	Ceftibuten Monohydrate	**66.7**	**24**	Anti-Infective
13	Cefazoline Sodium	33.3	12	Anti-Infective
14	Cefoperazone Sodium	33.3	12	Antibiotic
15	Cefoxitin Sodium	16.7	6	
16	Ceftazidime Pentahydrate	16.7	6	
17	**Cefotaxime Sodium**	**100**	**36**	
18	Ceftizoxime Sodium	33.3	12	
19	Cephalothin Sodium	33.3	12	
20	Cefpodoxime Acid	33.3	12	Antibacterial
21	Cefcapene Pivoxil	26.7	10	Antibiotic
22	Cefmetazole Sodium	33.3	12	
23	Cefmetazole	33.3	12	
24	**7-AVNA**	**166.7**	**60**	Cefixime Intermediate Cefdinir Intermediate Cefprozil Intermediate Cefpodoxime Proxetil Intermediate Cefditoren Pivoxil Intermediate
25	**MEAT (Thio Ester)**	**166.7**	**60**	
26	**7-APCA**	**100**	**36**	
27	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33.3	12	
28	**7-Amino3-thiazole cephalosporanic acid (7-ATCA)**	**66.7**	**24**	
29	Sitagliptin Phosphate	**50**	**18**	Antidiabetic
30	Prasugrel Hydrochloride	**50**	**18**	Anti-Hypertensive
31	Pregabalin	**50**	**18**	Anti-Convulsant
32	Diacerein	**50**	**18**	Anti-inflammatory
33	Linezolid	**50**	**18**	Antibiotic
34	Ropinirole Hydrochloride	**50**	**18**	Antidyskinetic

Sl. No.	Products	Quantity (Kg/Day)	Quantity (TPA)	Therapeutic Category / API Intermediate
35	D-Cycloserine	50	18	Antituberculosis
36	Clopidogrel Hydrogen Sulfate	50	18	Anti-thrombotic
37	Bosentan	50	18	Anti-Hypertensive
38	Candesartan Cilexitil	50	18	Anti-Hypertensive
39	Febuxostat	50	18	Antigout
40	Azilsartan medoxomil	50	18	Anti-Hypertensive
41	Solifenacin Succinate	50	18	Antimuscarinic Agent
42	Darifenacin Hydrobromide	50	18	Anticholinergic
43	Trospium Chloride	50	18	Antispasmodic
44	Tolterodine Tartrate	50	18	Antimuscarinic Agent
45	Valsartan	50	18	Anti-Hypertensive
	Total (Any 20 products at a time)	**6721**	**2420**	

2.0 Project Description

The manufacturing process of APIs consists of chemical synthesis and multiple stages of processing extending to maximum of 6 stages involving different types of chemical reactions. Typical process description with process details for all 45 products is enclosed at **Annexure-VII**.

2.1 Raw Materials

- Additional coal of about 100 TPD will be used in the additional 20 TPH coal fired boiler for 2 MW CPP with total coal of about 250 TPD.
- The chemicals (raw materials) required for the manufacture of proposed products is presented at **Annexure -VIII** and Hazardous chemicals list is presented at **Annexure-IX.**

3.0 Environmental Management Plan

The environmental management plan (EMP) is delineated based on scientific assessment of pollution generation, its handling, treatment and disposal for gaseous, liquid, and solid wastes.

3.1 Water requirement and Wastewater Generation and their Management / Disposal

The water requirement and wastewater generation for proposed products on regular/campaign basis is presented in **Table 3**.

Table 3: Proposed Water Balance

Sl. No.	Description	Input (KLD)		Output (KLD)		Segregation type of Wastewater	Treatment and Reuse Method
		Fresh Water	Recycled water	Evaporation / Handling Loss	Total Wastewater		
1	Process	162	-	-14	176	HCOD/HTDS	Segregation, Collection and Treatment separately in ETP with ZLD System for reusing the treated effluent in cooling towers
2	Washings (reactors, centrifuges, nutch filters, containers, floor moping, etc.)	25	-	-	25	LTDS/LCOD	
3	Boiler (30 & 20 TPH)	240	-	200	40	LTDS/LCOD	
4	Cooling Towers (5000 TR)	21	279	275	25	LTDS/LCOD	
5	DM Regeneration	12	-	-	12	HTDS/LCOD	
6	Scrubber	8	-	-	8	HTDS/LCOD	
7	Q.C and R&D	5	-	-	5	LTDS/LCOD	
8	Domestic	30	-	5	25		
9	Gardening	50	-	50	-		
Total		**553**	**279**	**516**	**316**	**Reuse:**	Total reuse is 279 KLD
		832		**832**			

The sources of wastewater generation are from the process, floor & reactor washings, utilities, Q.C, R&D, scrubber and plant domestic waste. Total proposed wastewater will be 316 KLD. The effluent will be segregated in to HTDS/ HCOD, HTDS from scrubber and other utilities, LTDS/LCOD and collected by gravity into collection tank separately and the details are presented in **Table 4.** This individual effluent will be pumped to the above ground level R.C.C lined tanks for storage and neutralization. The effluents segregated quantity, characteristics and treatment flow is briefly presented in **Table 4.**

Table 4: Effluent Treatment Flow as per Segregation

Effluent	Qty. (KLD)	pH	TDS (mg/l)	COD (mg/l)	Treatment Flow
HTDS/ HCOD & HTDS	196	2 to 12	<100000	<30000	Collection → Equalization → Neutralization → Settling → Holding → Steam stripper → MEE along with HTDS effluent → Condensate to ETP(biological treatment) → Concentrate to ATFD ATFD Condensate to ETP (Biological Treatment) along with domestic wastewater (septic tank overflow) → Pressure Sand Filter → Activated Carbon Filter → R.O → R.O rejects to MEE.

					R.O Permeate & Condensate to Boiler ATFD Salts to TSDF and stripped solvents to SPCB authorized cement industries
LTDS / LCOD	95	6-10	< 5000	< 3000	Collection → Equalization → Neutralization →ETP (Biological Treatment) along with MEE condensate.
Domestic	25	6-9	< 2000	< 1000	Septic tank→Overflow to Biological treatment of ETP

ETP – ZLD facility consists of primary treatment (equalization and neutralization), secondary treatment (stripper with MEE, ATFD & biological) and tertiary treatment (Pressure sand filter, Activated carbon filter & Reverse Osmosis) will be provided. Domestic wastewater will be sent to septic tank and the overflow to ETP (biological treatment). Concentrate from MEE system will be sent to ATFD and the salts from the evaporation system will be collected and sent to TSDF for safe disposal. Industry also proposes for another MEE.

3.2 Hazardous / Solid Waste Generation, Handling and their Disposal

Solid waste mainly segregated into process organic residues, inorganic salts, boiler ash spent mixed unrecoverable solvents and spent carbon. Hazardous / Solid waste will be segregated, detoxified and collected in the HDPE drums / bags and will be stored in the covered and raised platform with Leachate collection system. The proposed solid waste and other waste generated, handling and disposal method from the various stages of APIs & API intermediates manufacturing plant is presented in the **Table 5**.

Table 5: Hazardous / Solid Waste Generation from the Proposed Products

Sl. No.	Description	Proposed Quantity (TPD)	Handling Method	Disposal
1.	Process Organic	9.8	HDPE Bags / Drums	Sent to SPCB Authorized Cement industries / TSDF
2.	Spent carbon	1		
3.	Distillation residue	Lumpsum		
4.	Inorganic & Evaporation salt (Process)	16.3	HDPE Bags	
5.	Evaporation salt (Non-Process)	2.5		
6.	ETP Sludge	1		
7.	Boiler Ash	75	Stored in covered area	Sold to Cement Brick Manufacturers
Other Hazardous Waste generation from the Plant				
8.	Detoxified Container / Liners	200 Nos./ month	Designated covered	Disposed to SPCB Authorized agencies after complete

Sl. No.	Description	Proposed Quantity (TPD)	Handling Method	Disposal
	drums, HDPE Carboys, Fiber Drums, PP Bags	1000 Nos/month 500 nos/month 500 kg/month	area	detoxification
9.	Spent Mixed solvents	6 KLD	Stored Tanks/ Drums	Sent to SPCB Authorized Recyclers / Cement industries
10.	Waste oils & Grease	2 KL/annum	MS Drums	Sent to SPCB Authorized agencies for reprocessing / recycling.
11.	Used Lead acid Batteries	100 nos/month	Designated covered area	Sent to suppliers on buy-back basis.
12.	E- waste	0.001	Designated covered area	Send to authorized e-waste Collection centers/ registered dismantlers/ authorized recyclers/ return back to manufacturers
13.	Canteen food waste	Lumpsum	HDPE Bags	Disposed to Village authorized agencies
14.	Paper waste & Misc.	Lumpsum	HDPE Bags	Scrap Venders
15.	Misc. Waste (spill control waste)	Lumpsum	Stored in Drums	TSDF

Note: Solid waste quantities maximum on various combinations i.e., 20 products on campaign products at a point of time and R&D products

The overall comparison of various combinations of pollutants from permitted and proposed products are presented in **Table 6**.

Table 6: Comparison of Pollution Loads for the Permitted and Proposed Products

Sl. No.	Description	Permitted	Revised Pollution load (proposed)
1.	Total Production Capacity (TPM)	200	201.67
2.	Water Input for Process (KLD)	161	162
3.	Total Process Effluent (KLD)	171	176
4.	TDS (kg/day)	15518	16348
5.	COD (kg/day)	7153	6567
6.	Fresh Water requirement	457	553
7.	Total Effluent (KLD)	298	316
8.	Organic Residue (kg/day)	9357	9758
9.	Inorganic & Eva. Salts (kg/day)	15519	16339
10.	Spent Carbon (kg/day)	989	992
11.	Total Solid Waste (kg/day	25138	26842
12.	Process Emissions (kg/day)	1712	1507

3.3 Process Emissions Management

Manufacturing of APIs and APIs intermediate will result in gaseous emissions. Maximum process emissions for proposed products are given in **Table 7.** Proposed gaseous emissions will be scrubbed in two stages with water and caustic solution based on the characteristics of gases.

Table 7: Maximum Quantity of Process Emissions from Proposed Products

Name of the Gas	*Quantity (kg/day)	Treatment
CO_2	1316.27	Dispersed into atmosphere
HCl	61.07	Scrubber with water / caustic solution
HF	29.38	Scrubber with caustic sol.
H_2	1.87	Diffused with flame arrestor
SO_2	40.34	Scrubber with caustic solution
HBr	0.02	Scrubber with caustic sol.

3.4 Fugitive emissions

- Solvents used in the manufacturing process are stored in drums and bulk quantities are stored in underground/ above ground storage tanks.
- Solvents are handled in closed conditions thereby reducing the losses in the form of evaporation.
- Proper earthing will be provided to all the electrical equipment and the joints / connections wherever solvent handling is done.
- Reactor and solvent handling pump will have mechanical seals to prevent leakage.
- The industry will take measures for reduction of fugitive emissions and for further reduction industry will provide vent condensers to the tanks.
- Chilled brine circulation will be carried out to condensate the solvent vapour and to the receivers of the solvent vapors which ensures the maximum recovery.
- Solvent vapours from the Centrifuge and Catch pots will be connect to vent condensers.
- The height of the solvent receiver tank vent is above production block roof level and the diameter is 20 mm.
- Flame proof fitting / equipments / pumps / lighting will be used wherever solvents are used. The solvent storage tanks will be provided with breather valve to prevent losses
- Industry has proposed solvent recovery unit with 32 (existing 22 & proposed 10) simple and fractional distillation columns ranging from 2 KL to 8 KL capacity batch / continuous columns height ranging from 12 m to 20 m with Primary and Secondary condenser facility. Industry also proposes additional solvent recovery units.

Solvent Input	Solvent Loss in Effluent	Solvent Loss in Org. residue	Solvent Loss (Handling)	Solvent Recovery	Solvent Recovery
(KLD)	(KLD)	(KLD)	(KLD)	(KLD)	(%)
326	3.1	2.7	13.6	306.5	94

3.5 Emissions–Utilities

Industry has already installed 30 TPH coal fired boiler for 3 MW CPP. Proposes an additional 20 TPH coal fired boiler for 2 MW CPP. Existing 10 TPH, 4 TPH coal fired boilers and 15 lac K.cal/hr coal fired thermic fluid heater will remain standby and will be used during the maintenance. Existing DG sets of 320 KVA and 5x1010 KVA DG sets will be utilized only in case of power failure.

Additional 20 TPH boiler is to meet the steam requirement for recovery of by-products from waste streams, purification of by-products by adding additional stage and recovery of additional solvents.

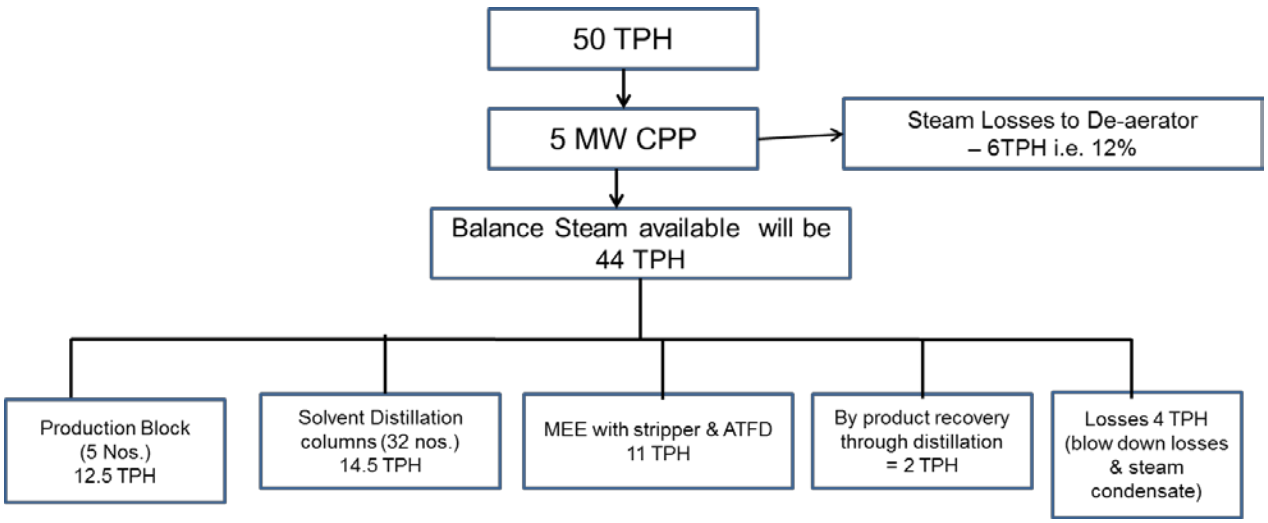
Table 8: Stack Emission Details

Source	Stack Height (m)	Diameter (m)	Temperature (°C)	Flue Gas Flow rate (m^3/hr)	Exit Gas Velocity (m/sec)	PM	SO_2	NOx
						kg/hr		
Coal Fired Boiler								
Additional 20 TPH	45	1.1	150	55440	16.2	2.93	35.42	26.24
Existing 30TPH	55	1.3	150	82404	17.3	4.32	56.23	39.38

The various measures proposed to minimize the pollution from the boiler are as follows:

- Electrostatic Precipitator (ESP) will be installed to control the particulate (PM) emissions within statutory limit of 115 mg/Nm^3. To facilitate wider dispersion of pollutants, 45 m height stack will be installed for 20 TPH Boiler.
- The NOx emissions from the boilers will be controlled by controlling combustion measures, which will be approached by way of low NOx burners or by air stagging in boiler. The NOx emissions will be restricted to below 500 mg/Nm^3.
- Fugitive dust are controlled by adopting dust extraction and dust suppression measures and development of greenbelt along the periphery of the proposed Boiler area.

Boiler Steam Distribution:



3.6 Waste Minimization

Industry proposed to purify some crude by-products using mixed solvents and reusing them in the products and recover some by-products out of waste, thereby minimizing the waste from the products manufactured.

4.0 Conclusions

After thoroughly verifying the requirements and approvals given to the industry, it was identified that the steam and power requirement has been underestimated by industry. Hence proposed to install an additional 20 TPH boiler for 2 MW Captive Power generation along with the permitted 3MW Captive Power Plant using 30 TPH coal fired boiler to meet the underestimated steam requirements of the industry. Industry also felt that about 20 products added does not have good market and hence proposed to drop 20 products from the total 65 products. Thereby total products reduced to 45 and modified production capacity marginally increased by 20 TPA. The industry also proposed to adopt waste minimization techniques and recover some by-products out of waste and purify some by-products for re-use in the plant.

Following points are identified from the above EMP:

1. Total production capacity marginally increased from 200 TPM to 201.67 TPM.
2. Overall process effluent marginally increased from 171 KLD to 176 KLD.
3. Overall solid waste has marginally increased from 25138 kg/day to 26842 kg/day.
4. Overall solvent recovery improved from 93% to 94%.
5. Overall reduction in gaseous emissions from 1712 kg/day to 1507 kg/day.
6. Spent Mixed solvents are used for purification and recovery of by-products that was previously included in Hazardous waste is now recovered.

Industry humbly requests the MoEF&CC and EAC to consider the above Amendments to Environmental Clearance and issue us the EC Amendment.

Annexures

F. No. J-11011/375/2013-IA II (I)
Government of India
Ministry of Environment, Forests and Climate Change
(I.A. Division)

Indira Paryavaran Bhawan
Aliganj, Jorbagh Road,
New Delhi -110003

E-mail: lk.bokolia@nic.in
Telefax: 011-24695313
Dated 30th December, 2015

To,

Shri M. Narayan Reedy, Managing Director
M/s Covalent Lab. Pvt. Ltd.
8-3-677/18, SKD Nagar,
Yellareddyguda,
Hyderabad – 500073

Email.: info@covalentlabs.com ; Fax.: 040-49483396

Subject: Expansion of bulk drugs & intermediate manufacturing unit-I alongwith CPP (3MW) at Village Gundlamachanoor, Mandal Halnoor, District Medak, Telangana (Formerly in Andhra Pradesh) by M/s Covalent Lab. Pvt. Ltd. – Environmental Clearance reg.

Ref.: Your online proposal no. IA/TG/IND/26256/2013 dated 27th January, 2015.

Sir,

This has reference to your online proposal no. IA/TG/IND/26256/2013 dated 27th January, 2015 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report alongwith Public Hearing Report regarding above mentioned project and subsequent submission of additional information vide letter dated 30th April, 2015.

2.0 The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for expansion of bulk drugs & intermediate manufacturing unit-I alongwith CPP (3MW) at Village Gundlamachanoor, Mandal Halnoor, District Medak, Telangana (Formerly in Andhra Pradesh) by M/s Covalent Lab. Pvt. Ltd. Cost of project is Rs. 212.94 crores. Out of which, Rs. 21.0 Crore and Rs. 6.0 Crore per annum towards capital cost and recurring cost per annum for implementation of environmental management plan. Nakka Vagu and Manjeera River is flowing at a distance of 1km and 2.5 Km respectively. It is reported that no ecological sensitive area or protected area as per wildlife protection Act, 1972 is located within 10 km distance. The said industry is located at a distance of 15 Km from the CEPI identified Patancheru-Bollaram stretch. Total plot area is 155197 m^2, of which greenbelt will be developed in 55871 m^2 area. It is proposed to manufacture 65 bulk drugs and its intermediates on campaign basis with any 20 products manufactured at a time along with 3 MW Captive Power Plant. List of existing products being manufactured is given below:

S.N.	Product Name	Quantity (TPA)
Environmental Clearance (EC)		
1	Flucinazole	2.16

2	Nalidixic acid	14.4
3	Naproxen	36
Consent from APPCB		
1	Cefixime	24.00
2	Cefpodoxime Proxetil	11.99
3	Cefurosime Axetil	24.00
4	Cefuroxime Sodium	3.00
5	Ceftriaxone Sodium	6.00
6	Cefpirome	3.00
7	Cefdini	6.00
8	Cefprozil	3.00
9	Cefepime	6.00

List of proposed products to be manufactured is as given below:

S.N.	Product Name	Quantity (TPA)
1	Cefixime Trihydrate	780
2	Cefpodoxime Proxetil	120
3	Cefurosime Axetil	180
4	Cefuroxime Sodium	180
5	Cefdinir Monohydrate	72
6	Cefprozil Monohydrate	60
7	Meropenem	60
8	Doripenem Monohydrate	60
9	7-AVNA	60
10	MEAT (Thio Ester)	60
11	Cefuroxime Acid	36
12	Cefotaxime Sodium	36
13	Faropenem Sodium	36
14	7-APCA	36
15	Cefuroxime Sodium	24
16	Cefpirome Sulfate	12
17	Cefepime Dihydrochloride Monohydrate	12
18	Cefditoren Pivoxil	12
19	Ceftibuten Monohydrate	24
20	Cefazoline Sodium	12
21	Cefoperazone Sodium	12
22	Cefoxitin Sodium	6
23	Ceftazidime Pentahydrate	6
24	Ceftizoxime Sodium	12
25	Cephalothin Sodium	12
26	Cefpodoxime Acid	12
27	Cefcapene Pivoxil	9.6
28	Cefmetazole Sodium	12
29	Cefmetazole	12
30	Imipenem	24
31	Cilastatin Sodium	24
32	Ertapenem Sodium	12
33	Biapenem	12
34	Panipenem	12
35	Tebipenem Pivoxil	1.2
36	Darifenacin Hydrabromide	6
37	Solifenacin Succunate	6
38	Tolterodine Tartrate	6
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thai-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7- AMCA)	12
40	7-Amino3-thiazole cephalosporanic acid (7-ATCA)	24
41	Lacosamide	120

42	Cinacalcet Hydrochloride	120
43	Fexofenadine Hydrochloride	120
44	Dronedarone Hydrochloride	120
45	Deferasirox	120
46	Silodosin	24
47	Fingolimod Hydrochloride	24
48	Sitaglinptin Phosphate	24
49	Prasugrel Hydrochloride	24
50	Venlafaxine Hydrochloride	24
51	Pregabalin	24
52	Diacerein	24
53	Linezolid	24
54	Ropinirole Hydrochloride	24
55	D-Cycloserine	24
56	Clopidogrel Hydrogen Sulfate	24
57	Bosentan	24
58	Candesartan Cilexitil	24
59	Febuxostat	24
60	Azilsartan medoxomil	24
61	Solifenacin Succinate	24
62	Darifenacin Hydrobromide	24
63	Trospium Chloride	24
64	Tolterodine Tartrate	24
65	Valsartan	24
Total production capacity 2400TPA (Maximum 20 Products at a time) with 3MW coal based CPP		

S.N.	By-Product	TPA	By product from the product
Proposed By- Products from APIs & API Intermediates			
1.	Triphenylphosphine oxide	565.5	CefiximeTrihydrate
		159.94	Cefdinir Monohydrate
		62.4	Cefprozil Monohydrate
		17.16	CefditorenPivoxil
		4.2	CeftazidimePentahydrate
		88.78	7-AVNA
		60.0	MEAT (Thio Ester)
		52.94	7-APCA
		34.32	7-Amino3-thiazole cephalosporanic acid (7-ATCA)
2.	2-Mercaptobenzothiazole	280.8	CefiximeTrihydrate
		57.6	CefpodoximeProxetil
		3.84	Cefpirome Sulfate
		88.46	Cefdinir Monohydrate
		3.6	CefepimeDihydrochloride Monohydrate
		6.0	CefditorenPivoxil
		4.8	CeftazidimePentahydrate
		100.8	Cefotaxime Sodium
		6.0	Ceftizoxime Sodium
		6.47	Cefpodoxime Acid
		36.36	MEAT (Thio Ester)
3.	Sodium Acetate	549.82	Cefuroxime Axetil

3.0 Electrostatic precipitator (ESP) and the stack of adequate height will be provided to coal fired boiler (30 TPH) and Multi cyclone dust collector followed by Bag filter with a adequate height will be provided 10 TPH Coal fired boiler (standby) and 4 TPH & 15 lac K.cal/hr Thermic Fluid heater (standby) for controlling the particulate matter and effective dispersion of flue gases. Scrubber will be provided to control process emissions viz. HBr, HCl, HF and SO_2. Fresh water requirement from ground water source /tanker supply will be increased from 53.5 m3/day to 457 m^3/day after expansion. Effluent generation will be increased from 9.2 m^3/day to 298 m^3/day after expansion. Industrial effluent will be segregated into low and high strength streams based on characteristics of wastewater viz. TDS, COD etc. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS/COD effluent stream will be treated in the effluent treatment plant (ETP) based biological treatment process followed by reverse osmosis (RO). No effluent will be discharged outside the premises and 'Zero' effluent discharge concept will be adopted. Evaporation salt, process inorganic salts and sludge from wastewater pre-treatment will be sent to TSDF. Process organic residues, spent carbon, spent mixed solvents will be sent cement manufacturers. Fly ash will be sent to cement plant. Catalyst, waste oil and used batteries will be sent to authorized recyclers.

4.0 Public hearing/consultation meeting was held on 4th December, 2014.

5.0 All Synthetic Organic Chemicals Industry located outside the notified industrial area/estate are listed at S.N. 5(f) under category 'A' and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry) in its meetings held during 29th - 30th January, 2014, 16th – 17th March, 2015 and 30th November, 2015-1st December, 2015 respectively. Project Proponent and the EIA Consultant namely M/s KKB Envirocare Consultants Pvt. Ltd. have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be adequate and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance. M/s Covalent Lab. Pvt. Ltd. has passed a resolution in a meeting of the Board of Directors held on 8th July, 2015 that violation of the Environmental (Protection) Act, 1986 will not be repeated. A copy of Board Resolution is submitted. Collector & District Magistrate, Medak has filed case against the unit at Addl. Judge First Class Magistrate Narsapur on 19.08.2015 for violation of provisions of the EIA Notification, 2006.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment and Forests hereby accords environmental clearance to above project under the provisions of EIA Notification dated 14th September 2006, subject to the compliance of the following Specific and General Conditions:

A. SPECIFIC CONDITIONS:

i) Compliance to all the environmental conditions stipulated in the environmental clearance letter no. J-11011/88/2004-IA II(I) dated 30th November, 2004 shall be satisfactorily implemented and compliance reports submitted to the Ministry's Regional Office at Bangalore.

ii) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.

iii) Electrostatic precipitator (ESP) and the stack of adequate height shall be provided to coal fired boiler (30 TPH) and Multi cyclone dust collector followed by Bag filter with a adequate height shall be provided 10 TPH Coal fired boiler (standby) and 30m combined stack for 4 TPH & 15 lac K.cal/hr Thermic Fluid heater (standby) for controlling the particulate matter and effective dispersion of flue gases.

iv) Scrubber shall be provided to control process emissions viz. HBr, HCl, HF and SO_2. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.

v) Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of $PM_{2.5}$, PM_{10}, SO_2, NOx, VOC, CO, HBr, HCl and HF shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and the State Pollution Control Board (SPCB).

vi) In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the SPCB. Odour management plan shall be implemented.

vii) The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.

viii) Solvent management shall be carried out as follows :

i. Reactor shall be connected to chilled brine condenser system

ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.

iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.

iv. Solvents shall be stored in a separate space specified with all safety measures.

v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.

vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

vii. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.

ix) Total fresh water requirement from ground water source and tanker supply shall not exceed 457 m^3/day and prior permission shall be obtained from the CGWA/SGWA.

x) Effluent generation shall not exceed 298 m^3/day. Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/reused within

factory premises. 'Zero' effluent discharge shall be adopted and no effluent will be discharged outside the premises.

xi) 'Zero' effluent discharge shall be adopted and no effluent shall be discharged outside the premises.

xii) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.

xiii) Automatic /online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the respective SPCB and in the Company's website.

xiv) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.

xv) As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/cement industry.

xvi) The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from TPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.

xvii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 *as* amended time to time. All Transportation of Hazardous Chemicals shall be *as per* the Motor Vehicle Act (MVA), 1989.

xviii) Fly ash should be stored separately as per CPCB guidelines so that it should not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing alongwith the storm water. Direct exposure of workers to fly ash & dust should be avoided.

xix) The company shall undertake following waste minimization measures :-

a. Metering and control of quantities of active ingredients to minimize waste.

b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.

c. Use of automated filling to minimize spillage.

d. Use of Close Feed system into batch reactors.

e. Venting equipment through vapour recovery system.

f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.

xx) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.

xxi) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

xxii) All the issues raised during the Public Hearing/consultation meeting held on 4th December, 2014 shall be satisfactorily implemented and adequate budget provision shall be made accordingly.

xxiii) At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment based on Public Hearing issues and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office at Bangalore. Implementation of such program shall be ensured accordingly in a time bound manner.

xxiv) As proposed, green belt of 55871 m^2 shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.

xxv) Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.

B. GENERAL CONDITIONS:

i. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), State Government and any other statutory authority.

ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In *case* of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

iii. The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.

iv. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).

v. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.

vi. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.

vii. Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.

viii. The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.

ix. The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.

x. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.

xi. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

xii. As proposed, the company shall earmark sufficient funds towards capital cost and recurring cost/annum to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.

xiii. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who suggestions/ representations, if any, were received while processing the proposal.

xiv. The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the AP Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

xv. The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.

xvi. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at http://envfor.nic.in. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.

xvii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

8.0 The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

9.0 The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

10.0 The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention &. Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Waste (Management, Handling

and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

(Lalit Bokolia)
Additional Director

Copy to :-

1. The Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Telangana, Hyderabad, A.P.
2. The Chief Conservator of Forests, Regional Office (Southern Zone, Bangalore) Kendriya Sadan, 4th Floor, E&F Wing, II Block Koramangala, Banglore-560034.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Telangana Pollution Control Board, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, Hyderabad - A.P.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, *Jorbagh Road*, New Delhi.
6. Guard File/Monitoring File/Record File.

(Lalit Bokolia)
Additional Director

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

Phone: 23887500
Fax: 040 – 23815631
Grams : Kalushya Nivarana

REGD.POST WITH ACK.DUE

CONSENT ORDER FOR ESTABLISHMENT – RED CATEGORY

Order No. 01/TSPCB/CFE/RO-SR-I/HO/2016 –1596 **Dt. 29.09.2016**

Sub: PCB – CFE - M/s. Covalent Laboratories Pvt. Ltd located at Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A Gundlamachanoor (V), Hatnoora (M), Medak District – Consent for Establishment of the Board for **Expansion** under Sec.25 of Water (P & C of P) Act, 1974 and Under Sec.21 of Air (P&C of P) Act, 1981 - Issued - Reg.

Ref:
1. EC order for expansion issued by MoEF, GoI dt. 31.12.2015.
2. Industry's CFE application received through the Commissioner of Industries, Hyderabad under TS-iPASS on 29.12.2015.
3. R.O's inspection report dt. 02.01.2016.
4. CFE Committee meeting held on 12.01.2016.
5. T.O. Letter No.01/TSPCB/CFE/RO-SR-I/HO/2016-2352 Dt. 13.01.2016.
6. Industry's lr. dt. 16.04.2016 & 31.05.2016.
7. CFE Committee meeting held on 15.06.2016.
8. T.O. Lr. dt. 15.07.2016.
9. Industry's lr. dt. 21.07.2016.
10. CFE Committee meeting held on 20.09.2016.
11. Industry's undertaking lr. dt. 23.09.2016.

***

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **Expansion** to produce the following products with an additional investment of Rs. 100.0 Crores;

The industry shall not produce more than 20 products and individual capacities mentioned therein at any given point of time.

Sl. No.	Name of the Product	Quantity (Kg/Day)	No. of Stages	Starting Raw Material	Quantity (Kg/Day)
1	Cefixime Trihydrate	2167	3	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenyl acetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	2762.5
2	Cefpodoxime Proxetil	333	2	7-Amino cephalosphoranic acid	262.86
3	Cefuroxime Axetil	500	3	7-Amino cephalosphoranic acid	341.82
4	Cefuroxime Sodium	67	1	Cefuroxime Acid	72
5	Ceftriaxone Sodium	500	1	Ceftriaxone Sodium (Crude)	520
6	Cefpirome	33	3	7-Aminodesacetoxy	21.33

	Sulfate			Cephalosphoranic acid	
7	Cefdinir Monohydrate	200	4	Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	185.71
8	Cefprozil Monohydrate	167	3	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	306.67
9	Cefepime Dihydrochloride Monohydrate	33	2	7-Aminodesacetoxy Cephalosphoranic acid	19.33
10	Cefuroxime Acid	100	2	7-Amino cephalosphoranic acid	75.2
11	Cefditoren Pivoxil	33	3	4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4-carboxylate	83.33
12	Ceftibuten Monohydrate	67	2	4-Nitrobenzyl-7-(2-phenyl acetamido)-8-oxo-5-thia-1-azabicyclo-[4,2,0]oct-2-ene-2-carboxylate	233.33
13	Cefazoline Sodium	33	3	7-Aminodesacetoxy Cephalosphoranic acid	28.33
14	Cefoperazone Sodium	33	3	7-Amino desacetoxy cephalosporanic acid	25
15	Cefoxitin Sodium	17	4	7-Aminocephalosporanic acid	30
16	Ceftazidime Pentahydrate	17	6	7-Aminodesacetoxy Cephalosphoranic acid	12.5
17	Cefotaxime Sodium	100	2	7-Aminocephalosporanic acid	457.14
18	Ceftizoxime Sodium	33	1	7-Amino-3-nor-3-cephem-4-carboxylic acid	21.67
19	Cephalothin Sodium	33	2	7-Aminocephalosporanic acid	30
20	Cefpodoxime Acid	33	1	7-Amino cephalosphoranic acid	30.26
21	Cefcapene Pivoxil	27	2	7-Amino Cephalosporanic acid	63.59
22	Cefmetazole Sodium	33	3	7-MAC	57.33
23	Cefmetazole	33	2	7-MAC	54.09
24	Meropenem	167	2	β-Methyl Vinyl Phosphate	473.33
25	Imipenem	67	3	p-Nitrophenylhydroxyet	257.33

				hyl-3,7-dione Carboxylate	
26	Cilastatin Sodium	67	3	S-2,2-Dimethyl cyclopropyl Caroboxamide	74.07
27	Ertapenem Sodium	33	2	*p*-Nitrobenzyl (4R,5S,6S)-3-(diphenyloxy) phosphoryloxy-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3,2,0]hept-2-ene-2-carboxylate	92.67
28	Doripenem Monohydrate	167	3	4-Nitrobenzyl(2S,4S)-4-acetyl thio-2-[[N-sulfonyl-N-(tert - butoxy carbonyl) amino] methyl]pyrrolidine-1-carboxylate	416.67
29	Biapenem	33	2	2-((4-Nitrobenzyloxy)carbonyl)-6-(1-hydroxyethyl)-4-methyl-7-oxo-1-aza-bicyclo [3,2,0] hept-2-en-3-yl diphenyl phosphite	139
30	Faropenem Sodium	100	5	4-Acetoxyazetidinone	198
31	Panipenem	33	2	4-Nitrobenzyl-6-(1-hydroxy ethyl)-4-methyl-3,7-dioxo-1-aza-bicyclo[3.2.0] heptane-2-carboxylate	10.87
32	Tebipenem Pivoxil	3	2	β-Methyl Vinyl Phosphate	5.5
33	Darifenacin Hydrobromide	17	6	N-BOC-3-hydroxy pyrrolidine	16.67
34	Solifenacin Succinate	17	5	Phenyl Ethylamine	7.17
35	Tolterodine Tartrate	17	4	3,4-dihydro-6-methyl-4-phenyl-2H-benzopyran-2-one	15.33
36	7-AVNA	167	2	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenyl acetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	433.67
37	MEAT (Thio Ester)	167	1	Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	131.31
38	7-APCA	100	2	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-	270.59

				bicyclo][4.2.0]octa-2-ene-2-carboxylate	
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33	1	7-Amino cefalosporanic acid	41.67
40	7-Amino3-thiazole cephalosporanic acid (7-ATCA)	67	1	4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4-carboxylate	166.67
41	Lacosamide	333	1	(R)-2-Amino-N-benzyl-3-methoxy propanamide	333.33
42	Silodosin	67	1	Protected Silodosin	111
43	Fingolimod Hydrochloride	67	1	2-(4-Octylbenzylsulfonyl)benzo [d]thiazole	133.33
44	Cinacalcet Hydrochloride	333	1	3-(3'-Trifluoromethyl phenyl) propyl bromide	256.67
45	Fexofenadine Hydrochloride	333	1	Azacyclanol	208.33
46	Sitagliptin Phosphate	67	1	(3R)-3-[(1,1-Dimethylethoxy carbonyl)-amino]-4-(2,4,5-trifluorophenyl)butanoic acid	69.33
47	Prasugrel Hydrochloride	67	2	Thienohydropyridone	53
48	Venlafaxine Hydrochloride	67	1	2-(4-Methoxyphenyl)-N,N-dimethyl acetamide	133.33
49	Pregabalin	67	1	Ethyl-2-Bromoacetate	133.33
50	Diacerein	67	2	Dibenzyl Aloe-Emodin	96
51	Dronedarone Hydrochloride	333	1	(2-Butyl-5-nitrobenzofuran-3-yl) (4-hydroxy phenyl)methanone	300
52	Linezolid	67	1	3-Fluoro-4-Morpholino benzenamine	55.67
53	Ropinirole Hydrochloride	67	1	2-(2-(2-(Dipropylamino) ethyl) phenyl)-N-hydroxyacetamide	78.33
54	D-Cycloserine	67	1	N-Benzyloxycarbonyl-D-Serine	196
55	Clopidogrel Hydrogen Sulfate	67	1	Methyl-2-bromo-2-(2-chloro phenyl)acetate	52.33
56	Bosentan	67	1	5-(2-Methoxyphenoxy)-4,6-dichloro-2-	55.67

				(pyrimidin-2-yl) pyrimidine	
57	Candesartan Cilexitil	67	1	Trityl Candesartan	94
58	Deferasirox	333	1	2-(2-Hydroxyphenyl)-4H-benzo[e][1,3] oxazin-4-one	266.67
59	Febuxostat	67	1	3-Cyano-4-isobutoxy benzothioamide	133.33
60	Azilsartan medoxomil	67	1	Azilsartan	66.67
61	Solifenacin Succinate	67	1	1-(S)-phenyl-1,2,3,4-tetrahydro-2-isoquinoline carboxylate	66.67
62	Darifenacin Hydrobromide	67	1	2,2-Diphenyl-2-((S)-pyrrolidin-3-yl)acetamide	46
63	Trospium Chloride	67	1	Spiro[bicyclo[3.2.1]octane-8,1'-pyrrolidin]-1'-ium chloride	44.33
64	Tolterodine Tartrate	67	1	3-(2-methoxy-5-methyl phenyl)-3-phenyl propan-1-ol	44.33
65	Valsartan	67	1	L-Valine	24
Maximum production capacity on worst combination i.e., for any 20 products at a time		**6667 kg/day**			
Coal based captive power plant		**3 MW**			

2. The above site was inspected by the Environmental Engineer, Regional Office-I, Sangareddy, T.S. Pollution Control Board on 31.12.2015 and observed that the site is surrounded by

North : M/s. Aurobindo Pharma Ltd., Unit – IX
South : Gundlamachanoor Village Road.
East : Agricultural lands.
West : Narsapur to Sangareddy Road

3. The issue of CFE to the industry was placed before the CFE Committee meetings held on 12.01.2016, 15.06.2016 & 20.09.2016. The Committee examined the provisions of TS-iPASS Act and stipulated timelines under the Act. As per the Act Red Category industry applications shall be processed within 21 days. The Committee after detailed examination recommended to grant provisional CFE order for expansion to the industry subject to condition that the industry will comply with the standards prescribed by the MoEF as well as the directions of Hon'ble National Green Tribunal, Principal Bench, at New Delhi.

4. The industry vide ref. 11th cited submitted undertaking on Rs. 100/- non-judicial stamp paper to abide by all the directions and orders of the Hon'ble NGT, Principal Bench, New Delhi in OA No. 100 of 2014 and Hon'ble NGT, Southern Bench, Chennai in Application No. 90 of 2013 and batch cases and any other Courts of Law, issued till now and also in future.

5. The Board, after careful scrutiny of the application and verification report of Regional Officer and recommendations of CFE Committee, hereby Issues **CONSENT FOR ESTABLISHMENT for Expansion** to your unit Under Section 25 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is Issued to manufacture the products as mentioned at para (1) only.**

6. **This order is subject to the directions of Hon'ble NGT, New Delhi in OA No. 100 of 2014 filed by Dr. A. Kishan Rao against Union of India & Ors.**

7. **This CFE order is issued as per the provisions of G.O.Ms.No. 64, dt. 23.07.2013 and is subject to the outcome of cases pending in the Hon'ble National Green Tribunal, Southern Zone, Chennai or in any other court.**

8. **The industry shall comply with the standards prescribed by the MoEF as well as the directions of Hon'ble National Green Tribunal, Principal Bench, at New Delhi.**

9. This Consent Order now issued is subject to the conditions mentioned in Schedule 'A' and Schedule 'B'.

10. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

Encl: Schedule 'A'
Schedule 'B'

Sd/-
MEMBER SECRETARY

To,
M/s. Covalent Laboratories Pvt. Ltd located.
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V), Hatnoora (M), Medak District.

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

SENIOR ENVIRONMENTAL ENGINEER

29/9

SCHEDULE - A

1. Progress on implementation of the project shall be reported to the concerned Regional Office, T.S. Pollution Control Board once in six months.

2. Separate energy meters shall be provided for Effluent Treatment Plant (ETP) and Air pollution Control equipments to record energy consumed.

3. The proponent shall obtain Consents for Operation (CFO) from TSPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981, before commencement of the activity.

4. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec.27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control of Pollution) Act, 1981 to review any or all the conditions imposed herein and to make such alternation as deemed fit and stipulate any additional conditions by the Board.

5. The consent of the Board shall be exhibited in the factory premises at a conspicuous place for the information of the inspecting officers of different departments.

6. Compensation is to be paid for any environmental damage caused by it, as fixed by the Collector and District Magistrate as civil liability.

7. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. The industry shall maintain a good housekeeping. All pipe valves, sewers, drains shall be leak proof. Dyke walls shall be constructed around storage of chemicals.

8. Rain Water Harvesting (RWH) structure (s) shall be established on the plant site. The proponent shall ensure that effluent shall not enter the Rain Water harvesting structure.

9. The rules and regulations notified by Ministry of Law and Justice, GOI, regarding the Public Liability Insurance Act, 1991 shall be followed.

10. **This order is valid for period of 5 years from the date of issue.**

SCHEDULE – B

Water:

1. The source of water from Bore Well / Private tanker supply. The maximum permitted fresh water consumption for worst combination after expansion is 457 **KLD**.

Sl. No.	Purpose	Quantity (KLD)
1	Process & Washings	186 KLD
2	Boiler Feed	145 KLD
3	Cooling tower makeup	23 KLD
4	DM Generation	10 KLD
5	Scrubber	8 KLD
6	QC & R & D	5 KLD
7	Gardening	50 KLD
8	Domestic	30 KLD
	Total:	**457 KLD**

2. The maximum Waste Water Generation (KLD) from worst combination shall not exceed the following after expansion:

Sl. No.	Purpose	Quantity (KLD)
1	Process a. HTDS process & washings b. LTDS process & wasings	175 KLD 25 KLD
2	Boiler Blow Down	25 KLD
3	Cooling towers	25 KLD
	DM Generation	10 KLD
	Scrubber	8 KLD
	QC & R & D	5 KLD
4	Domestic	25 KLD
	Total	**298 KLD**

Treatment & Disposal:

Outlet No.	Stream	Mode of final disposal
1	HTDS Effluents (Process)	• Shall be stripped off for organics recovery. • Stripper condensate for distillation 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 for evaporation. • Condensate from MEE & ATFD to Biological ETP. • Evaporation salts from ATFD to TSDF.
2	LTDS Effluents (Process, Boiler blow down, cooling blow down, DM water, domestic and others)	Shall be treated in Biological ETP followed by RO plant. RO Permeate shall be reused and rejects shall be sent to MEE.

3. The proponent shall collect effluents from all the streams and adopt treatment as mentioned above.

4. The industry shall strictly maintain ZLD system in closed circuit system. There shall not be any discharge / spillages of effluent within or outside the premises. All the units of the ZLD system shall be impervious to prevent ground water pollution.

5. **The industry shall use only fresh water for gardening purposes**

6. During transfer of materials, spillages shall be avoided and garland drains shall be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.

7. Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned below.

   a) Industrial cooling, boiler feed.
   b) Domestic purposes.
   c) Processing, whereby water gets polluted and pollutants are easily bio-degradable.
   d) Processing, whereby water gets polluted and the pollutants are not easily bio-degradable.

8. **The industry shall provide magnetic flow meters with totalisers with recording facility at inlet of collection tank, Stripper feed, MEE feed, RO feed and RO permeate separately for measuring effluent generation, treatment and recycled. The industry shall provide steam flow meter to the inlet collection line of MEE.**

9. **The industry shall maintain & operate IP camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability at HTDS & LTDS effluent collection system as per the CPCB norms & connect the same to CPCB & TSPCB servers.**

Air Pollution after expansion:

10. The proponent shall comply with the following for controlling air pollution after implementation of expansion.

	Details of Stack	Stack 1	Stack 2	Stack 3	Stack 3	Stack 4	Stack 6
a.	Attached to:	Coal Fired Boiler	Coal Fired Boiler	Coal Fired Boiler	Coal Fired thermic fluid heater **(Standby)**	DG Set	DG sets
b.	Capacity of Boiler / Furnace/ Kiln / Incinerator / D.G. Set / Others	4 TPH	10 TPH (Standby)	30 TPH	15 Lakh K.Cal/hr	1 x 320 KVA	5 x 1010 KVA
c.	Fuel form: Solid / Liquid / Gaseous	Coal				HSD	
d.	Fuel quantity (L/KL per day)	150 TPD				1075 Ltrs/Hr	
e.	Stack Height: i) Above the roof ii) Above the Ground (m)	30 mtrs	30 mtrs	55 mtrs	30 mtrs	As per CPCB Norms	
f.	Diameter / Size, in mtrs.	0.9 mtrs	0.9 mtrs	1.3 Mtrs	0.9 mtrs	–	0.8m
g.	Details of Air Pollution Control Equipment:	Multi Cyclone dust collector followed by bag filter	Multi Cyclone dust collector followed by bag filter	ESP with 3 Fields	Multi Cyclone dust collector followed by bag filter	Acoustic enclosures	Acoustic enclosures

11. **The industry shall use the high pressure steam generated from the 30 TPH boiler for power generation (Co-generation). The standby boiler shall not be used for power generation purpose under any circumstances. There shall not be any additional fuel usage for power generation.**

12. **The industry shall not operate the standby boiler for regular purpose under any circumstances. In case of any exigencies the industry shall operate the standby boiler with prior intimation to RO-I, Sangareddy.**

13. **The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoE&F, GoI vide notification No. GSR 826(E), dated. 16.11.2009 during construction and regular operational phase of the project.**

14. The industry shall install multi-stage scrubbers for control of gaseous emissions. The scrubbed solutions shall be reused to the possible extent. The industry shall keep the record of disposal of all such by-products and shall submit the record to concerned Regional Officer.

15. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.

16. The proponent shall not send the spent/mixed solvents to the recyclers. They shall process the same at solvent recovery plant within the plant premises. Solvents shall be recovered to the maximum extent possible and shall be reused.

17. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.

18. The evaporation losses in solvents shall be controlled by taking the following measures:

    i) Chilled brine circulation shall be carried out to effectively reduce the solvent losses into the atmosphere.
    ii) Transfer of solvents shall be done by using pumps instead of manual handling.
    iii) Closed centrifuges shall be used due to which solvent losses will be reduced drastically.
    iv) The reactor vents shall be connected with primary & secondary condensers to catch the solvent vapours.
    v) All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours.

19. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.

20. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack , from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.

21. The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.

Solid Waste:

22. The proponent shall comply with the following from worst combination after implementation of expansion:

HAZARDOUS WASTE WITH DISPOSAL OPTION:

Sl.No.	Solid Waste generated from	Quantity	Method of Disposal
1	Organic Process Residue	9.4 TPD	TSDF, Dundigal, RR District for incineration / cement plants for co-incineratoin in rotary kilns.
2	Spent Carbon	0.98 TPD	
3	Inorganic & Forced Evaporation Salts	18.6 TPD	TSDF, Dundigal, RR District for secured land filling
4	ETP sludge	1 TPD	
5	Boiler ash	45 TPD	Sold to cement brick manufacturers

HAZARDOUS WASTE WITH RECYCLING OPTION:

SL.No.	Solid Waste generated from	Total after expansion	Method of Disposal
1	Containers & container liners of Hazardous Chemicals and wastes including HDPE carboys, Fiber drums & PP Bags.	2200 Nos/month	After complete detoxification, it should to disposed to the outside agencies.
2	Spent mixed solvents	6 KLD	Recovery within the premises/ Spent to APPCB authorized agencies.
3	Waste oils & Grease	2 KL/Annum	Sent to APPCB authorized agencies for reprocessing / recycling.
4	Used lead acid batteries	100 Nos./ Annum	Sent to suppliers on buy back basis.

23. The proponent has furnished the list of the following by-products from the proposed list of products. There shall not be any new pollution load at on-site of the premises result in from reception, handling and disposal of these by-products / waste streams at source of the industry. The proponent shall maintain log registers on quantity of waste generation and details of end use of the waste disposed.

S.No.	By-Product	TPA	By product from the product
Proposed by-product from APIs & API intermediates			
1.	Triphenylphosphine oxide	565.5	CefiximeTrihydrate
		159.94	Cefdinir Monohydrate
		62.4	Cefprozil Monohydrate
		17.16	CefditorenPivoxil
		4.2	Ceftazidimephentahydrate
		88.78	7-AVNA
		60.0	MEAT (Thio Ester)
		52.94	7-APCA
		34.32	7-Amino3-thiazole cephalosporanic acid (7-ATCA)

2.	2-Mercaptabenzothiazole	280.8	Cefixime Trihydrate
		57.6	Cefpodoxime Proxetil
		3.84	Cefpirome Sulfate
		88.46	Cefdinir Monohydrate
		3.6	CefepimeDihydrochloride Monohycrate
		6.0	CefditorenPivoxil
		4.8	CeftazidimePentahydrate
		100.8	Cefotaxime Sodium
		6.0	Ceftizomine Sodium
		6.47	Cefpodoxime Acid
		36.36	MEAT (Thio Ester)
3.	Sodium Acetate	549.82	Cefuroxime Axetil

24. The industry shall explore to recover the by-products to the maximum extent possible for reuse or sell them so as to reduce TDS load in the effluents.

25. The proponent shall place the chemical drums and / or any drums in the concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system.

26. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.

27. The industry shall not store hazardous waste more than 90 days in their premises, as stipulated in HWM Rules.

28. The following rules and regulations notified by the MOE&F, GOI shall be implemented.

a) Hazardous and Other wastes (Management and Transboundary movement), Rules, 2016.

b) Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.

c) Batteries (Management & Handling) Rules,2010, Dt.4.5.2010

d) E-Waste (Management & Handling) Rules, 2012.

Other Conditions:

29. **The industry shall submit quarterly consumption of raw materials, chemicals including solvents and water to RO-I, Sangareddy on regular basis.**

30. **The industry shall submit quantity of hazardous wastes sent to TSDF and to cement industries for co-processing on monthly basis to RO-I, Sangareddy on regular basis.**

31. The existing green belt shall not be disturbed with proposed expansion activity and the industry shall develop green belt in an extent of 13.8 Acres, as stipulated in EC dt. 31.12.2015.

32. 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.

33. System of leak detection and repair of pump / pipeline shall be installed in the plant and immediate response team shall be identified for preventive maintenance.

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

33. The industry shall comply with all the directions issued by the Board from time to time.

34. 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.

35. **The Board reserves its right to modify above conditions or stipulate new / additional conditions and to take action including revocation of this order in accordance with the directions of Hon'ble NGT or any other Court of Law in the interest of environment protection in future. The industry cannot claim any liability from TSPCB in such case.**

36. 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 Andhra Pradesh Water Rules, 1976 and Air Rules,1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution)Act,1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

Sd/-
MEMBER SECRETARY

To,
M/s. Covalent Laboratories Pvt. Ltd located.
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V), Hatnoora (M), Medak District.

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

SENIOR ENVIRONMENTAL ENGINEER

29/9

TELANGANA STATE POLLUTION CONTROL BOARD
Paryavarana Bhavan, A-3, Industrial Estate,
Sanathnagar, Hyderabad – 500018
Ph: 040-23887500
Fax: 040- 23815631
Website: appcb.ap.nic.in

CONSENT & HW AUTHORISATION ORDER FOR EXPANSION

//By Registered Post with Acknowledgement Due//

Consent Order No : TSPCB/SRD /HO/CFO/2017 - 2861 **Date: 28.01.2017**

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 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorization / Renewal of Authorization under Rule 6 of the Hazardous and Other Wastes (Management and 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 of Air (Prevention & Control of Pollution) Act 1981 and Authorization under the provisions of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (hereinafter referred to as 'the Acts', 'the Rules') and the rules and orders made there under to:

M/s. Covalent Laboratories Pvt. Ltd located.
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V),
Hatnoora (M),
Sangareddy district.
E-mail: guptas@covalentlab.com

(hereinafter referred to as 'the Applicant') authorized to operate the industrial plant to discharge the effluents from the outlets and the quantity of Emissions per hour from the chimneys as detailed below.

i) Out lets for discharge of effluents:

Outlet No.	Description of Outlet	Max Daily Discharge in KLD	Method of treatment and Disposal
1.	High TDS effluents – 175 KLD	175 KLD	➢ Shall be stripped off for organics recovery. ➢ Strippers condensate to distillate for separation of organic compounds followed by disposal to cement plants for co-processing and distilled effluents shall be routed to CETP. ➢ Stripped effluents for Forced Evaporation in MEEs followed by ATFDs. ➢ Condensate from MEEs & ATFDs shall be routed to Biological ETP system. ➢ ATFDs salts to TSDF.
2.	Low TDS effluents: Process & Washings -25 KLD+ Boiler Blow Down – 25 KLD Cooling towers – 25 KLD + DM Generation - 10 KLD +	123 KLD	➢ LTDS effluents along with condensate from MEEs & ATFDs shall be treated in the Biological ETP. ➢ Treated effluents from ETP shall

	Scrubber – 8 KLD + QC & R & D – 5 KLD + Domestic - 25 KLD (Septic tank overflow)		be filtered in the RO Plant ➢ RO Permeate water to boiler / cooling tower makeup. ➢ RO rejects to ATFDs.
	TOTAL	**298 KLD**	

* The industry shall send the septic tank overflow to the LTDS treatment system and shall not use the soak pits.

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions in m3/hr. at peak flow
1.	Attached to 30 TPH Coal Fired Boiler	-
2.	Attached to 10 TPH Coal Fired Boiler (Stand by)	-
3.	Attached to 4 TPH Coal Fired Boiler	-
4.	Attached to 15 Lakh K.Cal/hr Coal Fired Thermic Fluid Heater (Standby)	-
5.	Attached to Process Vents	--
6.	Attached to 1 x 320 KVA + 5 x1010 KVA D.G. Sets	--

iii) HAZARDOUS WASTE AUTHORISATION (FORM – II) [See Rule 6 (2)] of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 & Amendments thereof:

1. Number of Authorization and date of issue - **TSPCB/SRD/HO/CFO/2017 - Date: 28.01.2017.**

2. **Reference of Application:** Reference No MEG0210039858CFO.

3. **M/s. Covalent Laboratories Pvt. Ltd located. Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A, Gundlamachanoor (V), Hatnoora (M), Sangareddy district**., is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:

- **HAZARDOUS WASTE WITH DISPOSAL OPTION:**

S. No.	Name of the Hazardous Waste	Stream	Total after expansion	Method of Disposal
1.	Organic Process Residue	28.1 of Schedule-I	9.4 TPD	TSDF, Dundigal, RR District for incineration / cement plants for co-incineratoin in rotary kilns.
2.	Spent Carbon	28.3 of Schedule-I	0.98 TPD	
3.	Inorganic & Forced Evaporation Salts	28.1 & 35.3 of Schedule-I	18.6 TPD	TSDF, Dundigal, RR District for secured land filling
4.	ETP sludge	35.3 of Schedule-I	1 TPD	

- **HAZARDOUS WASTE WITH RECYCLING OPTION:**

S. No.	Name of the Hazardous Waste	Stream	Total after expansion	Method of Disposal
1	Containers & Container liners of Hazardous Chemicals and wastes including HDPE carboys, Fiber drums & PP Bags.	33.1 of Schedule-I	2200 Nos/month	After complete detoxification, it should to disposed to the outside agencies.
2	Spent Mixed Solvents	28.6 of Schedule-I	6 KLD	Recovery within the premises/ Spent to APPCB authorized agencies.

3	Waste Oils & Grease	5.1 of Schedule-I	2 KL/Annum	Sent to APPCB authorized agencies for reprocessing / recycling.
4	Used lead acid batteries	A 1160 of Schedule-III	100 Nos./ Annum	Sent to suppliers on buy back basis.

➢ **OTHER WASTE:**

S. No.	Name of the Hazardous Waste	Stream	Total after expansion	Method of Disposal
1	Boiler ash	--	45 TPD	Sold to cement brick manufacturers

This consent order is valid for manufacture the following products along with quantities indicated only:

The industry shall not produce more than 20 products and individual capacities mentioned therein at any given point of time.

Sl. No.	Name of the Product	Quantity (Kg/Day)	No. of Stages	Starting Raw Material	Quantity (Kg/Day)
1	Cefixime Trihydrate	**2167**	3	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenyl acetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	2762.5
2	Cefpodoxime Proxetil	**333**	2	7-Amino cephalosphoranic acid	262.86
3	Cefuroxime Axetil	**500**	3	7-Amino cephalosphoranic acid	341.82
4	Cefuroxime Sodium	67	1	Cefuroxime Acid	72
5	Ceftriaxone Sodium	**500**	**1**	Ceftriaxone Sodium (Crude)	520
6	Cefpirome Sulfate	33	3	7-Aminodesacetoxy Cephalosphoranic acid	21.33
7	Cefdinir Monohydrate	**200**	4	Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	185.71
8	Cefprozil Monohydrate	**167**	3	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	306.67
9	Cefepime Dihydrochloride Monohydrate	33	2	7-Aminodesacetoxy Cephalosphoranic acid	19.33
10	Cefuroxime Acid	**100**	2	7-Amino cephalosphoranic acid	75.2
11	Cefditoren Pivoxil	33	3	4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4-carboxylate	83.33
12	Ceftibuten Monohydrate	67	2	4-Nitrobenzyl-7-(2-phenyl acetamido)-8-oxo-5-thia-1-azabicyclo-[4,2,0]oct-2-ene-2-carboxylate	233.33
13	Cefazoline	33	3	7-Aminodesacetoxy	28.33

	Sodium			Cephalosphoranic acid	
14	Cefoperazone Sodium	33	3	7-Amino desacetoxy cephalosporanic acid	25
15	Cefoxitin Sodium	17	4	7-Aminocephalosporanic acid	30
16	Ceftazidime Pentahydrate	17	6	7-Aminodesacetoxy Cephalosphoranic acid	12.5
17	Cefotaxime Sodium	**100**	2	7-Aminocephalosporanic acid	457.14
18	Ceftizoxime Sodium	33	1	7-Amino-3-nor-3-cephem-4-carboxylic acid	21.67
19	Cephalothin Sodium	33	2	7-Aminocephalosporanic acid	30
20	Cefpodoxime Acid	33	1	7-Amino cephalosphoranic acid	30.26
21	Cefcapene Pivoxil	27	2	7-Amino Cephalosporanic acid	63.59
22	Cefmetazole Sodium	33	3	7-MAC	57.33
23	Cefmetazole	33	2	7-MAC	54.09
24	Meropenem	**167**	2	β-Methyl Vinyl Phosphate	473.33
25	Imipenem	67	3	*p*-Nitrophenylhydroxyethyl-3,7-dione Carboxylate	257.33
26	Cilastatin Sodium	67	3	S-2,2-Dimethyl cyclopropyl Caroboxamide	74.07
27	Ertapenem Sodium	33	2	*p*-Nitrobenzyl (4R,5S,6S)-3-(diphenyloxy) phosphoryloxy-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3,2,0]hept-2-ene-2-carboxylate	92.67
28	Doripenem Monohydrate	**167**	3	4-Nitrobenzyl(2S,4S)-4-acetyl thio-2-[[N-sulfonyl-N-(tert -butoxy carbonyl) amino] methyl]pyrrolidine-1- carboxylate	416.67
29	Biapenem	33	2	2-((4-Nitrobenzyloxy)carbonyl)-6-(1-hydroxyethyl)-4-methyl-7-oxo-1-aza-bicyclo [3,2,0] hept-2-en-3-yl diphenyl phosphite	139
30	Faropenem Sodium	**100**	5	4-Acetoxyazetidinone	198
31	Panipenem	33	2	4-Nitrobenzyl-6-(1-hydroxy ethyl)-4-methyl-3,7-dioxo-1-aza-bicyclo[3.2.0] heptane-2-carboxylate	10.87
32	Tebipenem Pivoxil	3	2	β-Methyl Vinyl Phosphate	5.5
33	Darifenacin Hydrobromide	17	6	N-BOC-3-hydroxy pyrrolidine	16.67
34	Solifenacin Succinate	17	5	Phenyl Ethylamine	7.17
35	Tolterodine Tartrate	17	4	3,4-dihydro-6-methyl-4-phenyl-2H-benzopyran-2-one	15.33

36	7-AVNA	**167**	2	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenyl acetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	433.67
37	MEAT (Thio Ester)	**167**	1	Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	131.31
38	7-APCA	**100**	2	(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	270.59
39	7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid (7-AMCA)	33	1	7-Amino cefalosporanic acid	41.67
40	7-Amino3-thiazole cephalosporanic acid (7-ATCA)	**67**	1	4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4- carboxylate	166.67
41	Lacosamide	**333**	1	(R)-2-Amino-N-benzyl-3-methoxy propanamide	333.33
42	Silodosin	67	1	Protected Silodosin	111
43	Fingolimod Hydrochloride	67	1	2-(4-Octylbenzylsulfonyl)benzo [d]thiazole	133.33
44	Cinacalcet Hydrochloride	**333**	1	3-(3'-Trifluoromethyl phenyl) propyl bromide	256.67
45	Fexofenadine Hydrochloride	**333**	1	Azacyclanol	208.33
46	Sitagliptin Phosphate	67	1	(3R)-3-[(1,1-Dimethylethoxy carbonyl)-amino]-4-(2,4,5-trifluorophenyl)butanoic acid	69.33
47	Prasugrel Hydrochloride	67	2	Thienohydropyridone	53
48	Venlafaxine Hydrochloride	67	1	2-(4-Methoxyphenyl)-N,N-dimethyl acetamide	133.33
49	Pregabalin	67	1	Ethyl-2-Bromoacetate	133.33
50	Diacerein	67	2	Dibenzyl Aloe-Emodin	96
51	Dronedarone Hydrochloride	**333**	1	(2-Butyl-5-nitrobenzofuran-3-yl) (4-hydroxy phenyl)methanone	300
52	Linezolid	67	1	3-Fluoro-4-Morpholino benzenamine	55.67
53	Ropinirole Hydrochloride	67	1	2-(2-(2-(Dipropylamino) ethyl) phenyl)-N-hydroxyacetamide	78.33
54	D-Cycloserine	67	1	N-Benzyloxycarbonyl-D-Serine	196
55	Clopidogrel Hydrogen Sulfate	67	1	Methyl-2-bromo-2-(2-chloro phenyl)acetate	52.33

56	Bosentan	67	1	5-(2-Methoxyphenoxy)-4,6-dichloro-2-(pyrimidin-2-yl) pyrimidine	55.67
57	Candesartan Cilexitil	67	1	Trityl Candesartan	94
58	Deferasirox	**333**	1	2-(2-Hydroxyphenyl)-4H-benzo[e][1,3] oxazin-4-one	266.67
59	Febuxostat	67	1	3-Cyano-4-isobutoxy benzothioamide	133.33
60	Azilsartan medoxomil	67	1	Azilsartan	66.67
61	Solifenacin Succinate	67	1	1-(S)-phenyl-1,2,3,4-tetrahydro-2-Isoquinoline carboxylate	66.67
62	Darifenacin Hydrobromide	67	1	2,2-Diphenyl-2-((S)-pyrrolidin-3-yl)acetamide	46
63	Trospium Chloride	67	1	Spiro[bicyclo[3.2.1]octane-8,1'-pyrrolidin]-1'-ium chloride	44.33
64	Tolterodine Tartrate	67	1	3-(2-methoxy-5-methyl phenyl)-3-phenyl propan-1-ol	44.33
65	Valsartan	67	1	L-Valine	24
Maximum production capacity on worst combination i.e., for any 20 products at a time		**6667 kg/day**			
Coal based captive power plant		**3 MW**			

By-products:

S.No.	By-Product	TPA	By product from the product
Proposed by-product from APIs & API Intermediates			
1.	Triphenylphosphine oxide	565.5	CefiximeTrihydrate
		159.94	Cefdinir Monohydrate
		62.4	Cefprozil Monohydrate
		17.16	CefditorenPivoxil
		4.2	Ceftazidimephentahydrate
		88.78	7-AVNA
		60.0	MEAT (Thio Ester)
		52.94	7-APCA
		34.32	7-Amino3-thiazole cephalosporanic acid (7-ATCA)
2.	2-Mercaptabenzothiazole	280.8	Cefixime Trihydrate
		57.6	Cefpodoxime Proxetil
		3.84	Cefpirome Sulfate
		88.46	Cefdinir Monohydrate
		3.6	CefepimeDihydrochloride Monohycrate
		6.0	CefditorenPivoxil
		4.8	CeftazidimePentahydrate
		100.8	Cefotaxime Sodium
		6.0	Ceftizomine Sodium
		6.47	Cefpodoxime Acid
		36.36	MEAT (Thio Ester)
3.	Sodium Acetate	549.82	Cefuroxime Axetil

This Order is subject to the provisions of 'the Acts' and the Rules' & amendments made thereunder and further subject to the stipulations as mentioned below and to the terms & conditions incorporated in the Schedule A, B and C enclosed to this Order:

1. **This Consent for Operation Order is issued subject to the Orders of Hon'ble NGT, New Delhi in O.A.No.100 of 2014 filed by Dr. A. Kishan Rao Against Union of India & Ors., and also subject to outcome of cases pending in the Hon'ble NGT, Southern Bench, Chennai or any other Court of Law.**
2. **This Consent for Operation Order is issued at the risk and liability of the applicant on the investment made in case of orders against the industries in Hon'ble NGT or any Court of Law.**
3. **This CFO order is issued as per the provisions of G.O.Ms.No. 64, dt. 23.07.2013 and is subject to the outcome of cases pending in the Hon'ble National Green Tribunal, Southern Zone, Chennai or in any other court.**
4. **The industry shall comply with the standards prescribed by the MoEF as well as directions of Hon'ble NGT, Principal Bench, New Delhi & Hon'ble NGT, Chennai.**

This combined order of Consents and Authorization is valid for a period ending with the **30th day of September, 2021.**

Sd/-
MEMBER SECRETARY

To

M/s. Covalent Laboratories Pvt. Ltd located.
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V),
Hatnoora (M),
Sangareddy district.

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

Senior Environmental Engineer

SCHEDULE-A

1. The applicant shall make applications through online for renewal of Consent (under Water and Air Acts) and Authorization 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 Authorization of the Board along with detailed compliance to the conditions stipulated in the CFO and HWA Order.
2. 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.
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 Andhra Pradesh Water Rules, 1976 and Air Rules 1982, 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. All the conditions stipulated in the Schedule – A of the earlier combined CFO & HWA order No. **TSPCB/RCP/HO/CFO/2016- 490 Date :23.05.2016** remains same. The industry should ensure consistence compliance of each condition of Schedule-A.
6. 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. The pre-treated effluents sending to M/s. PETL, Patancheru, in case of maintenance / breakdown of RO system, shall not contain the constituents in excess of the tolerance limits prescribed below.

Outlet No.	Parameter	Limiting Standards
2 & 3	pH	5.50 – 9.00
	TDS (inorganic)	5,000 mg/l
	Chromium Hexavalent (as Cr^{+6})	2.00 mg/l
	Temperature ^0C	45.0
	Oil and Grease	20.00 mg/l
	Phenolic Compounds (as C_6H_5OH)	5.00 mg/l
	Ammonical Hexavalent (as N)	50.00 mg/l
	Cyanide (as CN)	2.00 mg/l
	Chromium (total) (as Cr)	2.00 mg/l
	Copper (as Cu)	3.00 mg/l
	Lead (as Pb)	1.00 mg/l
	Nickel (as Ni)	3.00 mg/l
	Zinc (as Zn)	15.00 mg/l
	Arsenic (as As)	0.20 mg/l
	Mercury (as Hg)	0.01 mg/l
	Cadmium (as Cd)	1.00 mg/l
	Selenium (as Se)	0.05 mg/l
	Fluoride (as F)	15.00 mg/l
	Boron (as B)	2.00 mg/l

2. The industry shall take steps to reduce water consumption to the extent possible and consumption shall NOT exceed the quantities prescribed below:

S.No	Purpose	:	Quantity in KLD
1	Process & Washings	:	186 KLD

2	Boiler Feed	:	145 KLD
3	Cooling tower makeup	:	23 KLD
4	DM Generation	:	10 KLD
5	Scrubber	:	8 KLD
6	QC and R & D	:	5 KLD
7	Gardening	:	50 KLD
8	Domestic	:	30 KLD
	Total:	**:**	**457 KLD**

3. The industry shall file the water cess returns in Form-I as required under section (5) of Water (Prevention and Control of Pollution) Cess Act, 1977 on or before the 5th of every calendar month, showing the quantity of water consumed in the previous month along with water meter readings. The industry shall remit water cess as per the assessment orders as and when issued by Board.

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

Chimney No.	Parameter	Emission Standards
1 to4	Particulate matter	115 mg/Nm^3
5	HCl Acid Vapor & Mist	35 mg/Nm^3

5. The industry shall comply with emission limits for DG sets of capacity 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 of capacity more than 800 KW shall 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 10 µm) - 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 industry shall manufacture only the consented products.**
8. **The industry shall not increase the capacity beyond the permitted capacity, without obtaining CFE & CFO of the Board.**
9. **The industry shall segregate the HTDS & LTDS effluents.**
10. **The industry shall regularly operate the existing pollution control systems i.e., Strippers, Multiple Effect Evaporators (MEEs), ATFDs, Biological ETP, RO plant etc. for treatment of HTDS & LTDS effluents.**
11. **The industry can send LTDS effluents to CETP for a period of maximum 15 days in a calendar year i.e. during maintenance / break down of RO system and shall maintain records.**
12. **The industry shall not discharge any effluents on land within or outside the plant premises.**
13. **The industry shall operate water meters for recording category-wise water consumption viz. Process, Boiler feed, Cooling tower makeup, Domestic etc.**
14. **The industry shall operate digital flow meters for recording waste water generation at inlet of various effluent streams of HTDS & LTDS, viz., Stripper/ MEE feed; MEE condensate; steam flow to Stripper, MEE & ATFD; inlet & outlet of Biological ETP; RO feed; RO Permeate & RO reject.**
15. **The industry shall use only fresh water for gardening purposes.**
16. **The industry shall operate online VOC analyzers for monitoring of VOCs.**
17. **The industry shall operate Multi-stage scrubbers in the plant for control of process emissions, so as to avoid odour nuisance.**

18. **The industry shall operate online pH meters for the Multi-stage scrubbers.**
19. **The industry shall identify the Air Pollution source of generation of odorous compounds from their process activities and shall take the required measures to contain the same to avoid smell nuisance. The industry shall not cause odour nuisance in the surroundings.**
20. **The industry shall transfer the chemicals /effluents/ In-process material in closed conditions to avoid smell nuisance.**
21. **The industry shall monitor the specific odorous compounds by using tube detectors at the point of sources i.e. Reactor vents, ETP, MEE etc. and also on the tallest building in the industry premises and to take immediate measures to prevent odour nuisance in the surroundings. This monitoring shall be carried, especially during complaints received from the public. The industry shall maintain records and furnish the same to the EE, RO, Sangareddy every month.**
22. **The industry shall maintain separate energy meter for the pollution control systems and maintain the records of the same.**
23. **The industry shall use vent condensers for all the bulk storage tanks, storing highly volatile solvents, wherever required. The industry shall provide & operate Nitrogen blanketing system, wherever required, with required pressure for the Solvents / Chemical/Product etc. storage tanks to avoid vapours escaping into the atmosphere to avoid odour nuisance in the surroundings.**
24. **The industry shall operate IP camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability, along with flow meter, with connection of the same to the website of CPCB & TSPCB.**
25. **The industry shall comply with the stipulations and conditions prescribed in the CFE Order for Expansion & previous CFO Order.**
26. **The industry should develop and maintain green belt all along the boundary of the industry and other vacant places. The industry shall take up extensive plantation under the Haritha Haram program of the State Government.**
27. **The industry shall use the high pressure steam generated from the 30 TPH boiler for power generation (Co-generation). The standby boiler shall not be used for power generation purpose under any circumstances. There shall not be any additional fuel usage for power generation.**
28. **The industry shall not operate the standby boiler for regular purpose under any circumstances. In case of any exigencies the industry shall operate the standby boiler with prior intimation to RO-I, Sangareddy.**
29. **The industry shall comply with the directions issued by the Task Force from time to time.**
30. The industry shall maintain records for generation of Process, utility & other effluents (HTDS and LTDS), domestic effluents and quantity of effluents (LTDS & HTDS) treated & disposed on daily basis and submit monthly report to the RO , Sangareddy - I.
31. The industry shall not discharge any effluents / contaminated rain water outside the industry premises or within the premises under any circumstances and shall close all the outlets of the industry.
32. The industry shall provide system for collection of contaminated rain water within the industry premises and shall treat them along with the effluent generated from production activities.
33. The industry shall not discharge any wastewater outside the factory premises and maintain zero discharge of effluents.
34. The industry shall isolate production, effluent treatment and Hazardous Waste storage & Handling area from Strom water drains. The industry shall ensure that effluents / Spillages do not mix with storm water to avoid contamination of rain water.
35. The industry shall evaluate the performance of solvent recovery system for each stream and maintain the efficiency of solvent recovery more than 95% for each stream.
36. The industry shall maintain the following records and the same shall be made available to the Board Officials during the inspection.
    a. Daily production details, RG-I records and Central Excise Returns.
    b. Quantity of Effluents generated, forced evaporated, treated & reused.
    c. Log Books for pollution control systems.

d. Daily solid waste generated and disposed to TSDF & Cement Plants.

37. There shall not be any spillages / chemicals / effluents on ground. The drums containing chemicals & wastes shall be stored on elevated platform with a provision to collect leachate / spillages in the collection pit. In no case the drums shall be stored on the naked open ground.

38. As per G.O.Rt.No.286, the industry shall transport the industrial effluents through the effluent tankers plying on the roads are allowed between 6 A.M. to 6 P.M. only.

39. The applicant shall submit Environment Statement in Form V before 30th September of every year as per Rule No.14 of E(P) Rules, 1986 & amendments thereof.

40. The conditions are without prejudice to the rights and contentions of this Board in any court of Law.

41. The Board reserves its right to modify above conditions or stipulate new / additional conditions and to take action including revocation of this order in accordance with the directions of Hon'ble NGT or any other Court of Law in the interest of environment protection in future. The industry cannot claim any liability from TSPCB in such case.

SCHEDULE - C

[see rule 6(2)]

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

A. General conditions of Authorization:

1. The authorized person shall comply with the provisions of the Environment (Protection) Act 1986, and the rules made there under.
2. The authorization or its renewal shall be produced for inspection at the request of an officer authorized by the State Pollution Control Board.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the Hazardous and other wastes except what is permitted through this authorization.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of his authorization.
5. The person authorized shall implement Emergency Response Procedure (ERP) for which this authorization is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc., and their possible impacts and also carryout mock drill in this regard at regular interval of time.
6. The person authorized shall comply with the provisions outlined in the Central Pollution Control Board guidelines on "Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty".
7. It is the duty of the authorized person to take prior permission of the State Pollution Control Board to close down the facility.
8. The Hazardous and other waste which gets generated during recycling or reuse or recovery or pre-processing or utilization of imported Hazardous or other wastes shall be treated and disposed of as per specific conditions of authorization.
9. The importer or exporter shall bear the cost of import or export and mitigation of damages if any.
10. An application for the renewal of an authorization shall be made as laid down under the Rules.
11. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate change or Central Pollution Control Board from time to time.
12. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.

B. Specific Conditions:

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 and Transboundary Movement) Rules, 2016 and amendments thereof.
3. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal.
4. The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors/ Recyclers.
5. The industry shall dispose Used Lead Acid Batteries to the manufacturers / dealers on buyback basis.
6. The industry shall not dispose spent solvents / mixed spent solvents to the traders.
7. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.
8. The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board Office and concerned Regional Office.
9. The industry shall maintain good house keeping & maintain proper records for Hazardous Wastes stated in Authorization.
10. The industry shall maintain proper Records for Hazardous Wastes stated in Authorization in FORM-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc. as per Rule 20(1) and file Annual Returns in Form- 4 as per Rule 20(2) of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and amendments thereof.
11. The industry shall dispose of e-waste to the authorized recyclers only.
12. 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.

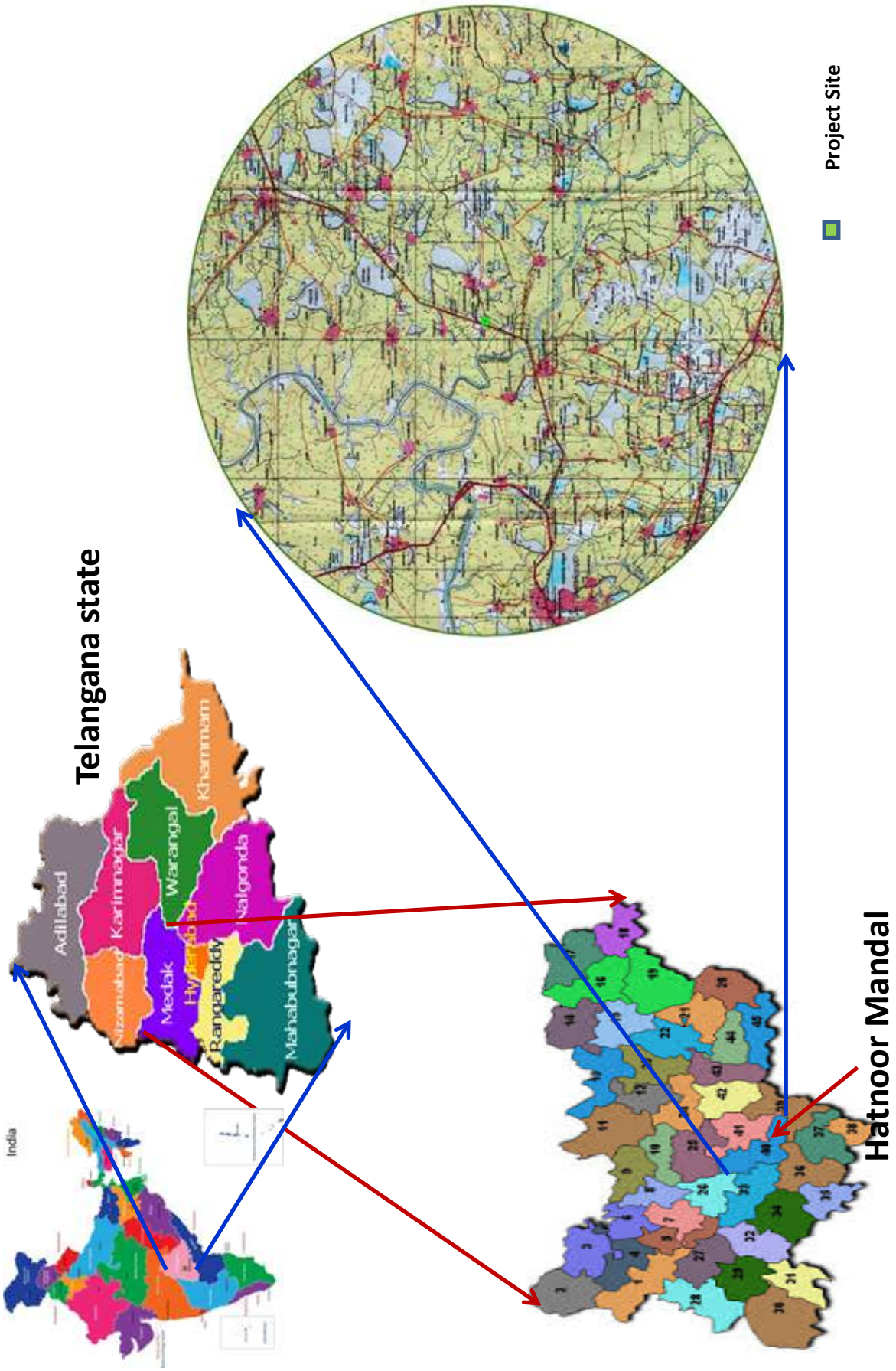
Sd/-
MEMBER SECRETARY

To
M/s. Covalent Laboratories Pvt. Ltd located.
Sy. No. 315/E, 337/A, 345, 346, 358, 359, 374/AA, 375, 376, 377/A,
Gundlamachanoor (V),
Hatnoora (M),
Sangareddy district.

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

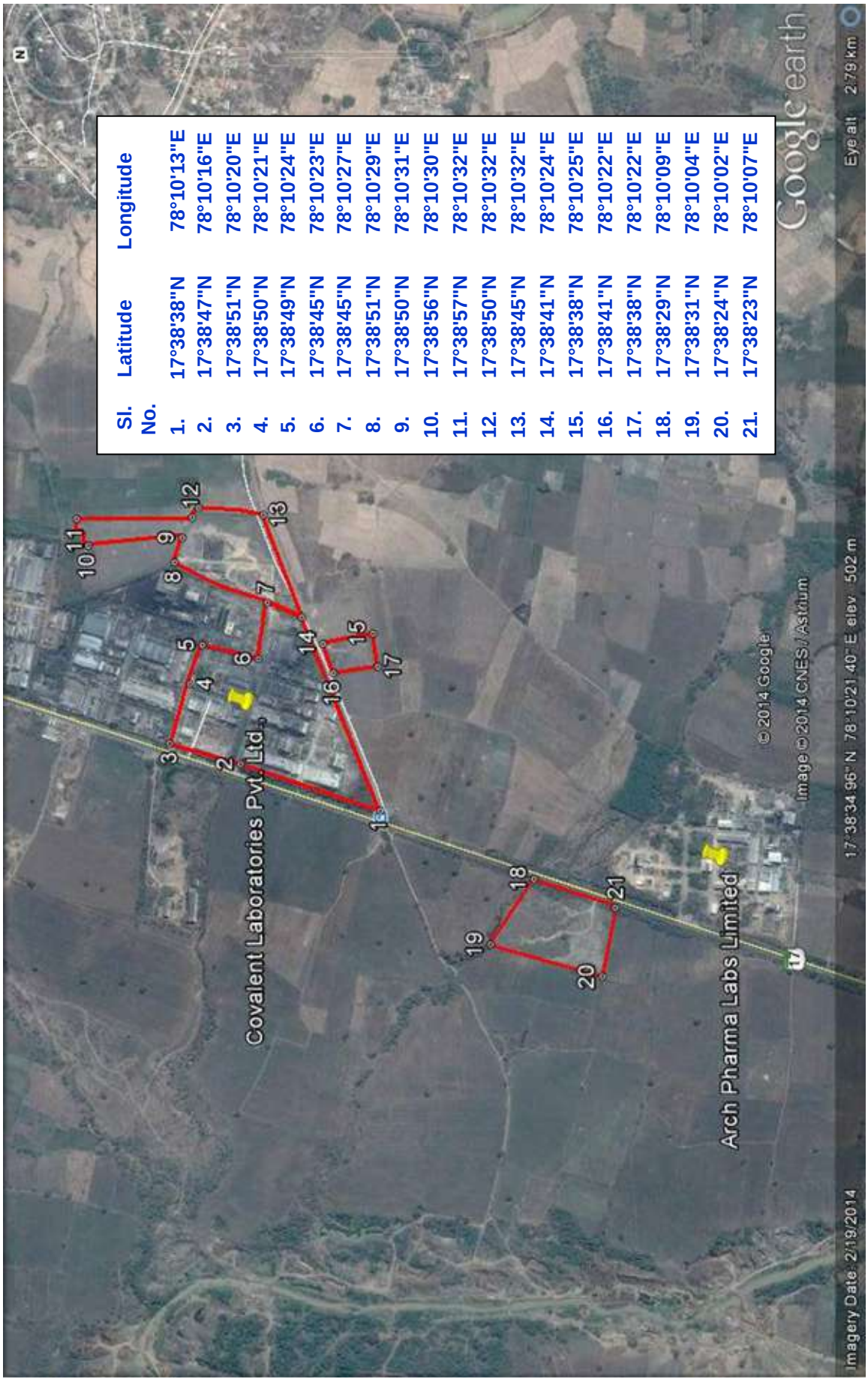
Senior Environmental Engineer

Project Site Location



ANNEXURE - V

Google Map showing Project Boundaries



PROPOSED AREA		
BOILER SHEAD–2	:	852.13 SQ.Mts
COAL SHEAD–2	:	123.82 SQ.Mts
C.TOTAL PROPOSED BUILTUP AREA		975.95 SQ.Mts

PROPOSED BUILDINGS				
S.NO.	DISCRIPTION	LENGTH	WIDTH	AREA(Sq.Mts)
1.	SECURITY ROOMS	10.50	3.70	38.85 (Sq.Mts)
2.	RAW MATERIAL GODOWN(G.F)	18.00	17.75	319.50 (Sq.Mts)
	RAW MATERIAL GODOWN(F.F)	18.00	17.75	319.50(Sq.Mts)
3.	U/G.SOLVENT STORAGE TANKS	19.30	6.50	125.45 (Sq.Mts)
4.	DRUM STORAGE SHED	21.40	13.00	278.20 (Sq.Mts)
5.	HYDROGENATION BLOCK(G.F)	21.50	8.00	172.00 (Sq.Mts)
	HYDROGENATION BLOCK(F.F)	21.50	8.00	172.00(Sq.Mts)
6.	PANEL BOARD ROOM	14.10	4.40	62.04 (Sq.Mts)
7.	PRODUCTION BLOCK–4(G.F)	60.00	16.20	972.00 (Sq.Mts)
	PRODUCTION BLOCK–4(F.F)	60.00	16.20	972.00 (Sq.Mts)
	PRODUCTION BLOCK–4(S.F)	15.00	16.20	243.00 (Sq.Mts)
8.	PRODUCTION BLOCK–5(G.F)	60.00	20.00	1200.00(Sq.Mts)
	PRODUCTION BLOCK–5(F.F)	60.00	20.00	1200.00(Sq.Mts)
9.	ADMN., BLOCK(G.FLOOR)	25.00	18.00	450.00 (Sq.Mts)
	Q.C. & Q.A. BLOCK(F.F)	25.00	18.00	450.00 (Sq.Mts)
10.	UTILITY BLOCK(G.FLOOR)	25.00	15.00	375.00 (Sq.Mts)
	UTILITY BLOCK(F.FLOOR)	25.00	15.00	375.00 (Sq.Mts)
11.	DISTILLATION COLUMN(G.F)	9.00	16.50	148.50 (Sq.Mts)
	DISTILLATION COLUMN(F.F)	9.00	16.50	148.50 (Sq.Mts)
	DISTILLATION COLUMN(S.F)	9.00	16.50	148.50 (Sq.Mts)
	DISTILLATION COLUMN(T.F)	9.00	16.50	148.50 (Sq.Mts)
12.	STORAGE TANKS AREA (2Nos)	16.50	8.20	270.60(Sq.Mts)
13.	PARKING SHED	25.00	5.90	147.50(Sq.Mts)
	D:TOTAL BUILTUP AREA			8,361.64(Sq.Mts)

EXISTING AREA'S

STERILE BLOCK–01		
GROUND FLOOR AREA	:	1575.00 SQ.Mtrs
FIRST FLOOR AREA	:	1575.00 SQ.Mtrs
SECOND FLOOR AREA	:	1575.00 SQ.Mtrs
STERILE BLOCK–02		
GROUND FLOOR AREA	:	759.99 SQ.Mtrs
FIRST FLOOR AREA	:	759.99 SQ.Mtrs
UTILITY BLOCK		
GROUND FLOOR AREA	:	230.00 SQ.Mtrs
FIRST FLOOR AREA	:	230.00 SQ.Mtrs
RECOVERY BLOCK		
GROUND FLOOR AREA	:	207.00 SQ.Mtrs
FIRST FLOOR AREA	:	207.00 SQ.Mtrs
SECOND FLOOR AREA	:	207.00 SQ.Mtrs
THIRD FLOOR AREA	:	207.00 SQ.Mtrs
D.G BUILDING		
GROUND FLOOR AREA	:	234.86 SQ.Mtrs
TOILET BLOCK	:	32.00 SQ.Mtrs
DRUM YARD –3	:	205.47 SQ.Mtrs
PANEL ROOM	:	9.00 SQ.Mtrs
B.TOTAL EXISTING BUILDING AREA	:	8014.31 SQ.Mts.

TOTAL BUILTUP AREA (A+B+C+D)	:	47243.04 SQ.Mts. (30.44%)
TOT–LOT AREA	:	33175.99 SQ.Mts. (21.38%)
GREENERY	:	55871.08 SQ.Mts (36.00%)
ROAD AREA	:	11994.17 SQ.Mtrs (7.73%)
ETP AREA	:	6913.18 SQ.Mtrs (4.45%)

SITE PLAN
SCALE:–1:800

DRG.No: CLPL–GEN–1/17

COMPOUND:
M/S.COVALENT LABORATORIES (P) LTD, UNIT–1
SY.NO.345,346,358,359,374,375,376,313/E,377/A,337/A,374 SITUATED AT GUNDLA MACHANUR(V)HATNOORA(M),MEDAK(DIST)

SITE AREA	:	38Ac–14Gnts
		155197.46 SQ.Mtrs
EXISTING AREA'S		
PRODUCTION BLOCK:3		
GROUND FLOOR AREA	:	2471.54 SQ.Mtrs
FIRST FLOOR AREA	:	2471.54 SQ.Mtrs
SECOND FLOOR AREA	:	2169.18 SQ.Mtrs
RAW MATERIAL STORE,Q.C,QA, & ADMINISTRATIVE OFFICE		
GROUND FLOOR AREA	:	1876.71 SQ.Mtrs
FIRST FLOOR AREA	:	1876.71 SQ.Mtrs
SPENT CARBON AND SCRAP YARD SHED	:	486.69 SQ.Mtrs
COAL SHED	:	1106.00 SQ.Mtrs
BOILER SHED:1	:	85.98 SQ.Mtrs
BOILER SHED:2	:	165.00 SQ.Mtrs
BOILER SHED:3	:	233.86 SQ.Mtrs
DRUM YARD SHED–1	:	484.92 SQ.Mtrs
PRODUCTION BLOCK:2		
GROUND FLOOR AREA	:	206.06 SQ.Mtrs
FIRST FLOOR AREA	:	206.06 SQ.Mtrs
SECOND FLOOR AREA	:	206.06 SQ.Mtrs
THIRD FLOOR AREA	:	68.50 SQ.Mtrs
FOURTH FLOOR AREA	:	68.50 SQ.Mtrs
FIFTH FLOOR AREA	:	68.50 SQ.Mtrs
SPRAY DRIER BLOCK–1		
GROUND FLOOR AREA	:	371.92 SQ.Mtrs
FIRST FLOOR AREA	:	371.92 SQ.Mtrs
UTILITY BLOCK–1 AND SAFETY DEPT.	:	244.13 SQ.Mtrs
UTILITY BLOCK:2		
GROUND FLOOR AREA	:	430.05 SQ.Mtrs
FIRST FLOOR AREA	:	430.05 SQ.Mtrs
ENGG.,STORAGE SHED AND DRUM YARD–2	:	728.77 SQ.Mtrs
SOLVENT RECOVERY		
GROUND FLOOR AREA	:	116.60 SQ.Mtrs
FIRST FLOOR AREA	:	116.60 SQ.Mtrs
SECOND FLOOR AREA	:	116.60 SQ.Mtrs
POWDER PROCESS AREA : 2	:	319.98 SQ.Mtrs
TOILET–1	:	26.05 SQ.Mtrs
TOILET – 2	:	7.90 SQ.Mtrs
RECOVERY BLOCK–3		
GROUND FLOOR AREA	:	424.65 SQ.Mtrs
FIRST FLOOR AREA	:	424.65 SQ.Mtrs
SECOND FLOOR AREA	:	424.65 SQ.Mtrs
THIRD FLOOR AREA	:	424.65 SQ.Mtrs
SECURITY ROOM	:	60.67 SQ.Mtrs
SECURITY ROOM–2	:	6.25 SQ.Mtrs
MEE PANEL ROOM	:	71.54 SQ.Mtrs
MESS ROOM	:	89.52 SQ.Mtrs
DISTILLATION COLUMN PLANT		
GROUND FLOOR AREA	:	155.58 SQ.Mtrs
FIRST FLOOR AREA	:	155.58 SQ.Mtrs
SECOND FLOOR AREA	:	155.58 SQ.Mtrs
THIRD FLOOR AREA	:	155.58 SQ.Mtrs
FOURTH FLOOR AREA	:	155.58 SQ.Mtrs
PRODUCTION BLOCK:1		
GROUND FLOOR AREA	:	339.24 SQ.Mtrs
FIRST FLOOR AREA	:	339.24 SQ.Mtrs
SECOND FLOOR AREA	:	87.13 SQ.Mtrs
THIRD FLOOR AREA	:	87.13 SQ.Mtrs
FOURTH FLOOR AREA	:	87.13 SQ.Mtrs
GENERATOR ROOM:1	:	106.63 SQ.Mtrs
SPRAY DRIER BLOCK:3 & UTILITY BLOCK:3		
GROUND FLOOR AREA	:	614.03 SQ.Mtrs
FIRST FLOOR AREA	:	614.03 SQ.Mtrs
SALT SHED	:	87.37 SQ.Mtrs
CARBON ROOMS	:	177.91 SQ.Mtrs
EXECUTIVE LUNCH ROOM	:	100.24 SQ.Mtrs
GENERATOR ROOM–2	:	271.99 SQ.Mtrs
W.B ROOM	:	11.17 SQ.Mtrs
BF –3 CYLINDER SHED	:	122.81 SQ.Mtrs
SALTS STORAGE SHED AREA	:	85.01 SQ.Mtrs
TOILET BLOCK –3 AREA	:	34.00 SQ.Mtrs
A.TOTAL BUILTUP AREA	:	23579.55 SQ.Mts.

GENERAL NOTES

1)ALL DIMENSIONS ARE IN MM & & Mtrs ONLY

PROPOSED ☐ EXISTING ☐ DELETION ☐

TITLE: **SITE PLAN**

ENGINEER SIGN:

SIGN OF OCCUPIER:

17.05.2014 A1

PRODUCT : Cefixime Trihydrate

Description :

Stage-1 : (4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate recting with formaldehide through wittig reaction in presence fo Triphenylphosphine, Sodium Bromide and Sodium Hydroxide in Methylene Dichloride, Dimethylformamide, Methanol and water mixture. The final product was islating by concentrating Methylene Dichloride and drying.

Recovery of Waste and Conversion into By-Product: Triphenylphosphine Oxide crude dissolved into Toluene+water mixture followed by layer seperation to remove the inorganic impurities in aqueous layer. TPPO pure isolated from Toluene layer after distillation of
Toluene upto 2.0-2.5 residual volume followed by solid filtration and drying.

Stage-2 : Averest (stage-1) is under going hydolysis in presence of Phenol and enzyme. The product was extracting into water by washing with Butyl acetate, and Acetone. The isolated product was drying under vacuum.

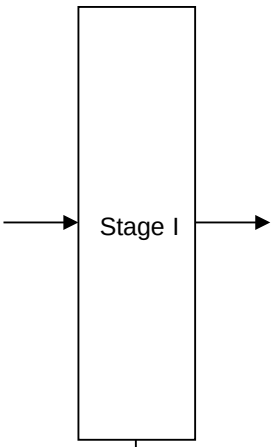
Stage-3 : AVNA is going under peptide condensation in presence of Triethylamine and further going into hydrolysis in presence of Sodium Hydroxide base in Methanol and water. The final compound was isolating by neutralizing pH. Final product was drying under vacuum.

Purification of By-Product : Dissolution of 2-Mercaptobenzothiazole crude in Recovered Mixed Solvent followed by Carbon treatment and solvent distillation upto ~2.0 residual volume and then solid filtration and drying to get pure 2-Mercaptobenzothiazole.

PRODUCT : Cefixime Trihydrate

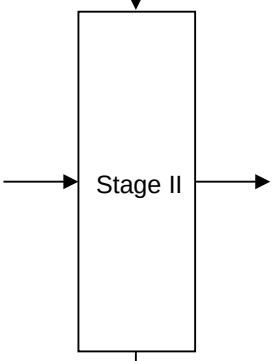
Flow Chart

(4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate
Triphenylphosphine
Formaldehyde (40%)
Methanol
Methylene Dichloride
Sodium Bromide
Sodium Hydroxide
Hydrochloric Acid (35%)
Dimethylformamide
Water



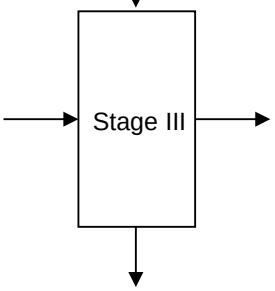
By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue

Stage-1
Phenol
Butyl Acetate
Sodium Bicarbonate
Sodium Chloride
Sodium Carbonate
Carbon
Ethylenediaminetetraacetic acid
Sulfuric acid
Acetone
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon
Process Emissions

Stage-2
MICA Ester
Triethylamine
Methanol
Hydrochloric acid (35%)
Sodium Hydroxide
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue

Cefixime Trihydrate

PRODUCT : Cefpodoxime Proxetil

Description :

Stage-1 : 7-ACA is hydrolysis and methoxylation in presence of Borantrifluoride and Methanol in Sulfolane. This was isolating water by adding with Treithylamine and the wet product further going under peptide condensation reaction with MAEM in water and Tetrhydrofuran in presence of Triethylamine base. The final product was extracting into water with by using Ethyl acetate. CPDA was isolating from water by using Sulfuric acid. The isolated product drying under vacuum.

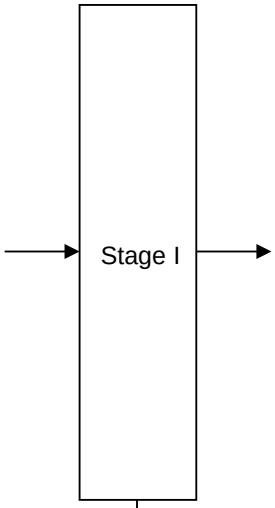
Stage-2 : Dissolution of 2-Mercaptobenzothiazole crude in Recovered Mixed Solvent followed by Carbon treatment and solvent distillation upto ~2.0 residual volume and then solid filtration and drying to get pure 2-Mercaptobenzothiazole.

Purification of By-Product : CEIPC is under going iodonation in presence of phase transfer catalyst. This is further using for esterification of Stage-1 in presence of TMG base. The product was extracting into Ethyl acetate and concentrating the Ethyl acetate under vacuum and the retained was dissolving by adding Methanol. This was poring into water to isolate the final product the final product was drying under vacuum.

PRODUCT : Cefpodoxime Proxetil

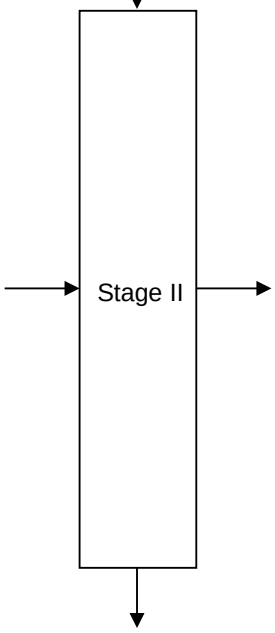
Flow Chart

7-Amino cephalosphoranic acid
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate
Triethylamine
Borantrifluoride
Sulfolane
Methylene Dichloride
Sodium Hydroxide
Sodium Chloride
Tetrahydrofuran
Ethyl Acetate
Methanol
Sulfuric Acid
Carbon
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon

Stage-1
1-Chloroethyl isopropyl carbonate
Sodium Iodide
18-Crown-6
1,1,3,3-Tetramethyl gunadine
Toluene
Ethyl Acetate
Methanol
Dimethylacetamide
Hydrochloric acid (35%)
Ammonia (10%)
Sodium Chloride
Sodium Thiosulfate
Carbon
TBAB
Water
Cyclohexane



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon
Process Emissions

Cefpodoxime Proxetil

PRODUCT : Cefuroxime Axetil

Description :

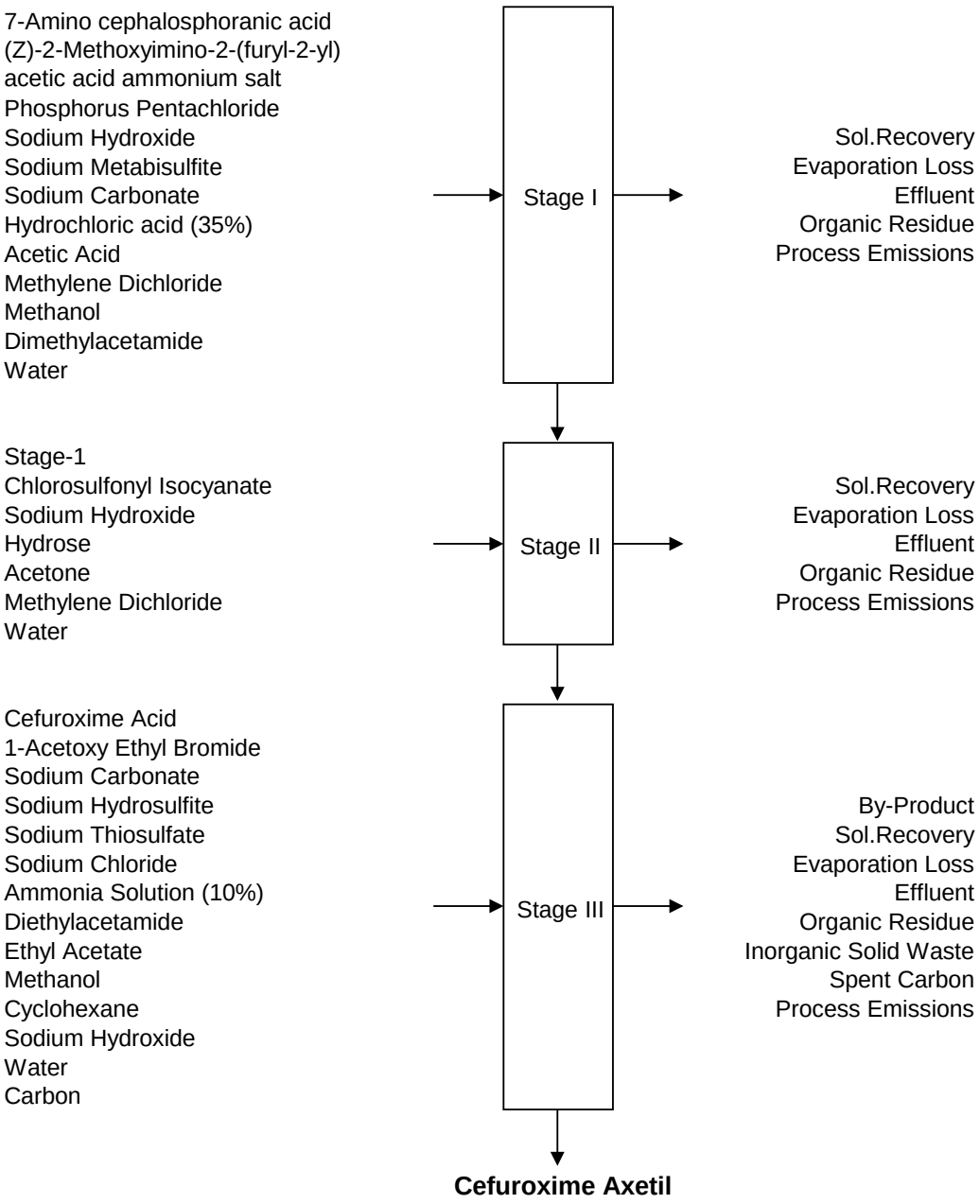
Stage-1 : 7-ACA is under going hydrolysis in presence of NaOH base in methanol. SMIA is under going chlorination in presence of PCl5 in MDC and DMAc. After reaction the excess Chlorin are removing by washing with water. The SMIA chloride reaction mass and 3-Hydroxy 7-ACA both are condensing in presence of sodium bicarbonate at neutral pH and forming as Stage-1. This product was isolating by using HCl and drying under vacuum.

Stage-2 : Stage-1 under going amido acylation with chloro sulfonyl iso cynate in acetone and water. The isolated product was further giving MDC and water slurry washings to remove inorganic salts. the final product dring under vacuum.

Stage-3 : Stage-2 is under going esterification with 1-Acetoxy ethyl bromide in presence of Na2CO3 base in DMAc. the product was extracting in to ethyl acetate by adding ethyl acetate and water mixture. Ethyl acetate was concentrating under vacuum and isolating by adding methanol + cyclohexane. The isolated product drying in FBD. During the reaction Cefuroxime acid with 1-AEB in presence of sodium carbonate Sodium bromide is forming as byproduct and it is going in aqueous layer during workup and Cefuroxime axetil isolated from organic layer. Sodium bromide isolated from aqueous layer after distillation of organic solvents and water finally addition of ethanol methanol mixture to get solid precepitate of sodium bromide and it has seperated by solid filtration.

PRODUCT : Cefuroxime Axetil

Flow Chart



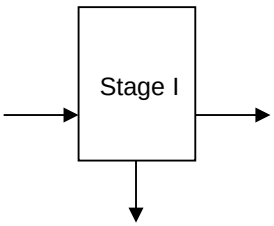
PRODUCT : Cefuroxime Sodium

Description :

Stage-1 : Cefuroxime Sodium is a sterile product. It is manufactured from Cefuroxime Acid by reacting with 2-Ethylsodium Hexonate in Acetone medium and purified with Carbon. Product is isolated and dried under vacuum.

Flow Chart

Cefuroxime Acid
2-Ethylsodium Hexanoate
Acetone
Carbon
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon

Cefuroxime Sodium

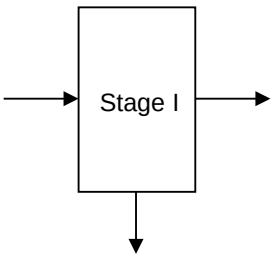
PRODUCT : Ceftriaxone Sodium

Description :

Stage-1 : Ceftriaxone sodium is an API sterile drug. This was manufacturing through dissolving and isolation Ceftriaxone sodium is dissolving in water and acetone mixture in presence of HCl. Again isolating after carbon treatment by adding sodium-2-ethyl hexanoic acid.

Flow Chart

Ceftriaxone Sodium (Crude)
Hydrochloric acid (35%)
2-Ethylsodium Hexanoate
Acetone
Water
Carbon



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon

Ceftriaxone Sodium

PRODUCT : Cefpirome Sulfate

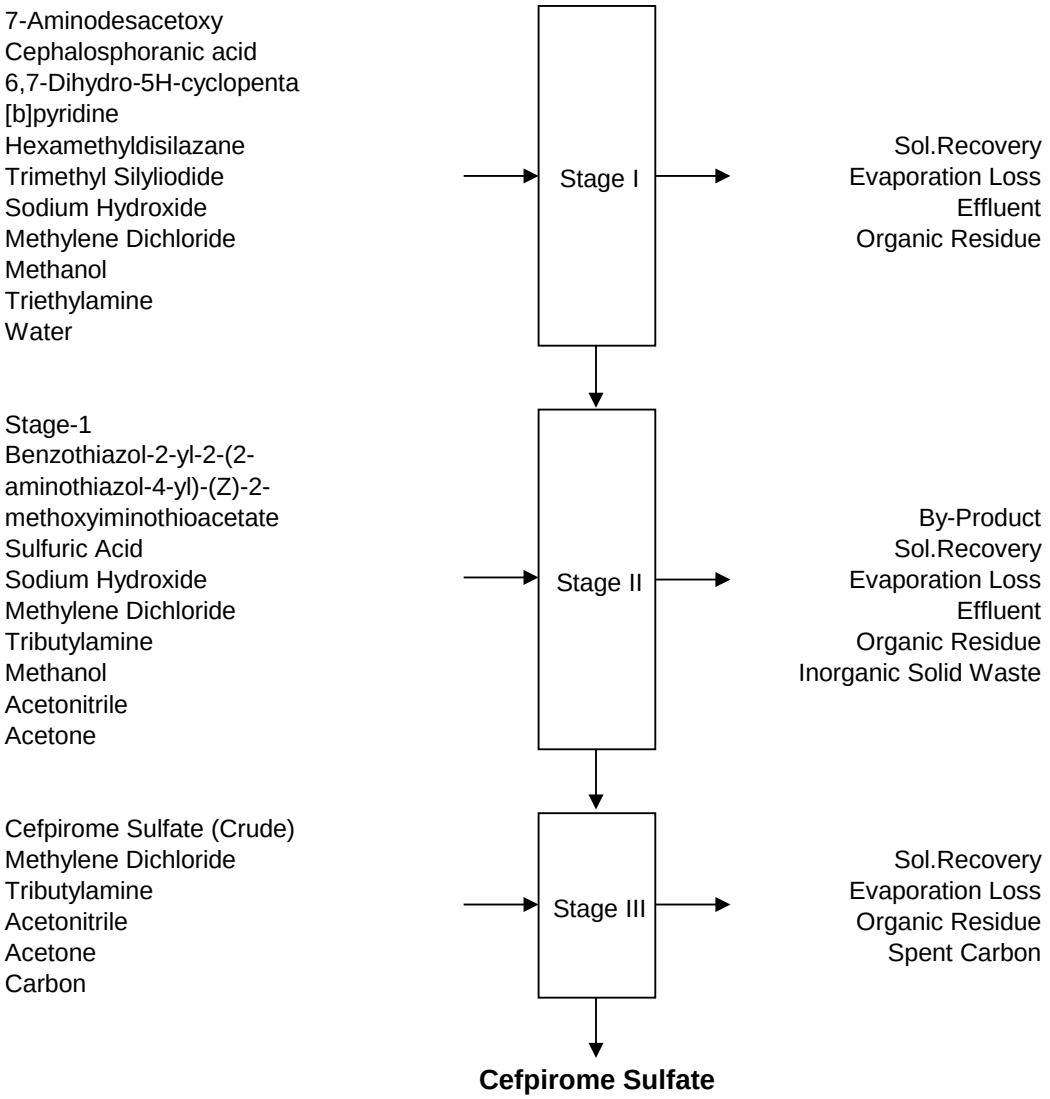
Description :

Stage-1 : 7-Aminodesacetoxy Cephalosphoranic acid is reacted with 6,7-Dihydro-5H-cyclopenta [b]pyridine in presence of Hexamethyldisilazane, Trimethyl Silyliodide and Sodium Hydroxide in Methylene Dichloride, Methanol and Triethylamine as solvent media forms Stage-1 product. Product is isolated and dried under vacuum.

Stage-2 : In the next step Stage-1 react with Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyimino thioacetate in presence of Sulfuric acid and Sodium Hydroxide in the medium of Methylene Dichloride, Tributylamine, Methanol, Acetonitrile and Acetone forms Cefpirome Sulfate. Product isolated and dried under vacuum.

Stage-3 : Cefpirome Sulfate dissolute in Acetonitrile, Methylene Dichloride, Tributylamine and Acetone as solvent media and gets purified with Carbon and reprecipitated in sterile condition to form pure Cefpirome Sulfate.

Flow Chart



PRODUCT : Cefdinir Monohydrate

Description :

Stage-1 : Dissolution of 2-Mercaptobenzothiazole in Recoverd Mixed Solvent followed by Carbon treatment and then reaction with Hydrogen Peroxide to form 2-Mercaptobenzothiazole disulfide. Precipitated solid material filtered washed with solvent and dried to get final compound 2-Mercaptobenzothiazole disulfide.

Stage-2 : EHATA is under going hydrolysis in presence of sodium hydroxide in water and going acylation in presence of acetic an hydride and sodium hydroxide at neutral pH condensation. This was isolating in centrifuge. The isolated product doing anhydrification in acetone and going condensation with bis mercaptobenz thiazole in presence of TEA and TPP in MDC. The product was isolating in centrifuge and further drying under vacuum.

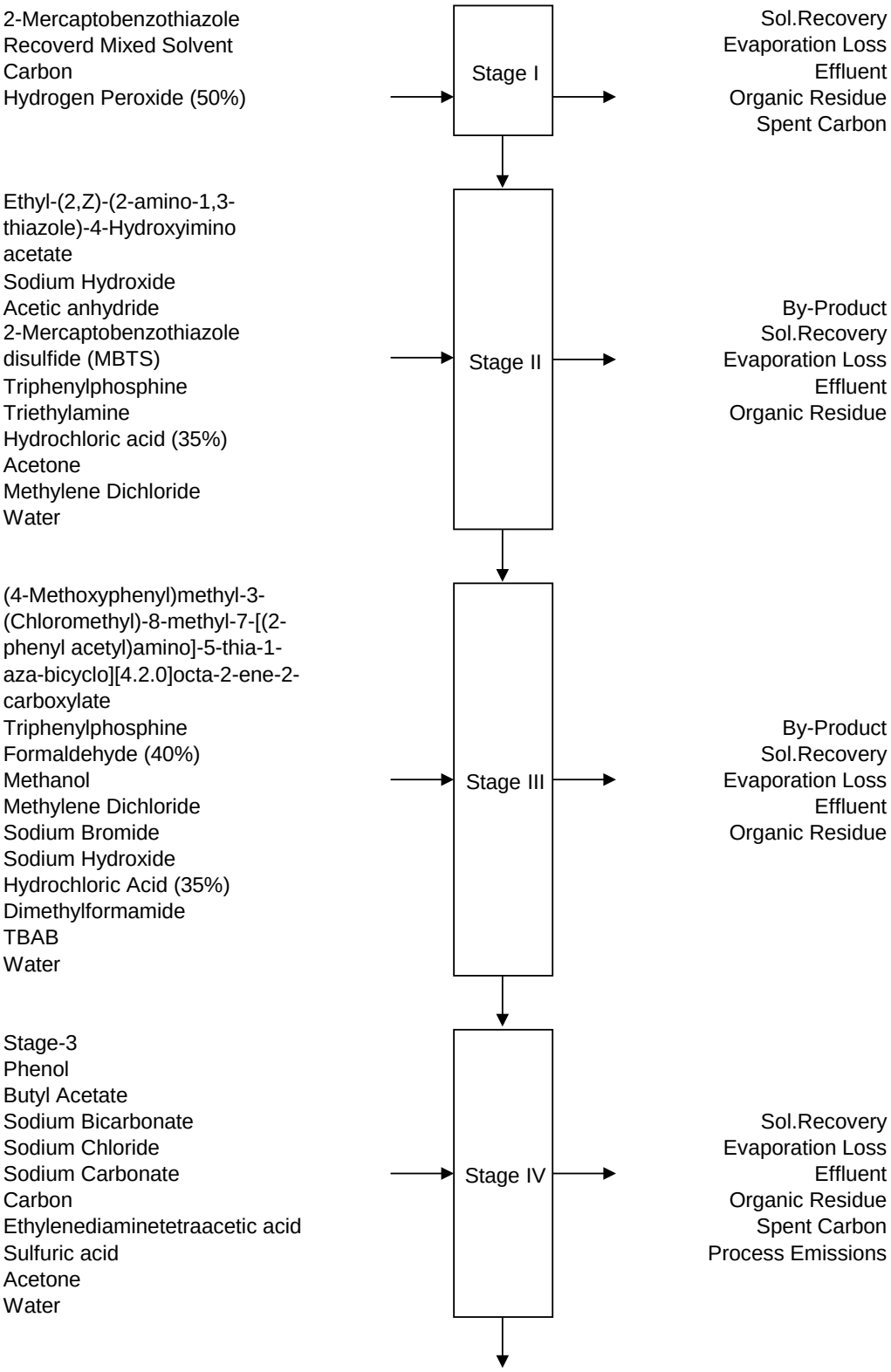
Stage-3 : (4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate recting with formaldehide through wittig reaction in presence fo Triphenylphosphine, Sodium Bromide and Sodium Hydroxide in Methylene Dichloride, Dimethylformamide, Methanol and water mixture. The final product was islating by concentrating Methylene Dichloride and drying.

Stage-4 : Averest (stage-1) is under going hydolysis in presence of Phenol and enzyme. The product was extracting into water by washing with Butyl acetate, and Acetone. The isolated product was drying under vacuum.

Stage-5 : 7-AVNA is under going peptide condensation with Thio ester in presence of TEA in water an THF media. The product was extracting into water and undergoing hydrolysis in presence of K_2CO_3 and NH_4Cl mixture and isolating as cefdinir potassium salt. This cefdinir potassium salt making as cefdinir by adding dil. sulfuric acid in water. The final product doing drying under vacuum.

PRODUCT : Cefdinir Monohydrate

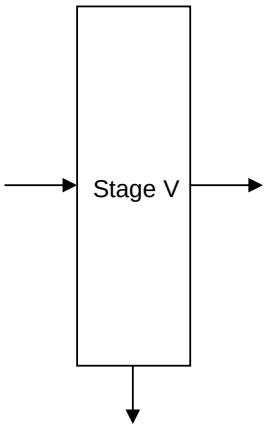
Flow Chart



PRODUCT : Cefdinir Monohydrate

Flow Chart

Stage-4
Stage-2
Tetrahydrofuran
Methylene Dichloride
Triethylamine
Ammonium Chloride
Potassium Carbonate
Acetone
Carbon
Sulfuric acid
EDTA
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon
Process Emissions

Cefdinir Monohydrate

PRODUCT : Cefprozil Monohydrate

Description :

Stage-1 : Triphenylphosphine Oxide reacts with Triphosgene in Chlorobenzene to form Dichlorotriphenyl phosphene and finally it is reacting with Aluminium metal to form Triphenylphosphene. After reaction completion addition of warer to quench the reaction mass followed by extraction of product in chlorobenzene. Distillation of chlorobenzene followed by addition of Methanol and solid filtration gives Triphenylphosphine.

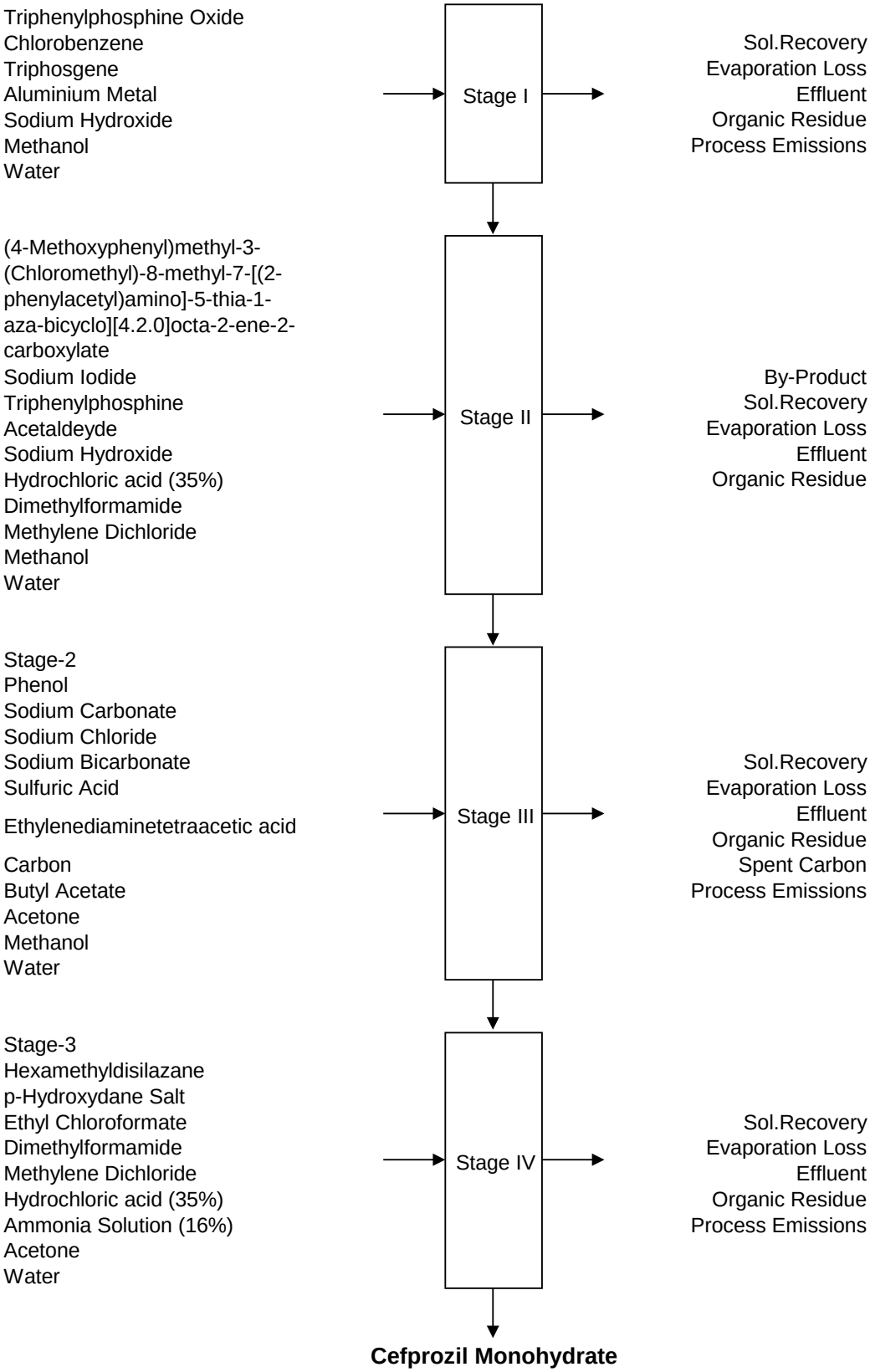
Stage-2 : (4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenylacetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate reacts with Triphenylphosphine in presence of Acetaldehyde, Sodium Hydroxide, Sodium Iodide and Hydrochloric acid in Dimethylformamide, Methylene Dichloride and Methanol solvent media to give Stage-2 Compound.

Stage-3 : Stage-2 Compound on reaction with Phenol in presence of Sodium Carbonate, Sodium Chloride, Sodium Bicarbonate, Sulfuric Acid and Ethylenediaminetetraacetic acid in Butyl Acetate, Acetone and Methanol solvent media to form Stage-3 Intermediate.

Stage-4 : Stage-3 Intermediate gets reacted with Hexamethyldisilazane in presence of p-Hydroxydane Salt, Ethyl Chloroformate, Hydrochloric acid and Ammonia in Dimethylformamide, Methylene Dichloride and Acetone solvent media to form Cefprozil Monohydrate.

PRODUCT : Cefprozil Monohydrate

Flow Chart



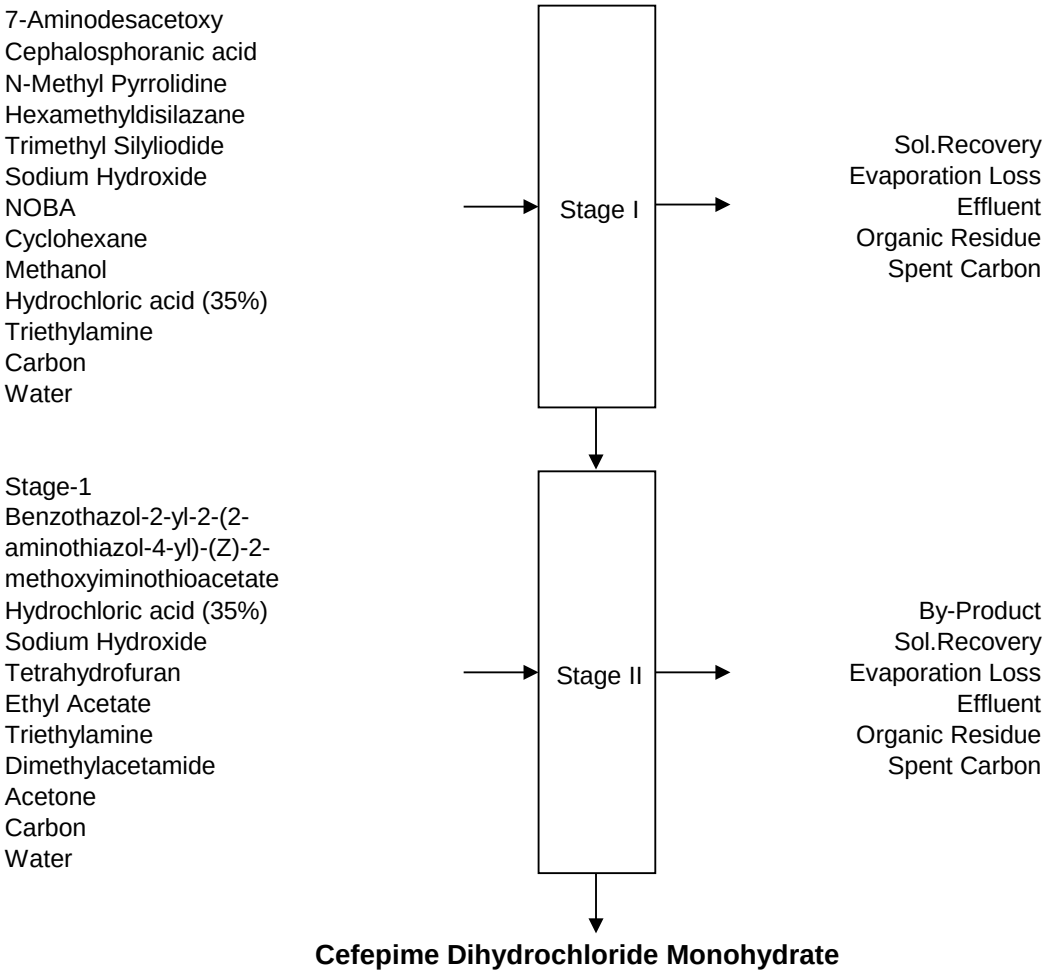
PRODUCT : Cefepime Dihydrochloride Monohydrate

Description :

Stage-1 : 7-Aminodesacetoxy Cephalosphoranic acid is reacted with N-Methyl Pyrrolidine in presence of Hexamethyldisilazane, Trimethyl Silyliodide, Sodium Hydroxide, Hydrochloric acid in Methanol, Cyclohexane and Triethylamine as solvent media forms Stage-1 product. Product is isolated and dried under vacuum.

Stage-2 : In the final step Stage-1 react with Benzothazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyimino thioacetate in presence of Hydrochloric acid and Sodium Hydroxide in the medium of Dimethylacetamide, Tetrahydrofuran, Ethyl Acetate, Triethylamine and Acetone as solvents forms Cefepime Dihydrochloride Monohydrate.

Flow Chart



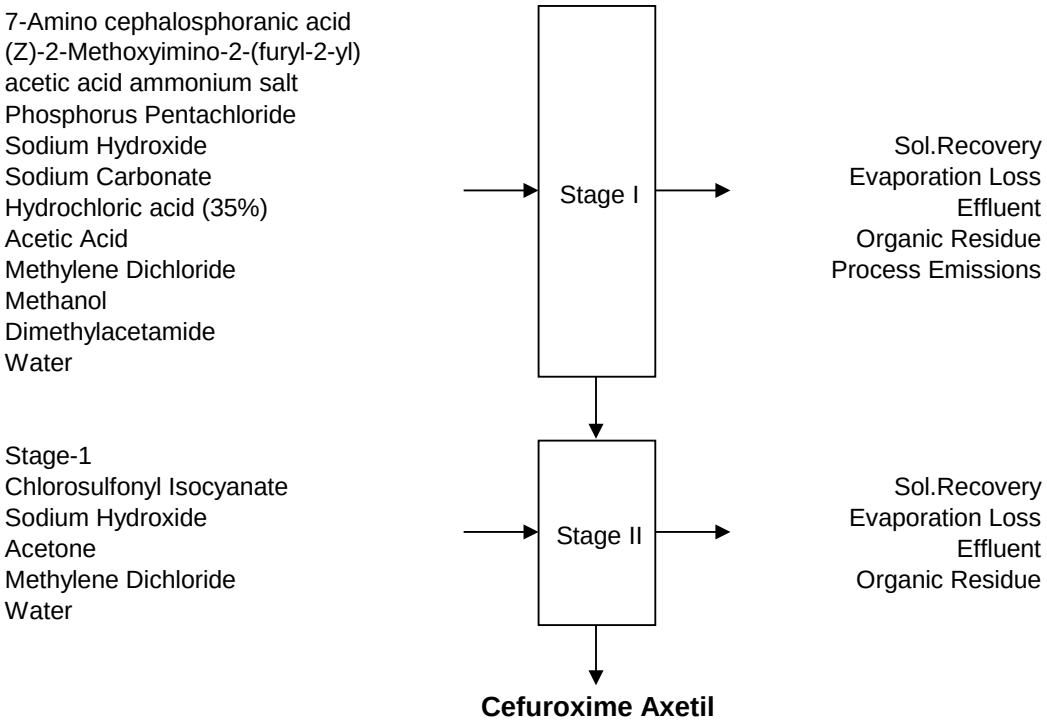
PRODUCT : Cefuroxime Acid

Description :

Stage-1 : 7-ACA is under going hydrolysis in presence of NaOH base in methanol. SMIA is under going chlorination in presence of PCl5 in MDC and DMAc. After reaction the excess Chlorin are removing by washing with water. The SMIA chloride reaction mass and 3-Hydroxy 7-ACA both are condensing in presence of sodium bicarbonate at neutral pH and forming as Stage-1. This product was isolating by using HCl and drying under vacuum.

Stage-2 : Stage-1 under going amido acylation with chloro sulfonyl iso cynate in acetone and water. The isolated product was further giving MDC and water slurry washings to remove inorganic salts. the final product dring under vacuum.

Flow Chart



PRODUCT : Cefditoren Pivoxil

Description :

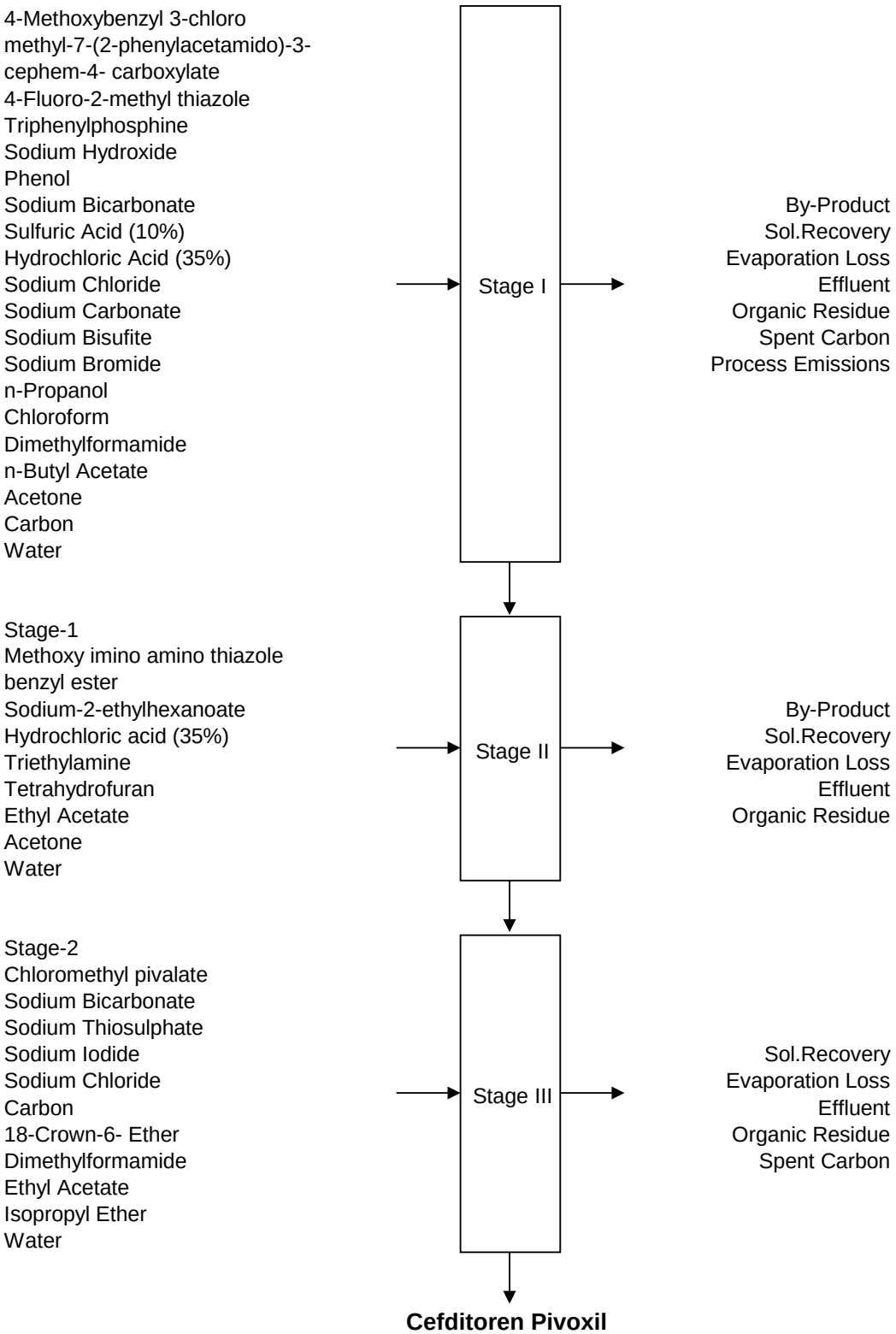
Stage-1 : 4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4- carboxylate is reacted with 4-Fluoro-2-methyl thiazole in presence of Triphenylphosphine, Sodium Hydroxide, Phenol, Hydrochloric acid, Sufuric acid, Sodium Bicarbonate, Sodium Chloride, Sodium Carbonate, Sodium Bisufite and Sodium Bromide in n-Propanol, Chloroform, Dimethylformamide, n-Butyl Acetate and Acetone solvent media and gets purified with Carbon to get Stage-1 Compound.

Stage-2 : Stage-1 Compound on reaction with Methoxyimino aminothiazole benzyl ester in presence of Sodium-2-ethylhexanoate, Hydrochloric acid and Triethylamine in Tetrahydrofuran, Ethyl Acetate and Acetone solvent media to form Stage-2 Intermediate.

Stage-3 : Stage-2 Intermediate gets reacted with Chloromethyl Pivalate in presence of Sodium Bicarbonate, Sodium Thiosulphate, Sodium Iodide, Sodium Chloride and 18-Crown-6- Ether in Dimethylformamide, Ethyl Acetate and Isopropyl Ether solvent media to obtain Cefditoren Pivoxil.

PRODUCT : Cefditoren Pivoxil

Flow Chart



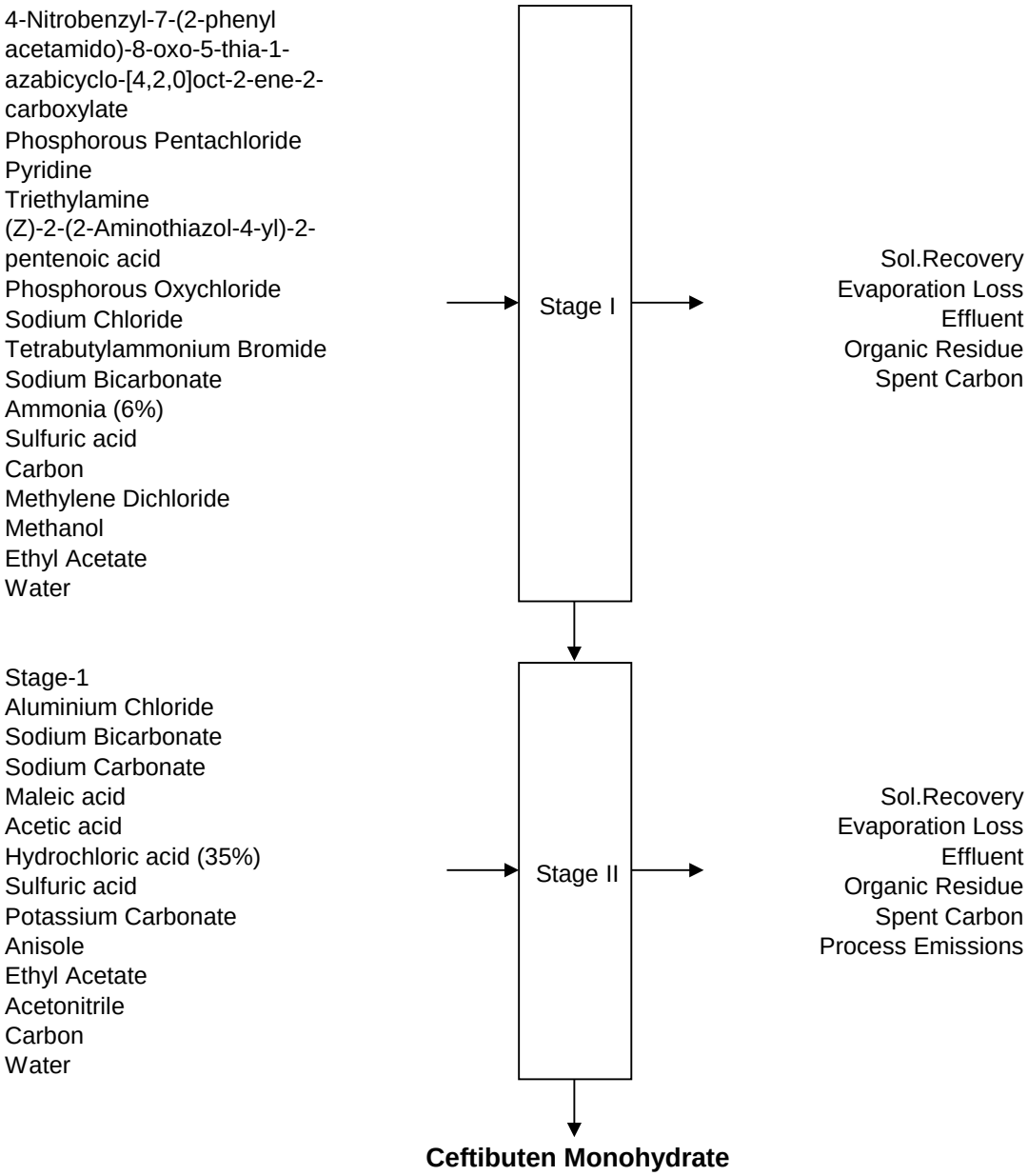
PRODUCT : Ceftibuten Monohydrate

Description :

Stage-1 : 4-Nitrobenzyl-7-(2-phenyl acetamido)-8-oxo-5-thia-1-azabicyclo-[4,2,0]oct-2-ene-2-carboxylate reacts with Phosphorous Pentachloride in presence of Pyridine, Triethylamine, (Z)-2-(2-Aminothiazol-4-yl)-2-pentenoic acid, Phosphorous Oxychloride, Sodium Chloride, Tetrabutylammonium Bromide, Sodium Bicarbonate, Ammonia and Sulfuric acid in Methylene Dichloride, Methanol and Ethyl Acetate solvent media and gets purified with Carbon to get Stage-1 Compound.

Stage-2 : Stage-1 Compound reacts with Aluminium Chloride in presence of Sodium Bicarbonate, Sodium Carbonate, Maleic acid, Acetic acid, Hydrochloric acid, Sulfuric acid and Potassium Carbonate in Anisole, Ethyl Acetate and Acetonitrile solvent media and gets purified with Carbon to obtain Ceftibuten Monohydrate.

Flow Chart



PRODUCT : Cefazoline Sodium

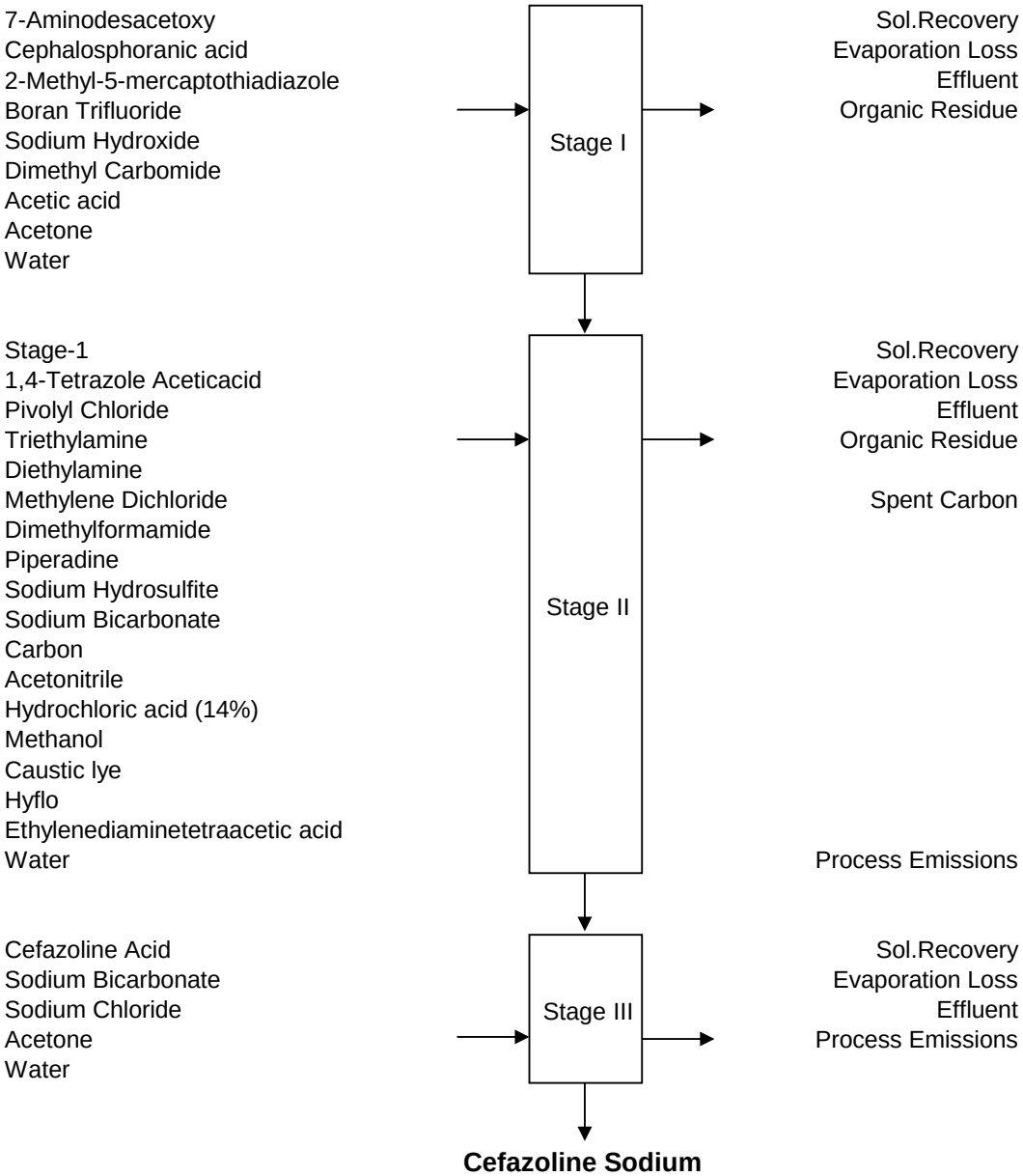
Description :

Stage-1 : In first step 7-Aminodesacetoxy Cephalosphoranic acid reacts with 2-Methyl-5-mercaptothiadiazole in presence of Boran Trifluoride and Sodium Hydroxide in basic media is used for reaction in Acetone and Dimethyl Carbomide solvent media to get Stage-1 Compound. The product is dried under vacuum.

Stage-2 : Stage-1 Compound is treated with 1,4-Tetrazole Aceticacid in presence of Diethylamine, Pivolyl Chloride, Triethylamine, Piperadine, Sodium Hydrosulfite, Sodium Bicarbonate, Ethylenediaminetetraacetic acid and Hydrochloric acid in Methylene Dichloride, Dimethylformamide, Acetonitrile and Methanol solvent media to get Cefazolin Acid.

Stage-3 : Cefazolin Acid is Reacted with Sodium Bicarbonate in presence of Sodium Chloride in Acetone as a Solvent media to get Cefazolin Sodium as the Final product.

Flow Chart



PRODUCT : Cefoperazone Sodium

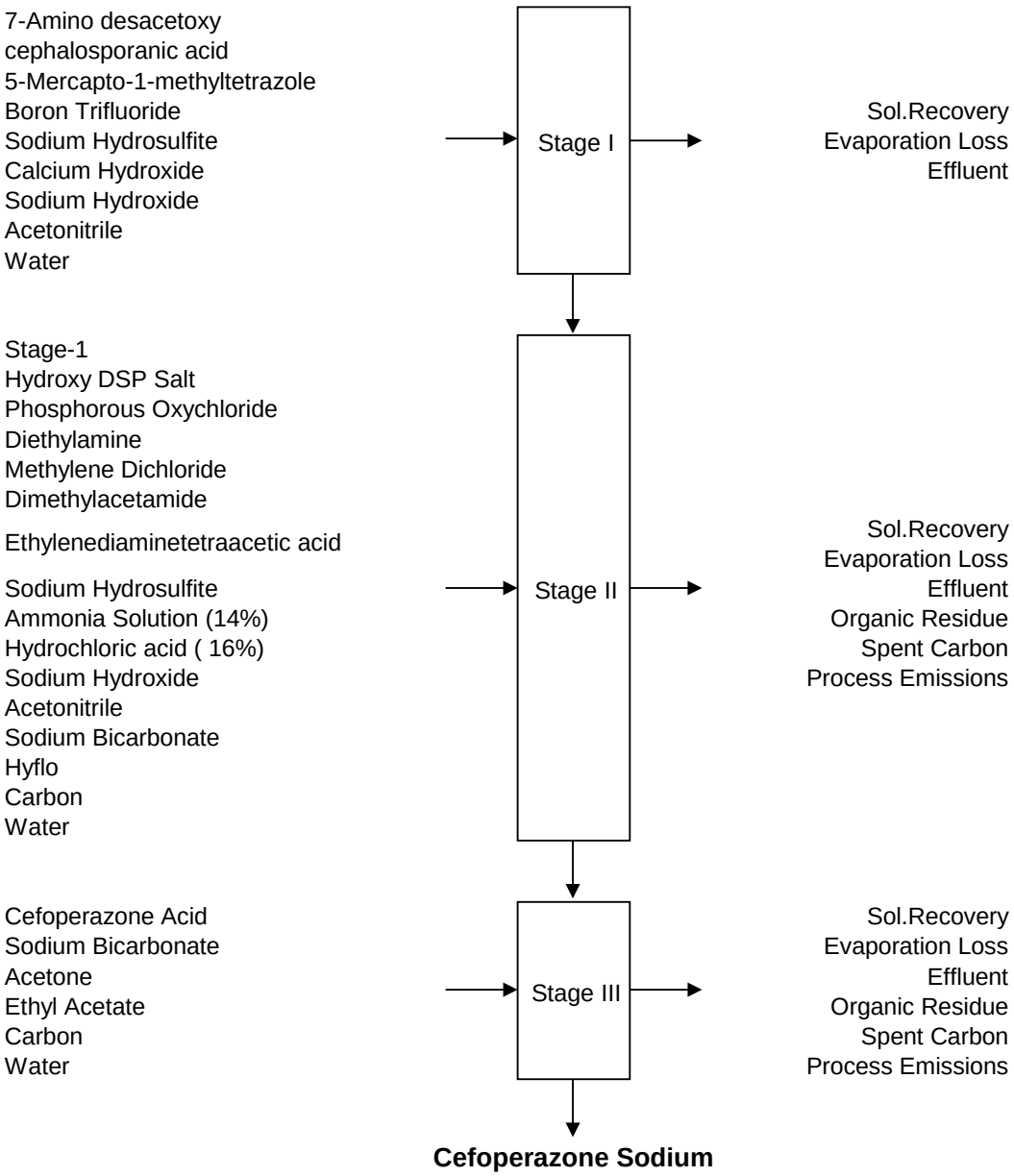
Description :

Stage-1 : 7-Amino desacetoxy cephalosporanic acid reacts with 5-Mercapto-1-methyltetrazole in presence of Boron Trifluoride, Calcium Hydroxide, Sodium Hydroxide and Sodium Hydrosulfite in Acetonitrile solvent medium to form Stage-1 Compound.

Stage-2 : Stage-1 Compound on reaction with Hydroxy DSP Salt in presence of Phosphorous Oxychloride, Sodium Hydroxide, Diethylamine, Ethylenediaminetetraacetic acid, Sodium Hydrosulfite, Ammonia, Sodium Bicarbonate and Hydrochloric acid in Methylene Dichloride, Dimethylacetamide and Acetonitrile solvent media to form Cefoperazone Acid.

Stage-3 : Cefoperazone Acid reacts with Sodium Bicarbonate in Acetone and Ethyl Acetate solvent media and gets purified with Carbon to obtain Cefoperazone Sodium.

Flow Chart



PRODUCT : Cefoxitin Sodium

Description :

Stage-1 : 7-Aminocephalosporanic acid reacts with Thiopheneacetyl Chloride in presence of Triethylamine, Sodium-2-ethylhexanoate and Hydrochloric acid in Methylene Dichloride and Acetone solvent media to get Stage-1 Compound.

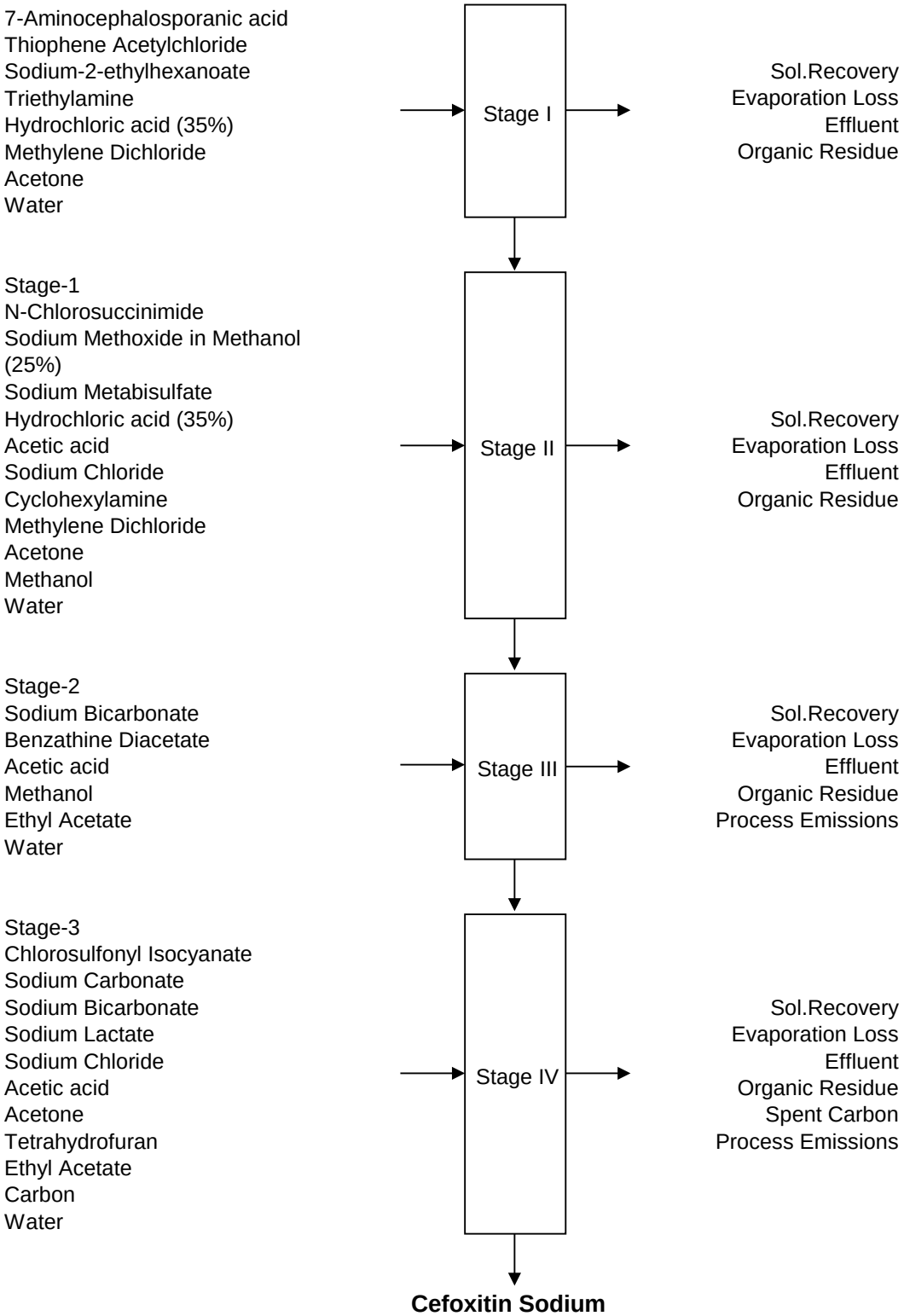
Stage-2 : Stage-1 Compound on reaction with N-Chlorosuccinimide in presence of Sodium Methoxide, Sodium Metabisulfate, Hydrochloric acid, Acetic acid, Sodium Chloride and Cyclohexylamine in Methylene Dichloride, Acetone and Methanol solvent medium to form Stage-2 Intermediate.

Stage-3 : Stage-2 Intermediate reacts with Sodium Hydroxide in presence of Benzathine Diacetate and Acetic acid in Methanol and Ethyl Acetate solvent media to get Stage-3 Compound.

Stage-4 : Stage-3 Compound is reacted with Chlorosulfonyl Isocyanate in presence of Sodium Carbonate, Sodium Bicarbonate, Sodium Lactate, Sodium Chloride and Acetic acid in Acetone, Tetrahydrofuran and Ethyl Acetate solvent media and gets purified with Carbon to obtain Cefoxitin Sodium.

PRODUCT : Cefoxitin Sodium

Flow Chart



PRODUCT : Ceftazidime Pentahydrate

Description :

Stage-1 : The condensation of Pyridine with 7-Aminodesacetoxy Cephalosphoranic acid in the presecne of silylating agent Hexamethyldisilazane, Trimethyl Silyliodide, Sodium Hydroxide and Hydrochloric acid in Methylene Dichloride, Methanol, Triethylamine and Acetone solvent media to get Stage-1 Compound.

Stage-2 : Ethyl(2,Z)-(2-amino-1,3-thiazole-4-yl)(hydroxyimino) acetate reacts with tert-Butyl-2-bromo-2-methyl propanoate in presence of Potassium Carbonate in Dimethylformamide solvent medium to form Stage-2 Intermediate.

Stage-3 : Stage-2 Intermediate on reaction with Potasium Hydroxide in presence of Hydrochloric acid and Sodium Hydroxide in Methanol and Acetone solvent media to get Stage-3 Compound.

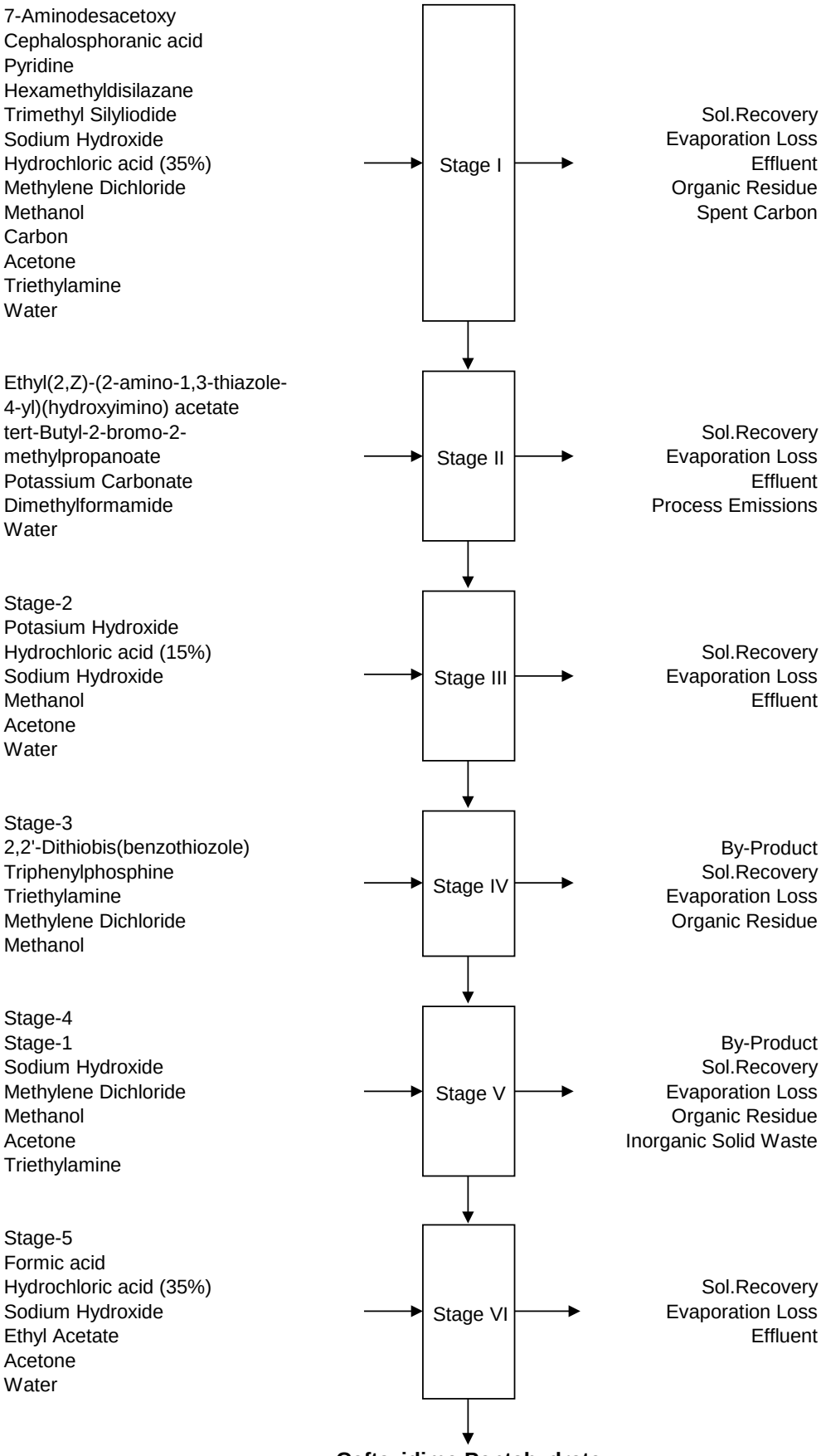
Stage-4 : Stage-3 Compound reacts with 2,2'-Dithiobis(benzothiozole) in presence of Triphenylphosphine and Triethylamine in Methylene Dichloride and Methanol solvent media to get Stage-4 Intermediate.

Stage-5 : Stage-4 Intermediate on condensation with Stage-1 Compound in presence of Sodium Hydroxide in Methylene Dichloride, Methanol, Acetone and Triethylamine solvent media to form Stage-5 Compound.

Stage-6 : Stage-5 Compound in presence of Sodium Hydroxide, Water and Hydrochloric acid in Formic acid, Ethyl Acetate and Acetone solvent media to obtain Ceftazidime Pentahydrate.

PRODUCT : Ceftazidime Pentahydrate

Flow Chart



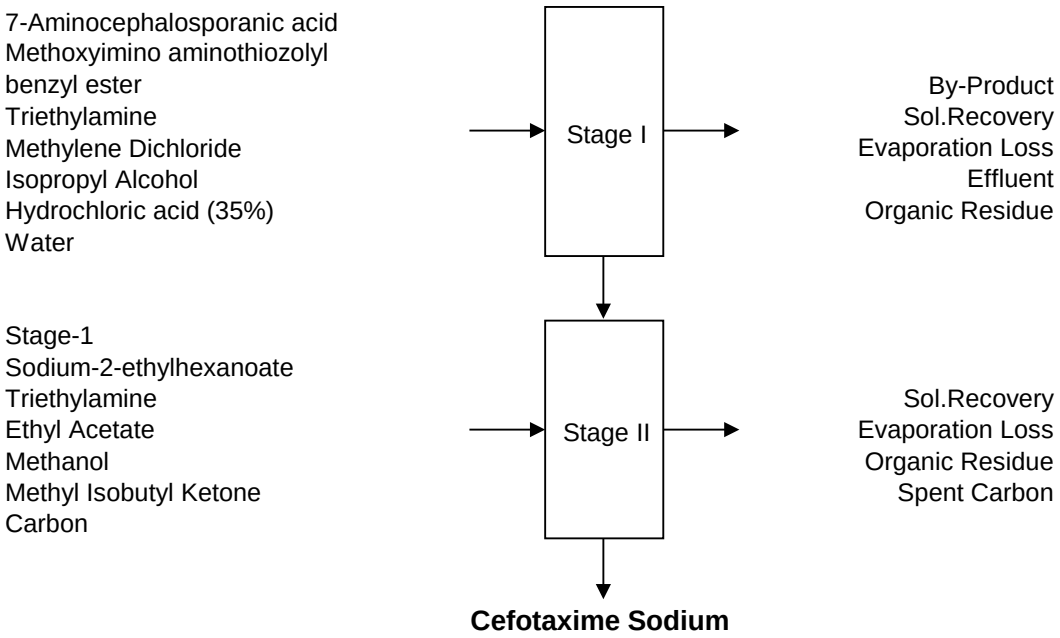
PRODUCT : Cefotaxime Sodium

Description :

Stage-1 : 7-Aminocephalosporanicacid reacts with Methoxyimino aminothiozolyl benzyl ester in presence of Triethylamine and Hydrochloric acid in Methylene Dichloride and Isopropyl Alcohol solvent media to get Stage-1 Compound.

Stage-2 : Stage-1 Compound reacts with Sodium-2-ethylhexanoate in presence of Triethylamine, Methanol, Ethyl Acetate and Methyl Isobutyl Ketone solvent media to obtain Cefotaxime Sodium.

Flow Chart



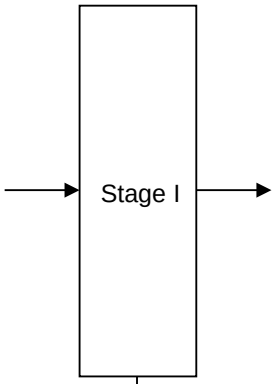
PRODUCT : Ceftizoxime Sodium

Description :

Stage-1 : 7-Amino-3-nor-3-cephem-4-carboxylic acid reacts with Methoxyimino aminothiozolyl benzyl ester in presence of Sodium-2-ethylhexanoate in Tetrahydrofuran, Ethyl Acetate, Acetone and Triethylamine solvent media and gets purified with Carbon to obtain Ceftizoxime Sodium.

Flow Chart

7-Amino-3-nor-3-cephem-4-carboxylic acid
Methoxyimino aminothiozolyl benzyl ester
Sodium-2-ethylhexanoate
Tetrahydrofuran
Ethyl Acetate
Acetone
Triethylamine
Carbon
Hyflo
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon

Ceftizoxime Sodium

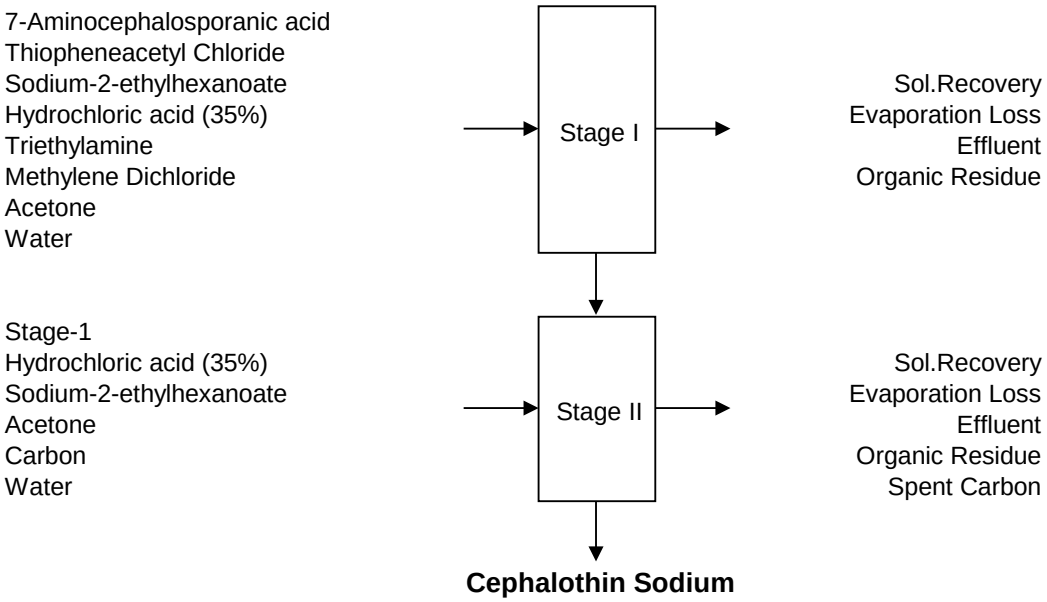
PRODUCT : Cephalothin Sodium

Description :

Stage-1 : 7-Aminocephalosporanic acid reacts with Thiopheneacetyl Chloride in presence of Triethylamine, Sodium-2-ethylhexanoate and Hydrochloric acid in Methylene Dichloride and Acetone solvent media to get Stage-1 Compound.

Stage-2 : Stage-1 Compound on reaction with Sodium-2-ethylhexanoate in presence of Hydrochloric acid in Acetone solvent medium and gets purified with Carbon to obtain Cephalothin Sodium.

Flow Chart

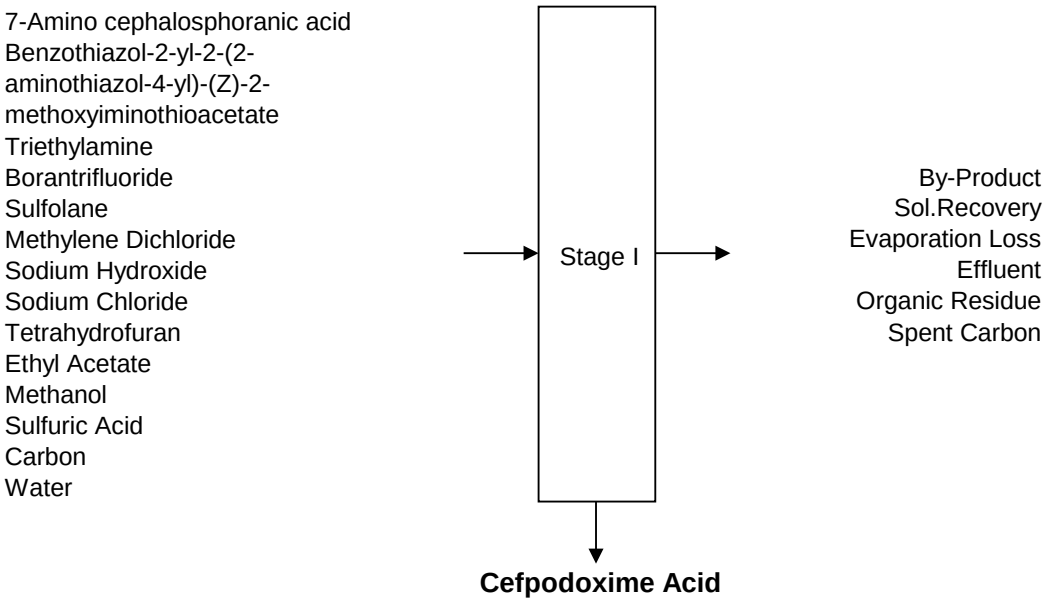


PRODUCT : Cefpodoxime Acid

Description :

Stage-1 : 7-ACA is hydrolysis and methoxylation in presence of Borantrifluoride and Methanol in Sulfolane. This was isolating water by adding with Treithylamine and the wet product further going under peptide condensation reaction with MAEM in water and Tetrhydrofuran in presence of Triethylamine base. The final product was extracting into water with by using Ethyl acetate. Cefpodoxime Acid was isolating from water by using Sulfuric acid. The isolated product drying under vacuum.

Flow Chart



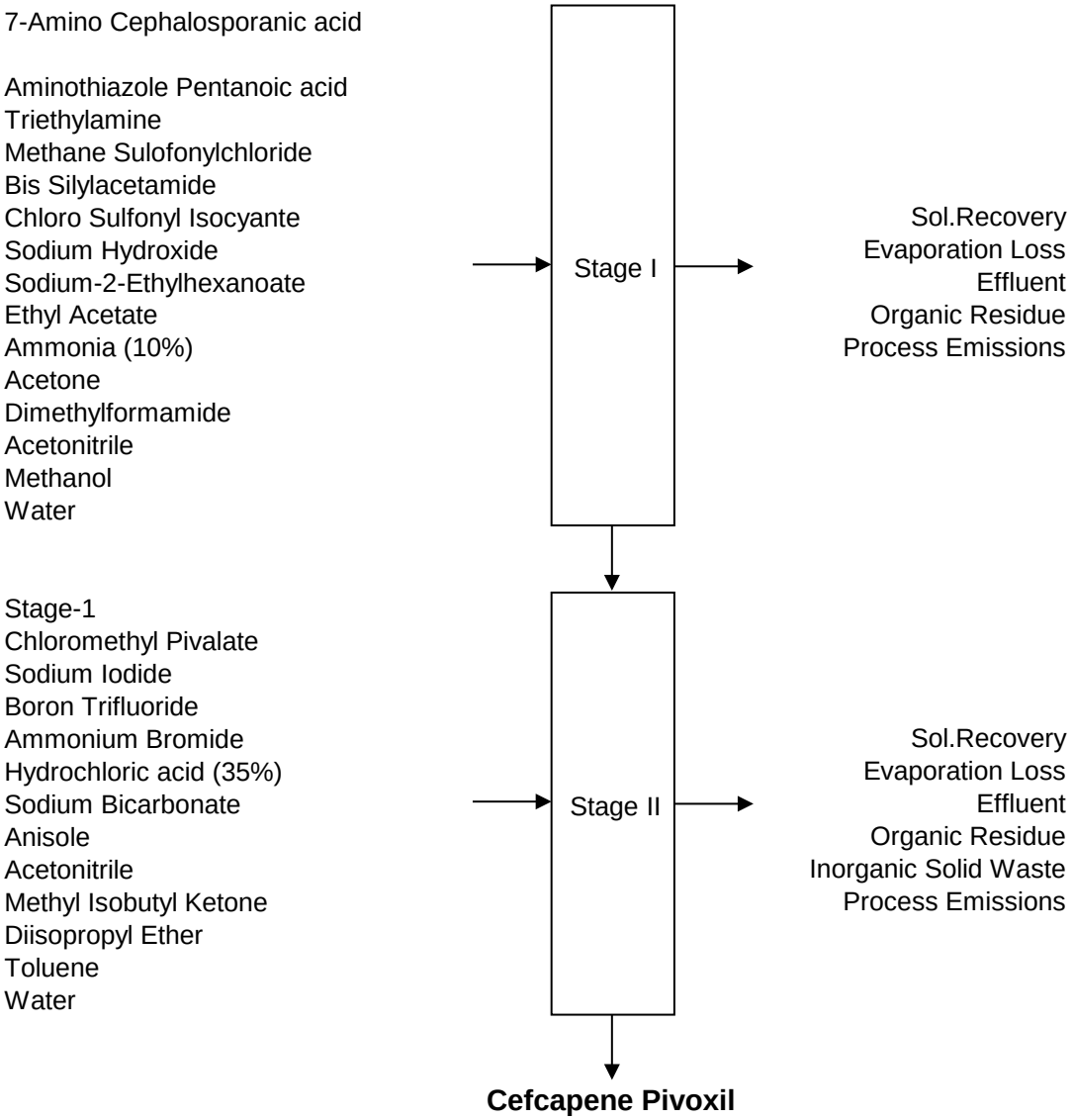
PRODUCT : Cefcapene Pivoxil

Description :

Stage-1 : Stage-1 is an intermediate for Cefcapene Pivoxil which was used as an oral drug. It is manufacturing from7-Amino Cephalosporanic acid by reacting with Methanesulfonyl Chloride, Aminothiazolyl Pentanoic acid and Chlorosulfonyl isocyanate in presence of Sodium Hydroxide & Bis Silylacetamide. The product was isolating as Sodium salt of Cefcapene by using Sodium-2-ethylhexanoate. The isolated product was drying under vacuum.

Stage-2 : Cefcapene pivoxil is a oral cephalosporin drug. It is manufacturing from Cefcapene sodium by reacting with Chloromethyl Pivalate in presence of Sodium Iodie, Boron Trifluoride. The product was extracting into Ethyl Acetate and concentrating the Ethyl Acetate under Vacuum. The product was further drying under vacuum to get fianl compound Cefcapene Pivoxil.

Flow Chart



PRODUCT : Cefmetazole Sodium

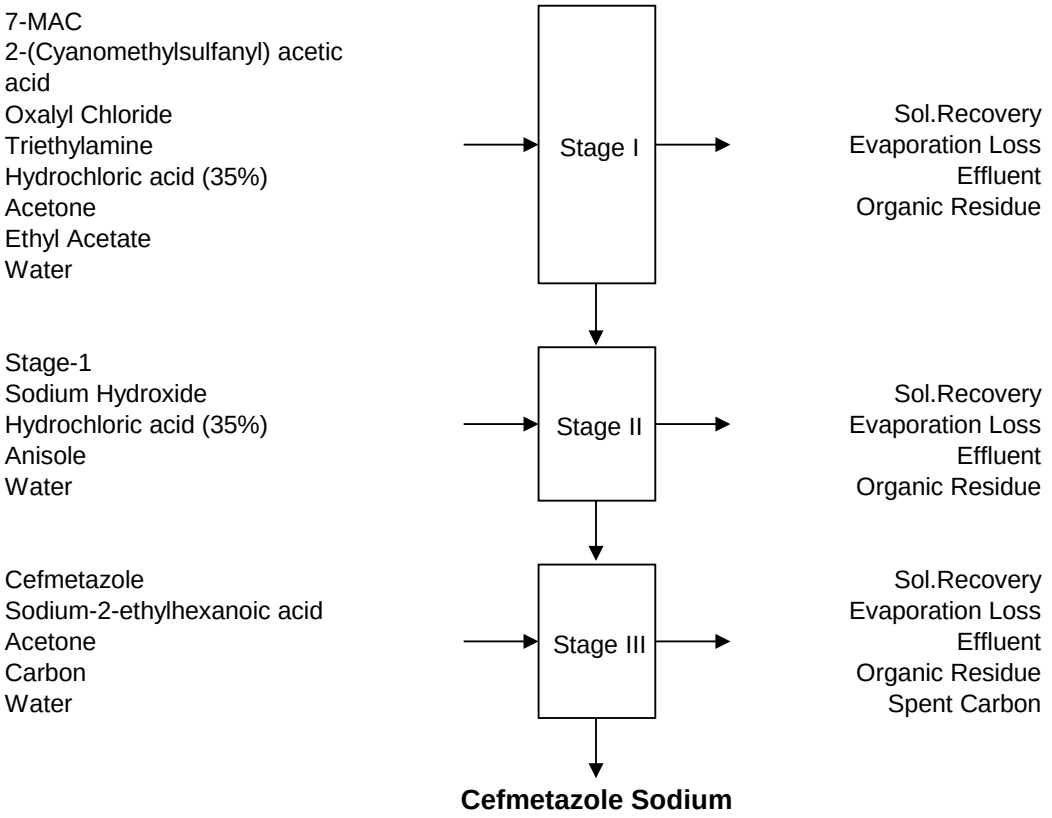
Description :

Stage-1 : 2-(Cyanomethylsulfanyl) acetic acid is chlorinating with Oxalyl Chloride and further going in condensation reaction with 7-MAC for protected Cefmetazole in presence of Triethylamine in Acetone solvent media. The product was extracting into Ethyl acetate and Water mixture. Further concentrating under vacume to get crystaline Protected Cemetazole as Stage-1 compound.

Stage-2 : Protected Cemetazole is going Hydrolysis in prepsence of Sodium Hydroxide in Anisole solvent media. Further hydrolysed product extracting into water, product was isolating by ading Hydrochloric acid and filtering toget Cemetazole as Stage-2 compound.

Stage-3 : Cefmetazole is suspending in water and disoolving by adding Sodium-2-Ethylhexanoic acid, mass was charcoal by adding Acetone finally to obtain Cefmetazole Sodium.

Flow Chart



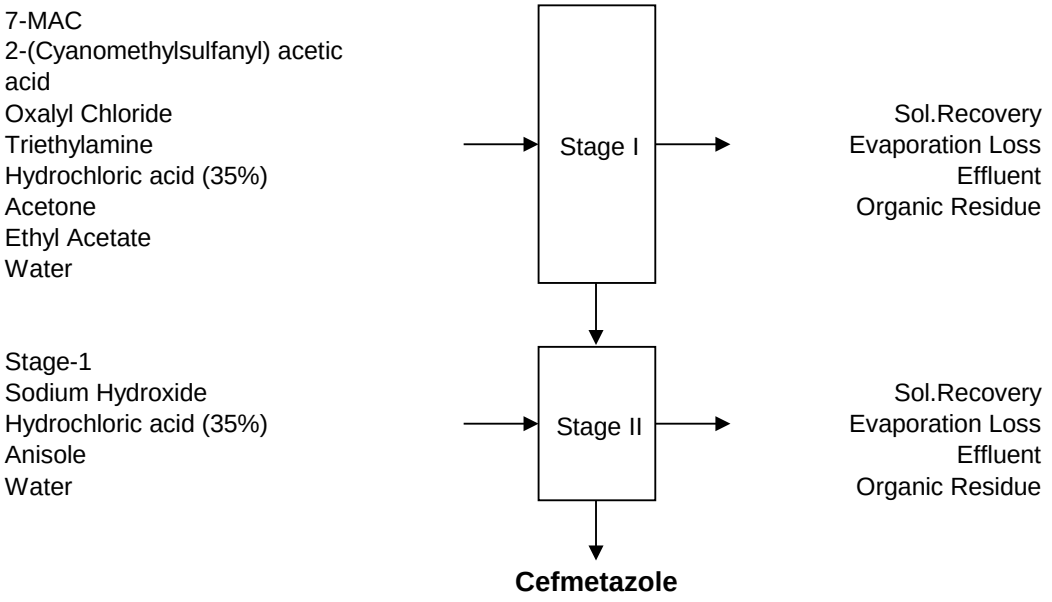
PRODUCT : Cefmetazole Sodium

Description :

Stage-1 : 2-(Cyanomethylsulfanyl) acetic acid is chlorinating with Oxalyl Chloride and further going in condensation reaction with 7-MAC for protected Cefmetazole in presence of Triethylamine in Acetone solvent media. The product was extracting into Ethyl acetate and Water mixture. Further concentrating under vacume to get crystaline Protected Cemetazole as Stage-1 compound.

Stage-2 : Protected Cemetazole is going Hydrolysis in prepsence of Sodium Hydroxide in Anisole solvent media. Further hydrolysed product extracting into water, product was isolating by ading Hydrochloric acid and filtering toget Cemetazole as Stage-2 compound.

Flow Chart



PRODUCT : 7-AVNA

Description :

Stage-1 : (4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate recting with formaldehide through wittig reaction in presence fo Triphenylphosphine, Sodium Bromide and Sodium Hydroxide in Methylene Dichloride, Dimethylformamide, Methanol and water mixture. The final product was islating by concentrating Methylene Dichloride and drying.

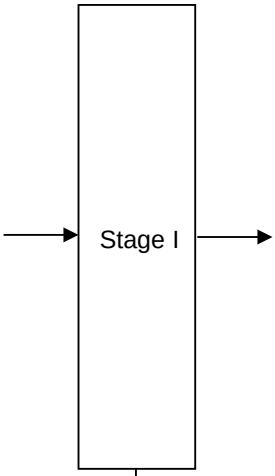
Stage-2 : Averest is reacting with phenol at 48 to 52°C to hydrolyze and to give PVC acid. After reaction complies extract PVC acid in to water by adding Butyl Acetate+Water mixture in presence of Sodium bicarbonate and Sodium Chloride sol. This PVC acid further hydrolyze to give 7-AVNA and Phenylacetic acid in presence of Enzyme and Sodium Carbonate solution. 7-AVNA solution charcolized with Carbon and EDTA and Hydrose and isolated by acidify with Sulfuric acid solution to get pH 3.90 to 4.10. Filter the compound and wash with water followed by drying to get desired MC. Take mother liquor from (7-AVNA) distilled the water up to ~10% residual vol .pH adjustment with HCl solution. Filteration and washing with water. We will get crude Phenylacetic acid material.

Purification of By-Product : Dissolution of Phenylacetic acid in water in presence of Sodium Hydroxide followed by Carbon treatment to get good color of Phenylacetic acid solution. Finally adjustment of pH 3.0-3.2 with Hydrogen Chloride to precipitate the Phenylacetic acid. Filtration of solid material drying gives pure Phenylacetic acid.

PRODUCT : 7-AVNA

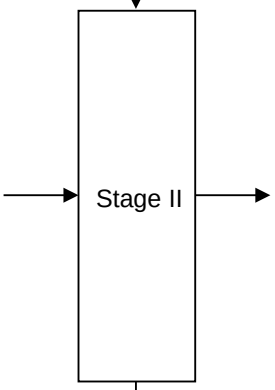
Flow Chart

(4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate
Triphenylphosphine
Formaldehyde (40%)
Methanol
Methylene Dichloride
Sodium Bromide
Sodium Hydroxide
Hydrochloric Acid (35%)
Dimethylformamide
TBAB
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue

Stage-1
Phenol
Butyl Acetate
Sodium Bicarbonate
Sodium Chloride
Sodium Carbonate
Carbon
Ethylenediaminetetraacetic acid
Sulfuric acid
Methanol
Enzyme(Wet)
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Spent Carbon
Process Emissions

7-AVNA

PRODUCT : MEAT (Thio Ester)

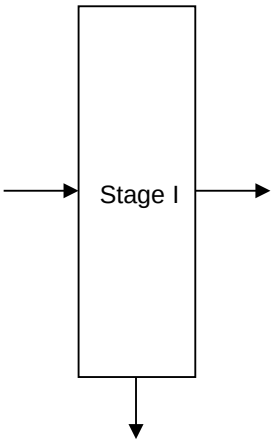
Description :

Stage-1 : EHATA is under going hydrolysis in presence of sodium hydroxide in water and going acylation in presence of acetic an hydride and sodium hydroxide at neutral pH condensation. This was isolating in centrifuge. The isolated product doing anhydrification in acetone and going condensation with bis mercaptobenz thiazole in presence of TEA and TPP in MDC. The MEAT (Thio Ester) product was isolating in centrifuge and further drying under vacuum.

Purification of By-Product : Dissolution of 2-Mercaptobenzothiazole crude in Recovered Mixed Solvent followed by Carbon treatment and solvent distillation upto ~2.0 residual volume and then solid filtration and drying to get pure 2-Mercaptobenzothiazole.

Flow Chart

Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate
Sodium Hydroxide
Acetic anhydride
Bismercapto benzothiazole
Triphenylphosphine
Triethylamine
Hydrochloric acid (35%)
Acetone
Methylene Dichloride
Water



By-Product
Sol.Recovery
Evaporation Loss
Effluent
Organic Residue

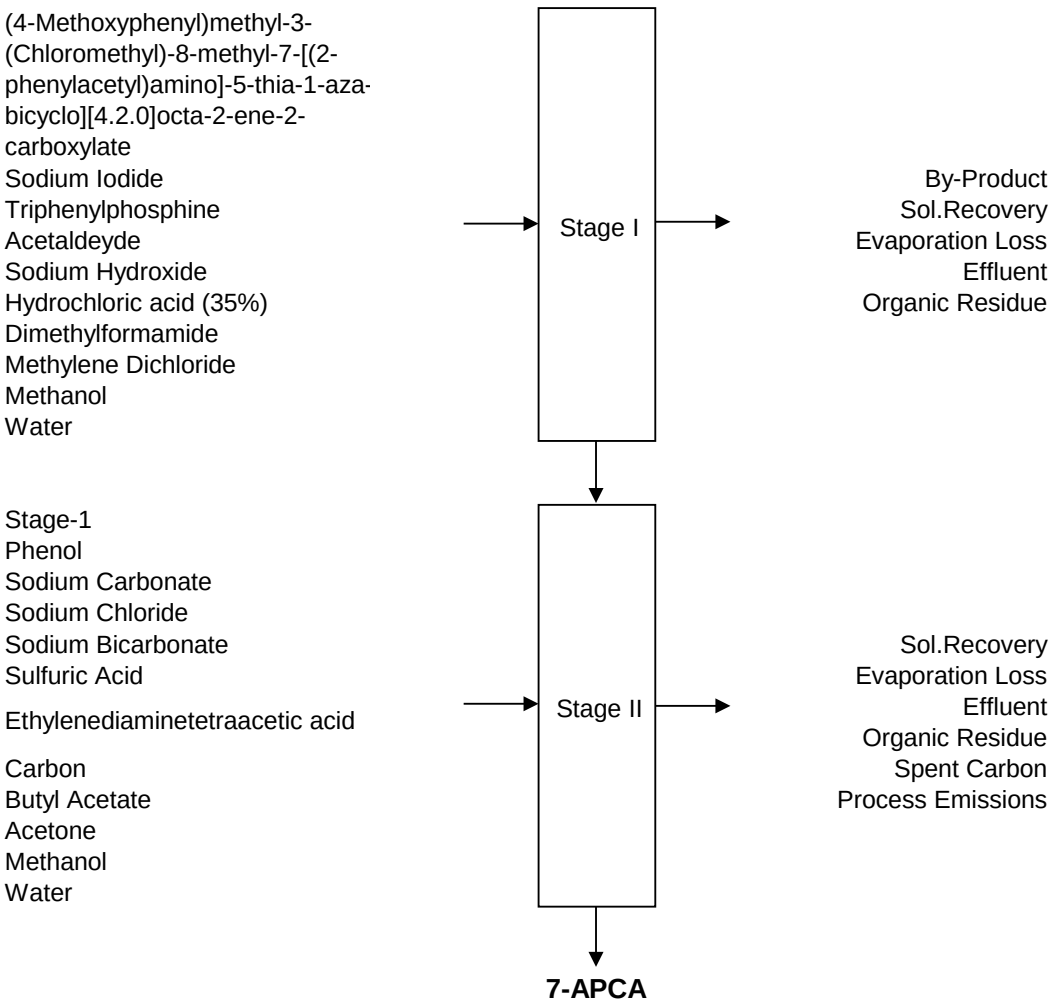
PRODUCT : 7-APCA

Description :

Stage-1 : (4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenylacetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate reacts with Triphenylphosphine in presence of Acetaldehyde, Sodium Hydroxide, Sodium Iodide and Hydrochloric acid in Dimethylformamide, Methylene Dichloride and Methanol solvent media to give Stage-1 Compound.

Stage-2 : Stage-1 Compound on reaction with Phenol in presence of Sodium Carbonate, Sodium Chloride, Sodium Bicarbonate, Sulfuric Acid and Ethylenediaminetetraacetic acid in Butyl Acetate, Acetone and Methanol solvent media to form 7-APCA.

Flow Chart

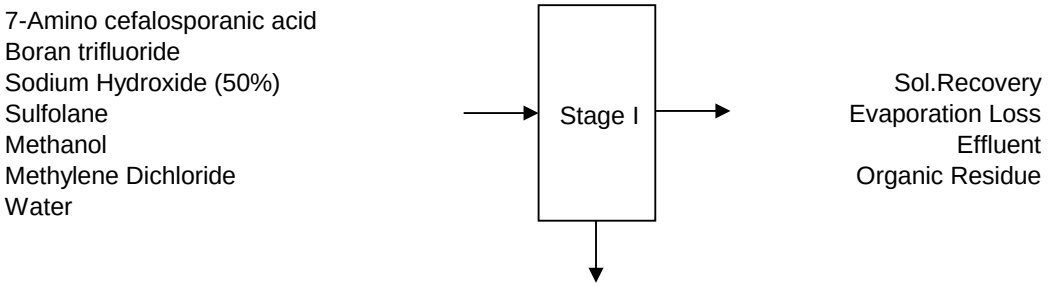


PRODUCT : 7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (7-AMCA)

Description :

Stage-1 : 7-AMCA is an intermediate for Cefodoxime proxetill. This product was manufacturing through a series of chemical reactions. 7-ACA is hydrolysis and methoxylation in presence of Boron trifluoride and Methanol in Sulfolane solvent media. This was isolating after extraction of Sulfolane with Methylene Dichloride, from the aqueous layer by adding Sodium Hydroxide and the wet cake further purifying to get pure 7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (7-AMCA).

Flow Chart



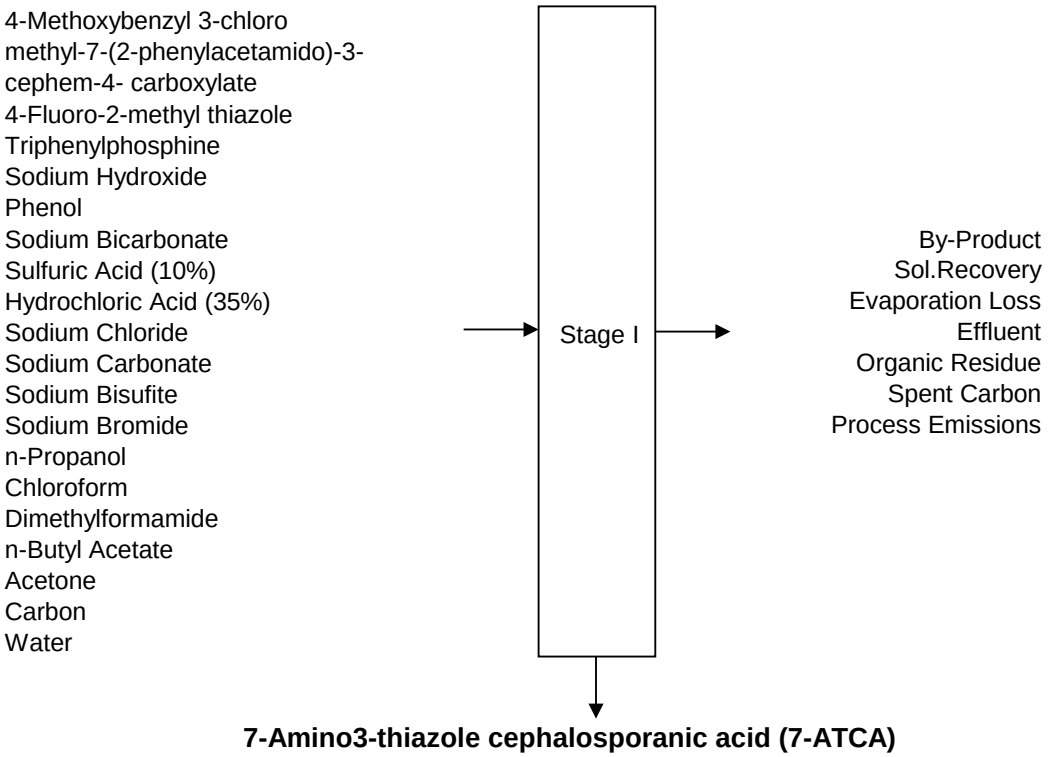
7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (7-AMCA)

PRODUCT : 7-Amino3-thiazole cephalosporanic acid (7-ATCA)

Description :

Stage-1 : 4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4- carboxylate is reacted with 4-Fluoro-2-methyl thiazole in presence of Triphenylphosphine, Sodium Hydroxide, Phenol, Hydrochloric acid, Sufuric acid, Sodium Bicarbonate, Sodium Chloride, Sodium Carbonate, Sodium Bisufite and Sodium Bromide in n-Propanol, Chloroform, Dimethylformamide, n-Butyl Acetate and Acetone solvent media and gets purified with Carbon to get 7-Amino3-thiazole cephalosporanic acid (7-ATCA).

Flow Chart



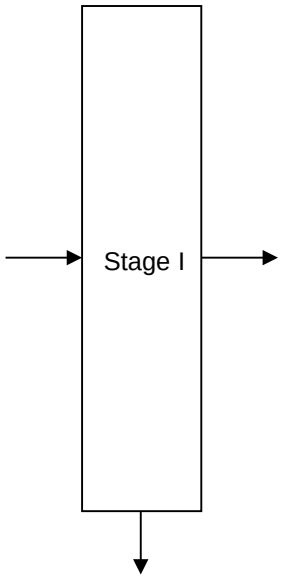
PRODUCT : Sitagliptin Phosphate

Description :

Stage-1 : (3R)-3-[(1,1-Dimethylethoxy carbonyl)-amino]-4-(2,4,5-trifluorophenyl)butanoic acid is coupled with 3-(Trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4triazol[4,3-a] pyrazine in presence of 1-Ethyl-3-(3'-dimethylamino propyl) carbodiimide Hydrochloride, Hydroxybenzotriazole and Diisopropylethylamine in Dimethylformamide solvent. Methylene Dichloride extraction, washing with water and solvent evaporation gave crude protected Sitagliptin, Which on acidification with Phosphoric acid in presence of Isopropyl Alcohol solvent medium gives Sitagliptin Phosphate.

Flow Chart

(3R)-3-[(1,1-Dimethylethoxy carbonyl)-amino]-4-(2,4,5-trifluorophenyl)butanoic acid
3-(Trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4triazol[4,3-a] pyrazine
1-Ethyl-3-(3'-dimethylamino propyl) carbodiimide Hydrochloride
Hydroxybenzotriazole
Phosphoric acid
Diisopropylethylamine
Dimethylformamide
Methylene Dichloride
Isopropyl Alcohol
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Process Emissions

Sitagliptin Phosphate

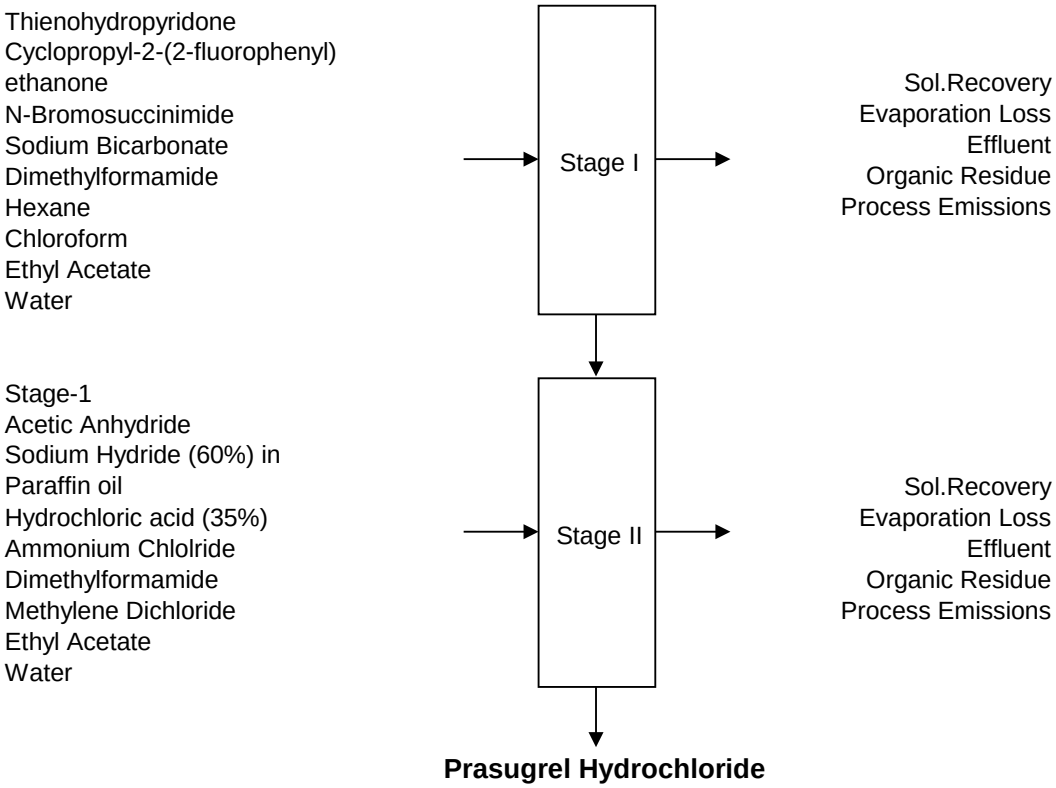
PRODUCT : Prasugrel Hydrochloride

Description :

Stage-1 : Cyclopropyl-2-(2-fluorophenyl) ethanone reacts with N-Bromo succinimide in presence of Sodium Bicarbonate to give Bromoderivative of ketone. The compound was isolated by extraction with Chloroform followed by evaporation of solvent. The bromo compound in-situ reacts with Thienohydropyridone to give Stage-1 coupled product. The intermediate was isolated by Ethyl Acetate and crystallized by titration with Hexane. This intermediate directly used for next step without further purification.

Stage-2 : Stage-1 product reacts with Acetic Anhydride in presence of Sodium Hydride in Dimethylformamide solvent to give Prasugrel. After completion of reaction, the compound extracted by Methylene Dichloride and solvent evaporated to give crude Prasugrel. Finally, Prasugrel Hydrochloride salt has been prepared by using Hydrochloric acid and Ethyl Acetate as solvent.

Flow Chart

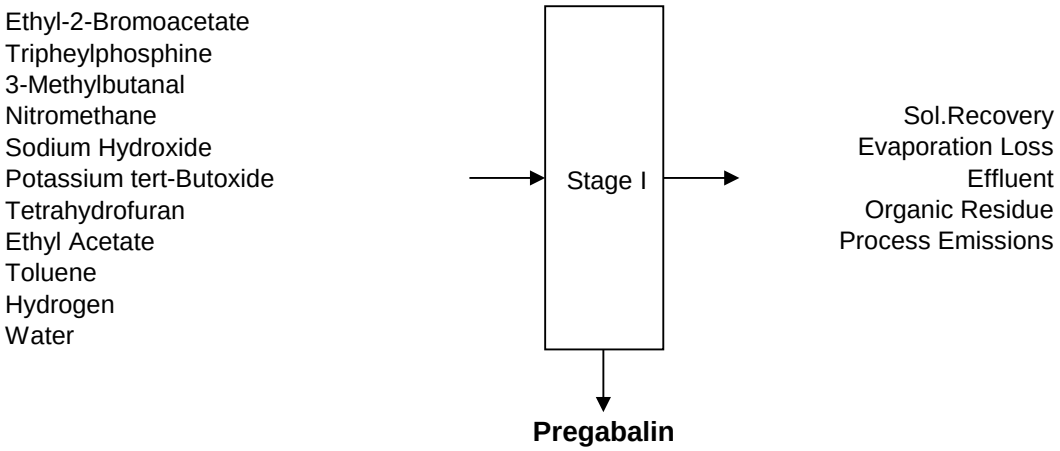


PRODUCT : Pregabalin

Description :

Stage-1 : First Wittig salt has been prepared by reaction with Ethyl-2-Bromoacetate with Triphenylphosphine which reacts with 3-Methylbutanal in presence of Sodium Hydroxide to give an olefin intermediate. This intermediate reacts with anion of Nitromethane (prepared by using Potassium tert-Butoxide) followed by nitro reduction with Hydrogen in presence of Tetrahydrofuran, Ethyl Acetate and Toluene solvent media to obtain Pregabalin.

Flow Chart



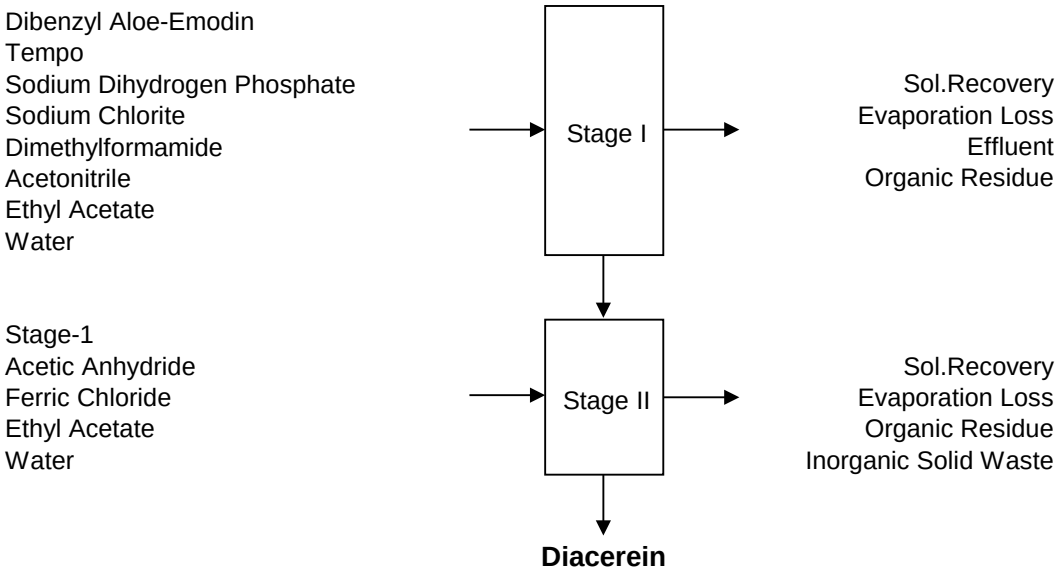
PRODUCT : Diacerein

Description :

Stage-1 : Alcoholic functionality of Dibenzyl Aloe-Emodin has been converted to acid functionality by using Sodium Chlorite (oxidizing agent) in presence of Tempo and Sodium Dihydrogen Phosphate. The compound was extracted by Ethyl Acetate and solvent evaporation gave dibenzylrhein as an intermediate of Diacerine. This intermediate directly used for next step without further purification.

Stage-2 : Stage-1 product was deprotected by Ferric Chloride and acetylated by Acetic Anhydride. The reaction has been done in single step and compound isolated by Ethyl Acetate. Washing with water followed by evaporation of solvent gave Diacerein.

Flow Chart

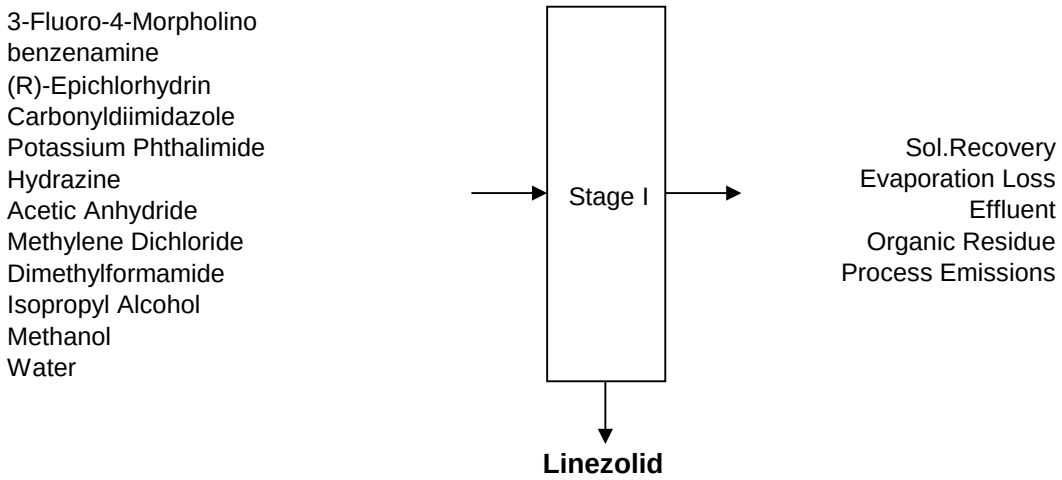


PRODUCT : Linezolid

Description :

Stage-1 : 3-Fluoro-4-Morpholino benzenamine reacts with (R)-Epichlorhydrin in presence of Carbonyldiimidazole to give Chloroethyl carbamate intermediate. This intermediate allowed to reacts with Potassium Phthalimide followed by hydrolysis by Hydrazine to give amine intermediate. This amine reacts with Acetic anhydride in presence of Methylene Dichloride, Dimethylformamide, Isopropyl Alcohol and Methanol solvent media to give Linezolid.

Flow Chart

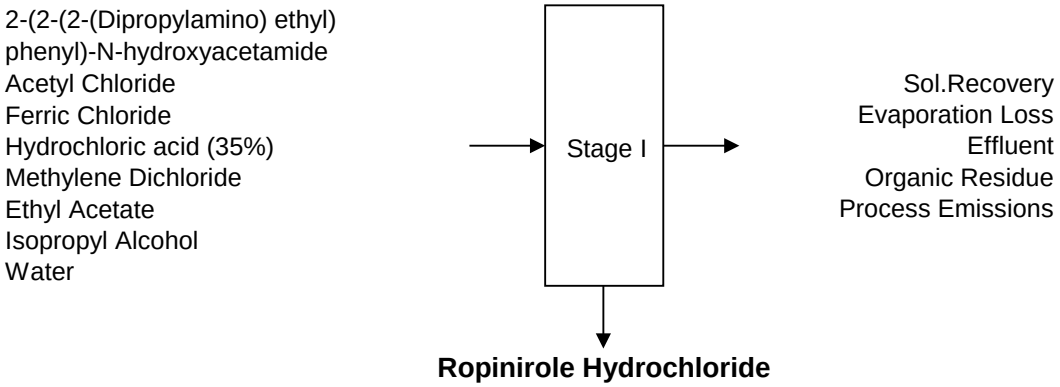


PRODUCT : Ropinirole Hydrochloride

Description :

Stage-1 : 2-(2-(2-(Dipropylamino) ethyl) phenyl)-N-hydroxyacetamide reacts with Acetyl Chloride followed by ring cyclization by Ferric Chloride in presence of Ethyl Acetate and Isopropyl Alcohol solvent media to give Ropinirole. The crude Ropinirole was treated with Hydrochloric acid in presence of Methylene Dichloride medium to form Ropinirole Hydrochloride.

Flow Chart



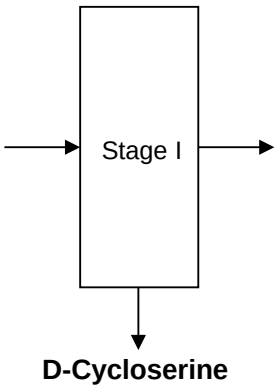
PRODUCT : D-Cycloserine

Description :

Stage-1 : N-Benzyloxycarbonyl-D-Serine reacts with Thionyl Chloride to give Cbz protected Chloromethyl hydroxyamide derivative. Cyclization done by Sodium Hydride and finally deprotection done by Hydroxylamine Hydrochloride in presence of Methylene Dichloride and Tetrahydrofuran solvent media to get D-Cycloserine.

Flow Chart

N-Benzyloxycarbonyl-D-Serine
Hydroxylamine Hydrochloride
Thionyl Chloride
Sodium Hydride (60%) in
Paraffin oil
Sodium Bicarbonate
Methylene Dichloride
Tetrahydrofuran
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Process Emissions

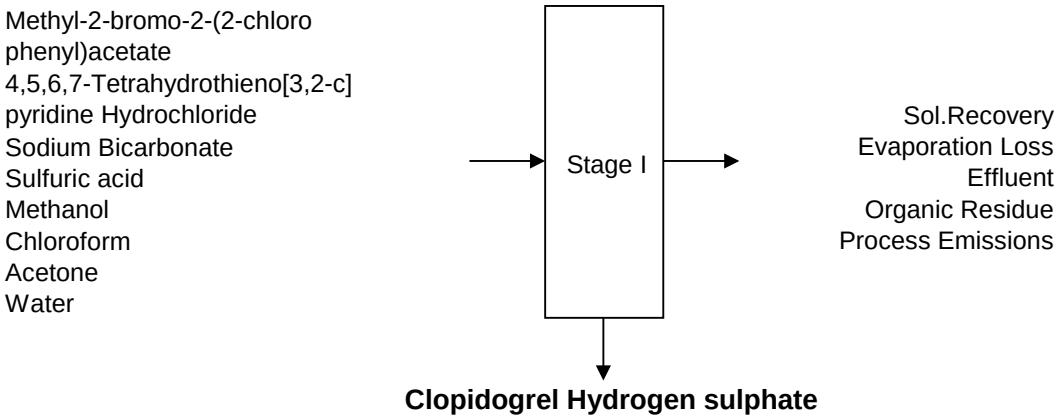
D-Cycloserine

PRODUCT : Clopidogrel Hydrogen Sulfate

Description :

Stage-1 : 4,5,6,7-Tetrahydrothieno[3,2-c] pyridine Hydrochloride reacts with Methyl-2-bromo-2-(2-chlorophenyl) acetate in presence of Sodium Bicarbonate in Methanol and Acetone Solvent medium to form Clopidogrel. The purification / resolution of Clopidogrel to pure form done by Acetone medium and finally Clopidogrel converted to Clopidogrel Hydrogen Sulfate by using Sulfuric acid in Chloroform madium.

Flow Chart



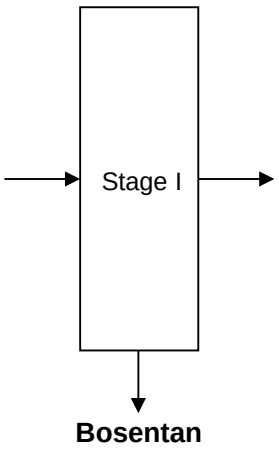
PRODUCT : Bosentan

Description :

Stage-1 : 5-(2-Methoxyphenoxy)-4,6-dichloro-2-(pyrimidin-2-yl)pyrimidine reacts with 4-(tert-Butyl)benzene-1-sulfonamide in presence of Sodium Bicarbonate to give 4-substitutes pyrimidine which further couples with Ethylene glycol in presence of Sodium Methoxide in Toluene and Methylene Dichloride solvent media to give desired Bosentan.

Flow Chart

5-(2-Methoxyphenoxy)-4,6-dichloro-2-(pyrimidin-2-yl) pyrimidine
4-(tert-Butyl)benzene-1-sulfonamide
Ethylene glycol
Sodium Methoxide
Sodium Bicarbonate
Toluene
Methylene Dichloride
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Process Emissions

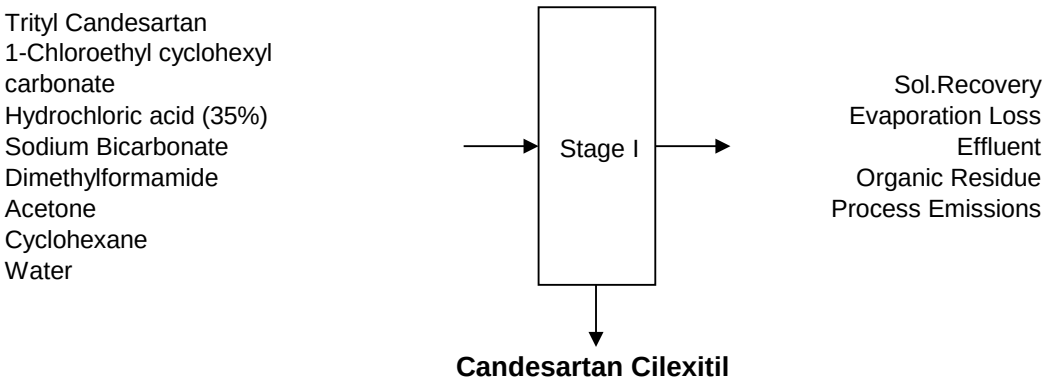
Bosentan

PRODUCT : Candesartan Cilexitil

Description :

Stage-1 : 1-Chloroethyl cyclohexyl carbonate is condensed with Trityl Candesartan in Dimethylformamide solvent in presence of Sodium Bicarbonate to give crude wet Trityl Candesartan cilexitil. The wet material dried by Acetone wash and deprotection done by Hydrochloric acid in Cyclohexane-Acetone solvent mixture. Finally, material isolated by neutralization and titration by Cyclohexane to get Candesartan Cilexitil.

Flow Chart

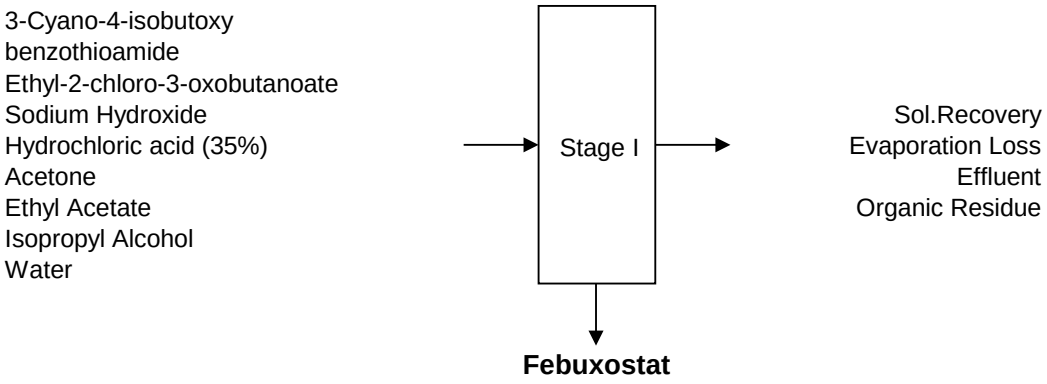


PRODUCT : Febuxostat

Description :

Stage-1 : A mixture of Ethyl-2-chloro-3-oxobutanoate and 3-Cyano-4-isobutoxy benzothioamide taken in Isopropyl Alcohol and refluxued for stipulated period of time. The reaction was cooled to get crude Ethyl ester protected Febuxostat. The intermediate was hydrolyzed in Sodium Hydroxide - Acetone and compound was extracted by Ethyl Acetate after neutralization by acid. Solvent evaporated under reduced pressure followed by Acetone wash gave Febuxostat in pure form.

Flow Chart

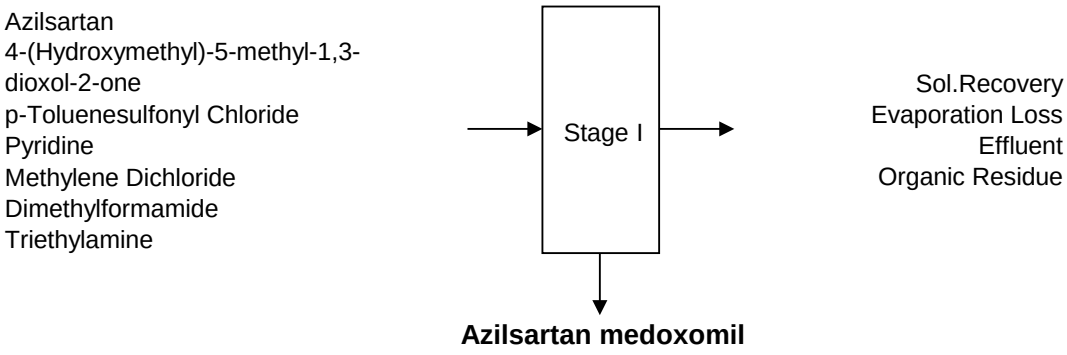


PRODUCT : Azilsartan medoxomil

Description :

Stage-1 : Cyclic carbonate was taken in Dimethylformamide and to which Pyridine, p-Toluenesulfonyl Chloride were added successively to prepare Tosyl derivative. The reaction was quenched with water and the compound was isolated by extraction with Methylene Dichloride followed by evapotaion of solvent. This intermediate was taken in Methylene Dichloride and Triethylamine followed by Azilsartan were added successively. The reaction was quenched with water, compound extracted with Methylene Dichloride and solvent evaporation gave desired Azilsartan Medoxomil.

Flow Chart

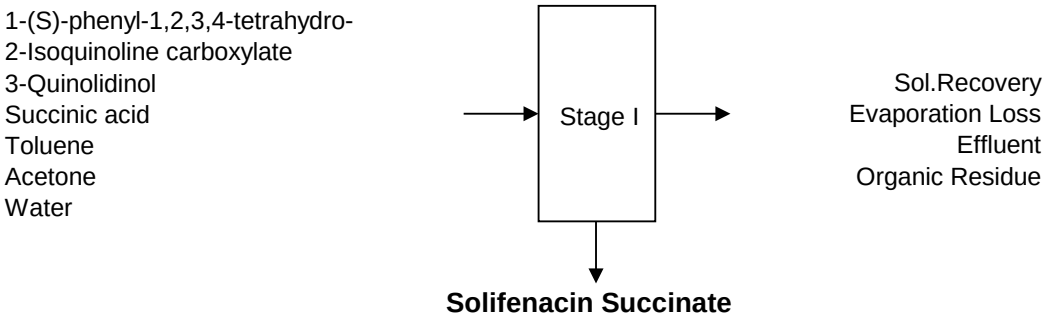


PRODUCT :Solifenacin Succinate

Description :

Stage-1 : A mixture of 1-(S)-phenyl-1,2,3,4-tetrahydro-2-Isoquinoline carboxylate and 3-Quinolidinol taken in Toluene and refluxed for stipulated period of time with continuous removal of Ethanol. The reaction mixture was poured in water and Solifenacin was extracted by Toluene extraction followed by evaporation. The crude Solifenacin was dissolved in Acetone and to which Succinic acid was added. Filtration and drying of compound gave pure Solifenacin Succinate.

Flow Chart

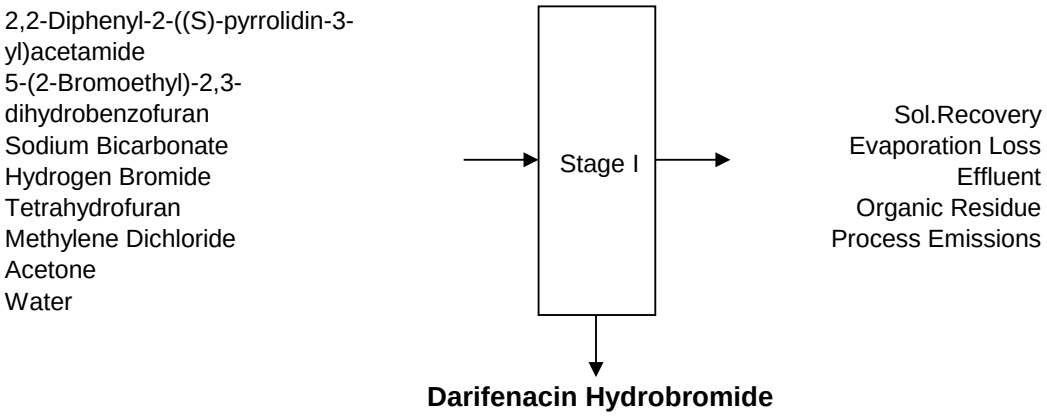


PRODUCT : Darifenacin Hydrobromide

Description :

Stage-1 : A Suspension of 2,2-Diphenyl-2-((S)-pyrrolidin-3-yl)acetamide, 5-(2-Bromoethyl)-2,3-dihydro benzofuran and Sodium Bicarbonate was refluxed in Tetrahydrofuran solvent for a stipulated period of time. The reaction mixture was partitioned between water and Methylene Dichloride, Organic layer separated and evaporated to give Crude Darifenacin. Darifenacin was taken in Acetone and to which Hydrogen Bromide was added. Filtration and drying gave desired Darifenacin Hydrobromide in pure form.

Flow Chart



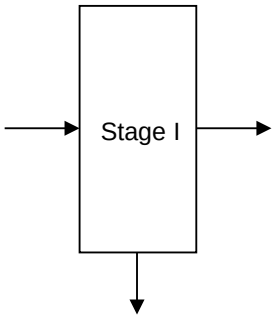
PRODUCT : Trospium chloride

Description :

Stage-1 : 2-Hydroxy-2,2-diphenylacetic acid taken in Methylene Dichloride and to which Carbonyldiimidazole was added. The reaction mixture was stirred for stipulated period of time and Spiro[bicyclo[3.2.1]octane-8,1'-pyrrolidin]-1'-ium chloride was added. After completion of reaction, the reaction mixture was partitioned between water and Methylene Dichloride, organic layer separated and Trospium Chloride isolated by addition of Cyclohexane.

Flow Chart

Spiro[bicyclo[3.2.1]octane-8,1'-pyrrolidin]-1'-ium chloride
2-Hydroxy-2,2-diphenylacetic acid
Carbonyldiimidazole
Methylene Dichloride
Cyclohexane
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Process Emissions

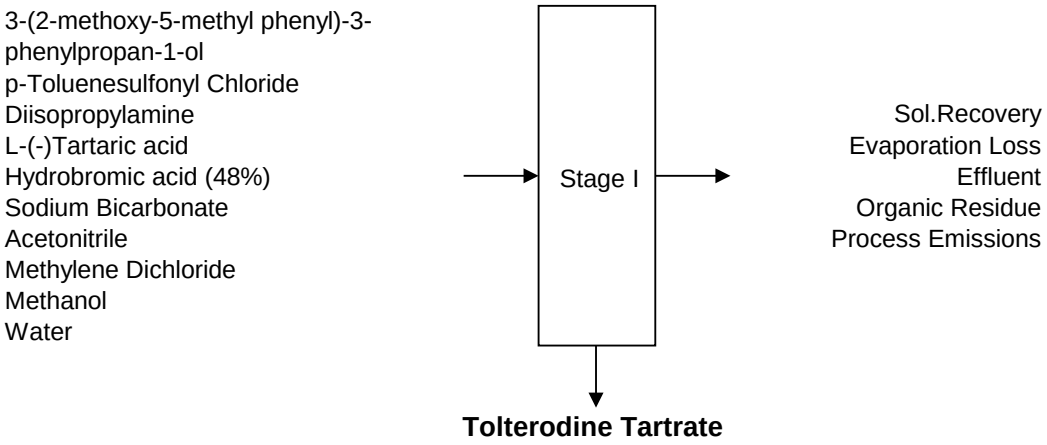
Trospium chloride

PRODUCT : Tolterodine Tartrate

Description :

Stage-1 : 3-(2-methoxy-5-methyl phenyl)-3-phenylpropan-1-ol was taken in Acetonitrile and to which Diisopropylamine followed by p-Toluenesulfonyl Chloride were added. The Diisopropyl coupled product was isolated by Methylene Dichloride extraction and after evaporation of organic solvent, the reaction mixture was treated with Hydrobromic acid for de-methylation to get Tolterodine. Crude compound in Methylene Dichloride was treated with Tartaric acid in Methanol to get desired Tolterodine Tartrate.

Flow Chart



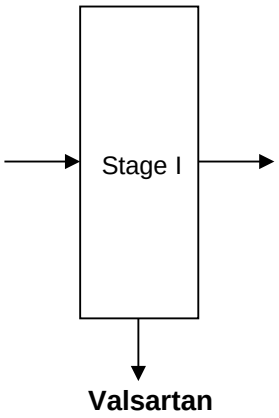
PRODUCT : Valsartan

Description :

Stage-1 : L-Valine on condensation with tetrazole derivative in presence of sodium bicarbonate leads to an intermediate which further coupled with pentanoyl chloride in presence of diisopropylethylamine to give Valsartan.

Flow Chart

L-Valine
Biphenyl bromomethyl-1H-tetrazole
Sodium Bicarbonate
Diisopropylethylamine
Pentanoyl Chloride
Dimethylformamide
Methylene Dichloride
Methanol
Water



Sol.Recovery
Evaporation Loss
Effluent
Organic Residue
Process Emissions

Valsartan

PRODUCT : Cefixime Trihydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	255	3895.125
Acetone	=	630	9623.25
Activated Carbon	=	2	30.55
Butyl Acetate	=	1000	15275
Carbon	=	23	351.325
Dimethylformamide	=	365	5575.375
Ethylenediaminetetraacetic acid	=	2	30.55
Formaldehyde (40%)	=	50	763.75
Hydrochloric Acid (35%)	=	56	855.4
Hydrose	=	1	15.275
Methanol	=	2330	35590.75
Methylene Dichloride	=	750	11456.25
MICA Ester	=	178	2718.95
Phenol	=	365	5575.375
Recovered Mixed Solvent	=	650	9928.75
Sodium Bicarbonate	=	56	855.4
Sodium Bromide	=	59	901.225
Sodium Carbonate	=	30	458.25
Sodium Chloride	=	5	76.375
Sodium Hydroxide	=	42	641.55
Sulfuric acid	=	27	412.425
Toluene	=	725	11074.375
Triethylamine	=	52	794.3
Triphenylphosphine	=	140	2138.5

PRODUCT : Cefpodoxime Proxetil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
1,1,3,3-Tetramethyl gunadine	=	41	195.16
18-Crown-6	=	5	23.80
1-Chloroethyl isopropyl carbonate	=	60	285.60
7-Amino cephalosphoranic acid	=	138	656.88
Activated Carbon	=	5	23.80
Ammonia (10%)	=	13	61.88
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate	=	178	847.28
Borantrifluoride	=	104	495.04
Carbon	=	26	123.76
Cyclohexane	=	3500	16660.00
Dimethylacetamide	=	700	3332.00
Ethyl Acetate	=	3240	15422.40
Hydrochloric acid (35%)	=	8	38.08
Hydrose	=	2	9.52
Methanol	=	1130	5378.80
Methylene Dichloride	=	2100	9996.00
Recovered Mixed Solvent	=	760	3617.60
Sodium Chloride	=	225	1071.00
Sodium Hydroxide	=	220	1047.20
Sodium Iodide	=	55	261.80
Sodium Thiosulfate	=	8	38.08
Sulfolane	=	1380	6568.80
Sulfuric Acid	=	18	85.68
TBAB	=	1	4.76
Tetrahydrofuran	=	620	2951.20
Toluene	=	470	2237.20
Triethylamine	=	830	3950.80

PRODUCT : Cefuroxime Axetil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(Z)-2-Methoxyimino-2-(furyl-2-yl) acetic acid ammonium salt	=	135	408.93
1-Acetoxy Ethyl Bromide	=	100	302.91
7-Amino cephalosphoranic acid	=	188	569.47
Acetic Acid	=	17	51.49
Acetone	=	1075	3256.27
Ammonia Solution (10%)	=	138	418.01
Carbon	=	50	151.45
Chlorosulfonyl Isocyanate	=	100	302.91
Cyclohexane	=	700	2120.36
Diethylacetamide	=	750	2271.82
Dimethylacetamide	=	265	802.71
Ethyl Acetate	=	1200	3634.91
Hydrochloric acid (35%)	=	40	121.16
Hydrose	=	8	24.23
Methanol	=	950	2877.64
Methylene Dichloride	=	4990	15115.16
Phosphorus Pentachloride	=	150	454.36
Sodium Carbonate	=	58	175.69
Sodium Chloride	=	15	45.44
Sodium Hydrosulfite	=	5	15.15
Sodium Hydroxide	=	345	1045.04
Sodium Metabisulfite	=	2	6.06
Sodium Thiosulfate	=	10	30.29

PRODUCT : Cefuroxime Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-Ethylsodium Hexanoate	=	11	29.33
Acetone	=	465	1240
Carbon	=	6	16
Cefuroxime Acid	=	27	72

PRODUCT : Ceftriaxone Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-Ethylsodium Hexanoate	=	27	270
Acetone	=	1040	10400
Carbon	=	5	50
Ceftriaxone Sodium (Crude)	=	52	520
Hydrochloric acid (35%)	=	17	170

PRODUCT : Cefpirome Sulfate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
6,7-Dihydro-5H-cyclopenta [b]pyridine	=	7	9.33
7-Aminodesacetoxy Cephalosphoranic acid	=	16	21.33
Acetone	=	945	1260
Acetonitrile	=	285	380
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate	=	18.5	24.67
Carbon	=	15	20
Hexamethyldisilazane		9.5	12.67
Methanol	=	215	286.67
Methylene Dichloride	=	1040	1386.67
Sodium Hydroxide	=	6	8
Sulfuric Acid	=	5.5	7.33
Tributylamine	=	66	88
Triethylamine	=	20	26.67
Trimethyl Silyliodide	=	24	32

PRODUCT : Cefdinir Monohydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(4-Methoxyphenyl)methyl-3-(Chloromethyl)-8-methyl-7-[(2-phenyl acetyl)amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	255	364.29
2-Mercaptobenzothiazole	=	224	320.00
2-Mercaptobenzothiazole disulfide (MBTS)	=	200	285.71
Acetic anhydride	=	70	100.00
Acetone	=	3380	4828.57
Ammonium Chloride	=	25	35.71
Butyl Acetate	=	2625	3750.00
Carbon	=	45	64.29
Dimethylformamide	=	365	521.43
EDTA	=	1	1.43
Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	=	130	185.71
Ethylenediaminetetraacetic acid	=	2	2.86
Formaldehyde (40%)	=	250	357.14
Hydrochloric acid (35%)	=	101	144.29
Methanol	=	2040	2914.29
Methylene Dichloride	=	6065	8664.29
Phenol	=	365	521.43
Potassium Carbonate	=	35	50.00
Recoverd Mixed Solvent	=	2240	3200.00
Sodium Bicarbonate	=	56	80.00
Sodium Bromide	=	59	84.29
Sodium Carbonate	=	23	32.86
Sodium Chloride	=	43	61.43
Sodium Hydroxide	=	60	85.71
Sulfuric acid	=	72	102.86
TBAB	=	1	1.43
Tetrahydrofuran	=	850	1214.29
Triethylamine	=	93	132.86
Triphenylphosphine	=	300	428.57

PRODUCT : Cefprozil Monohydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	92	306.67
Acetaldeyde	=	8.5	28.33
Acetone	=	1420	4733.33
Aluminium Metal	=	8	26.67
Ammonia Solution (16%)	=	17	56.67
Butyl Acetate	=	650	2166.67
Carbon	=	1	3.33
Chlorobenzene	=	400	1333.33
Dimethylformamide	=	2295	7650.00
Ethyl Chloroformate	=	15.5	51.67
Ethylenediaminetetraacetic acid	=	0.5	1.67
Hexamethyldisilazane	=	23	76.67
Hydrochloric acid (35%)	=	34	113.33
Methanol	=	1855	6183.33
Methanol	=	130	433.33
Methylene Dichloride	=	2295	7650.00
Phenol	=	16	53.33
p-Hydroxydane Salt	=	43	143.33
Sodium Bicarbonate		23	76.67
Sodium Carbonate	=	9	30.00
Sodium Chloride		10	33.33
Sodium Hydroxide	=	10	33.33
Sodium Hydroxide	=	3	10.00
Sodium Iodide	=	28.5	95.00
Sulfuric Acid	=	7	23.33
Triphenylphosphine	=	50	166.67
Triphenylphosphine Oxide	=	67	223.33
Triphosgene	=	43	143.33

PRODUCT : Cefepime Dihydrochloride Monohydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Aminodesacetoxy Cephalosphoranic acid	=	29	19.33
Acetone	=	745	496.67
Benzothazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate	=	34	22.67
Carbon	=	21	14
Cyclohexane	=	744	496
Dimethylacetamide	=	60	40
Ethyl Acetate	=	745	496.67
Hexamethyldisilazane	=	17.5	11.67
Hydrochloric acid (35%)	=	75	50
Methanol	=	595	396.67
N-Methyl Pyrrolidine	=	9.5	6.33
NOBA	=	74	49.33
Sodium Hydroxide	=	78	52
Tetrahydrofuran	=	600	400
Triethylamine	=	500	333.33
Trimethyl Silyliodide	=	43	28.67

PRODUCT : Cefuroxime Acid

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(Z)-2-Methoxyimino-2-(furyl-2-yl) acetic acid ammonium salt	=	135	54
7-Amino cephalosphoranic acid	=	188	75.2
Acetic Acid	=	5	2
Acetone	=	1075	430
Chlorosulfonyl Isocyanate	=	95	38
Dimethylacetamide	=	265	106
Hydrochloric acid (35%)	=	8	3.2
Methanol	=	550	220
Methylene Dichloride	=	4990	1996
Phosphorus Pentachloride	=	145	58
Sodium Carbonate	=	2	0.8
Sodium Hydroxide	=	137	54.8

PRODUCT : Cefditoren Pivoxil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
18-Crown-6- Ether	=	3.5	1.17
4-Fluoro-2-methyl thiazole	=	85	28.33
4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4- carboxylate	=	250	83.33
Acetone	=	7050	2350
Carbon	=	35	11.67
Chloroform	=	2500	833.33
Chloromethyl pivalate	=	55	18.33
Dimethylformamide	=	1550	516.67
Ethyl Acetate	=	4900	1633.33
Hydrochloric Acid (35%)	=	65	21.67
Isopropyl Ether	=	3150	1050
Methoxy imino amino thiazole benzyl ester	=	140	46.67
n-Butyl Acetate	=	6500	2166.67
n-Propanol	=	500	166.67
Phenol	=	1000	333.33
Sodium Bicarbonate	=	76.5	25.5
Sodium Bisufite	=	25	8.33
Sodium Bromide	=	60	20
Sodium Carbonate	=	50	16.67
Sodium Chloride	=	545	181.67
Sodium Hydroxide	=	25	8.33
Sodium Iodide	=	80	26.67
Sodium Thiosulphate	=	60	20
Sodium-2-ethylhexanoate	=	165	55
Sulfuric Acid (10%)	=	750	250
Tetrahydrofuran	=	800	266.67
Triethylamine	=	50	16.67
Triphenylphosphine	=	135	45

PRODUCT : Ceftibuten Monohydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(Z)-2-(2-Aminothiazol-4-yl)-2-pentenoic acid	=	60	200
4-Nitrobenzyl-7-(2-phenyl acetamido)-8-oxo-5-thia-1-azabicyclo-[4,2,0]oct-2-ene-2-carboxylate	=	70	233.33
Acetic acid	=	70	233.33
Acetonitrile	=	1070	3566.67
Aluminium Chloride	=	52	173.33
Ammonia (6%)	=	280	933.33
Anisole	=	1400	4666.67
Carbon	=	14	46.67
Ethyl Acetate	=	510	1700
Hydrochloric acid (35%)	=	45	150
Maleic acid	=	160	533.33
Methanol	=	1190	3966.67
Methylene Dichloride	=	1870	6233.33
Phosphorous Oxychloride	=	28	93.33
Phosphorous Pentachloride	=	75	250
Potassium Carbonate	=	47	156.67
Pyridine	=	25	83.33
Sodium Bicarbonate	=	44	146.67
Sodium Carbonate	=	105	350
Sodium Chloride	=	38	126.67
Sulfuric acid	=	30	100
Tetrabutylammonium Bromide	=	2	6.67
Triethylamine	=	227	756.67

PRODUCT : Cefazoline Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
1,4-Tetrazole Acetic acid	=	8	13.33
2-Methyl-5-mercaptothiadiazole	=	9	15
7-Aminodesacetoxy Cephalosphoranic acid	=	17	28.33
Acetic acid	=	10	16.67
Acetone	=	450	750
Acetonitrile	=	200	333.33
Boran Trifluoride	=	5	8.33
Carbon	=	3	5
Caustic lye	=	6	10
Diethylamine	=	5	8.33
Dimethyl Carbomide	=	200	333.33
Dimethylformamide	=	30	50
Ethylenediaminetetraacetic acid	=	0.5	0.83
Hydrochloric acid (14%)	=	60	100
Hyflo	=	2	3.33
Methanol	=	200	333.33
Methylene Dichloride	=	400	666.67
Piperadine	=	2	3.33
Pivolyl Chloride	=	7	11.67
Sodium Bicarbonate	=	10	16.67
Sodium Chloride	=	12	20
Sodium Hydrosulfite	=	1	1.67
Sodium Hydroxide	=	15	25
Triethylamine	=	6	10

PRODUCT : Cefoperazone Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
5-Mercapto-1-methyltetrazole	=	8	13.33
7-Amino desacetoxy cephalosporanic acid	=	15	25
Acetone	=	600	1000
Acetonitrile	=	550	916.67
Ammonia Solution (14%)	=	26	43.33
Boron Trifluoride	=	4	6.67
Calcium Hydroxide	=	7	11.67
Carbon	=	5	8.33
Diethylamine	=	10	16.67
Dimethylacetamide	=	40	66.67
Ethyl Acetate	=	50	83.33
Ethylenediaminetetraacetic acid	=	1	1.67
Hydrochloric acid (16%)	=	96	160
Hydroxy DSP Salt	=	17	28.33
Hyflo	=	2	3.33
Methylene Dichloride	=	480	800
Phosphorous Oxychloride	=	10	16.67
Sodium Bicarbonate	=	17	28.33
Sodium Hydrosulfite	=	2	3.33
Sodium Hydroxide	=	24	40

PRODUCT : Cefoxitin Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Aminocephalosporanic acid	=	36	30
Acetic acid	**=**	30	25
Acetone	=	920	766.67
Benzathine Diacetate	=	16	13.33
Carbon	=	3	2.5
Chlorosulfonyl Isocyanate	=	15	12.5
Cyclohexylamine	**=**	12	10
Ethyl Acetate	=	710	591.67
Hydrochloric acid (35%)	=	55	45.83
Methanol	**=**	250	208.33
Methylene Dichloride	=	570	475
N-Chlorosuccinimide	**=**	26	21.67
Sodium Bicarbonate	=	29	24.17
Sodium Carbonate	=	15	12.5
Sodium Chloride	**=**	19	15.83
Sodium Lactate	=	13	10.83
Sodium Metabisulfate	**=**	2	1.67
Sodium Methoxide in Methanol (25%)	**=**	145	120.83
Sodium-2-ethylhexanoate	=	27	22.5
Tetrahydrofuran	=	270	225
Thiophene Acetylchloride	=	22	18.33
Triethylamine	=	15	12.5

PRODUCT : Ceftazidime Pentahydrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2,2'-Dithiobis(benzothiozole)	=	18	15
7-Aminodesacetoxy Cephalosphoranic acid	=	15	12.5
Acetone	=	1170	975
Carbon	=	10	8.33
Dimethylformamide	=	350	291.67
Ethyl Acetate	=	360	300
Ethyl(2,Z)-(2-amino-1,3-thiazole-4-yl) (hydroxyimino) acetate	=	14	11.67
Formic acid	=	240	200
Hexamethyldisilazane	=	9	7.5
Hydrochloric acid (15%)	=	252	210
Methanol	=	1290	1075
Methylene Dichloride	=	700	583.33
Potasium Hydroxide	=	7	5.83
Potassium Carbonate	=	6	5
Pyridine	=	5	4.17
Sodium Hydroxide	=	64	53.33
tert-Butyl-2-bromo-2-methylpropanoate	=	15	12.5
Triethylamine	=	231	192.5
Trimethyl Silyliodide	=	21	17.5
Triphenylphosphine	=	14	11.67

PRODUCT : Cefotaxime Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Aminocephalosporanicacid	=	160	80.00
Carbon	=	30	15.00
Ethyl Acetate	=	2600	1300.00
Hydrochloric acid (35%)	=	60	30.00
Isopropyl Alcohol	=	200	100.00
Methanol	=	700	350
Methoxyimino aminothiozolyl benzyl ester	=	220	110.00
Methyl Isobutyl Ketone	=	200	100.00
Methylene Dichloride	=	1300	650.00
Sodium-2-ethylhexanoate	=	140	70
Triethylamine	=	170	85.00

PRODUCT : Ceftizoxime Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Amino-3-nor-3-cephem-4-carboxylic acid	=	13	21.67
Acetone	=	390	650
Carbon	=	2	3.33
Ethyl Acetate	=	160	266.67
Hyflo	=	1	1.67
Methoxyimino aminothiozolyl benzyl ester	=	25	41.67
Sodium-2-ethylhexanoate	=	16	26.67
Tetrahydrofuran	=	100	166.67
Triethylamine	=	10	16.67

PRODUCT : Cephalothin Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Aminocephalosporanic acid	=	18	30
Acetone	=	550	916.67
Carbon	=	2	3.33
Hydrochloric acid (35%)	=	17	28.33
Methylene Dichloride	=	110	183.33
Sodium-2-ethylhexanoate	=	28	46.67
Thiopheneacetyl Chloride	=	14	23.33
Triethylamine	=	10	16.67

PRODUCT : Cefpodoxime Acid

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Amino cephalosphoranic acid	=	138	30.26
Benzothiazol-2-yl-2-(2-aminothiazol-4-yl)-(Z)-2-methoxyiminothioacetate	=	178	39.04
Borantrifluoride	=	104	22.81
Carbon	=	14	3.07
Ethyl Acetate	=	1050	230.26
Methanol	=	320	70.18
Methylene Dichloride	=	4140	907.89
Sodium Chloride	=	180	39.47
Sodium Hydroxide	=	218	47.81
Sulfolane	=	1380	302.63
Sulfuric Acid	=	18	3.95
Tetrahydrofuran	=	620	135.96
Triethylamine	=	830	182.02

PRODUCT : Cefcapene Pivoxil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Amino Cephalosporanic acid	=	186	63.59
Acetone	=	715	244.44
Acetonitrile	=	860	294.02
Aminothiazole Pentanoic acid	=	143	48.89
Ammonia (10%)	=	14	4.79
Ammonium Bromide	**=**	10	3.42
Anisole	**=**	250	85.47
Bis Silylacetamide	=	258	88.21
Boron Trifluoride	**=**	100	34.19
Chloro Sulfonyl Isocyante	=	183	62.56
Chloromethyl Pivalate	**=**	75	25.64
Diisopropyl Ether	**=**	800	273.50
Dimethylformamide	=	14	4.79
Ethyl Acetate	=	715	244.44
Hydrochloric acid (35%)	**=**	50	17.09
Methane Sulofonylchloride	=	129	44.10
Methanol	=	715	244.44
Methyl Isobutyl Ketone	**=**	500	170.94
Sodium Bicarbonate	**=**	50	17.09
Sodium Hydroxide	=	204	69.74
Sodium Iodide	**=**	75	25.64
Sodium-2-Ethylhexanoate	=	116	39.66
Toluene	**=**	500	170.94
Triethylamine	=	125	42.74

PRODUCT : Cefmetazole Sodium

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-(Cyanomethylsulfanyl) acetic acid	=	21.5	14.33
7-MAC	=	86	57.33
Acetone	=	720	480
Anisole	=	406	270.67
Carbon	=	2	1.33
Ethyl Acetate	=	330	220
Hydrochloric acid (35%)	=	21	14
Oxalyl Chloride	=	15	10
Sodium Hydroxide	=	7	4.67
Sodium-2-ethylhexanoic acid	=	20	13.33
Triethylamine	=	28	18.67

PRODUCT : Cefmetazole

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-(Cyanomethylsulfanyl) acetic acid	=	21.5	13.52
7-MAC	=	86	54.09
Acetone	=	130	81.76
Anisole	=	406	255.35
Ethyl Acetate	=	330	207.55
Hydrochloric acid (35%)	=	21	13.21
Oxalyl Chloride	=	15	9.43
Sodium Hydroxide	=	7	4.40
Triethylamine	=	28	17.61

PRODUCT : 7-AVNA

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenyl acetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	255	433.67
Butyl Acetate	=	3150	5357.14
Carbon	=	15	25.51
Dimethylformamide	=	365	620.75
EDTA	=	0.3	0.51
Enzyme(Wet)	=	315	535.71
Ethylenediaminetetraacetic acid	=	1	1.70
Formaldehyde (40%)	=	250	425.17
Hydrochloric Acid (35%)	=	3	5.10
Hydrogen Chloride	=	14	23.81
Hydrose	=	0.3	0.51
Methanol	=	2800	4761.90
Methylene Dichloride	=	765	1301.02
Phenol	=	630	1071.43
Sodium Bicarbonate	=	50	85.03
Sodium Bromide	=	59	100.34
Sodium Carbonate	=	30	51.02
Sodium Chloride	=	20	34.01
Sodium Hydroxide	=	40	68.03
Sulfuric acid	=	58	98.64
TBAB	=	1	1.70
Triphenylphosphine	=	140	238.10

PRODUCT : MEAT (Thio Ester)

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
Acetic anhydride	=	70	70.71
Acetone	=	2000	2020.20
Bismercapto benzothiazole	=	201	203.03
Ethyl-(2,Z)-(2-amino-1,3-thiazole)-4-Hydroxyimino acetate	=	130	131.31
Hydrochloric acid (35%)	=	50	50.51
Methylene Dichloride	=	1100	1111.11
Sodium Hydroxide	=	32	32.32
Triethylamine	=	48	48.48
Triphenylphosphine	=	160	161.62

PRODUCT : 7-APCA

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(4-Methoxyphenyl)methyl-3-(Chloro methyl)-8-methyl-7-[(2-phenylacetyl) amino]-5-thia-1-aza-bicyclo][4.2.0]octa-2-ene-2-carboxylate	=	92	270.59
Acetaldeyde	=	8.5	25
Acetone	=	490	1441.18
Butyl Acetate	=	650	1911.76
Carbon	=	1	2.94
Dimethylformamide	=	1365	4014.71
Ethylenediaminetetraacetic acid	=	0.5	1.47
Hydrochloric acid (35%)	=	3	8.82
Methanol	=	1855	5455.88
Methylene Dichloride	=	1365	4014.71
Phenol	=	16	47.06
Sodium Bicarbonate		23	67.65
Sodium Carbonate	=	9	26.47
Sodium Chloride		10	29.41
Sodium Hydroxide	=	10	29.41
Sodium Iodide	=	28.5	83.82
Sulfuric Acid	=	7	20.59
Triphenylphosphine	=	50	147.06

PRODUCT : 7-Amino-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (7-AMCA)

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
7-Amino cefalosporanic acid	=	125	41.67
Boran trifluoride	=	35	11.67
Methanol	=	250	83.33
Methylene Dichloride	=	3330	1110
Sodium Hydroxide (50%)	=	161	53.67
Sulfolane	=	1110	370

PRODUCT : 7-Amino3-thiazole cephalosporanic acid (7-ATCA)

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
4-Fluoro-2-methyl thiazole	=	85	56.67
4-Methoxybenzyl 3-chloro methyl-7-(2-phenylacetamido)-3-cephem-4- carboxylate	=	250	166.67
Acetone	=	250	166.67
Carbon	=	15	10
Chloroform	=	2500	1666.67
Dimethylformamide	=	250	166.67
Hydrochloric Acid (35%)	=	15	10
n-Butyl Acetate	=	6500	4333.33
n-Propanol	=	500	333.33
Phenol	=	1000	666.67
Sodium Bicarbonate	=	75	50
Sodium Bisufite	=	25	16.67
Sodium Bromide	=	60	40
Sodium Carbonate	=	50	33.33
Sodium Chloride	=	175	116.67
Sodium Hydroxide	=	25	16.67
Sulfuric Acid (10%)	=	750	500
Triphenylphosphine	=	135	90

PRODUCT : Sitagliptin Phosphate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(3R)-3-[(1,1-Dimethylethoxy carbonyl)-amino]-4-(2,4,5-trifluorophenyl)butanoic acid	=	208	52.00
1-Ethyl-3-(3'-dimethylamino propyl) carbodiimide Hydrochloride	=	120	30
3-(Trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4triazol[4,3-a] pyrazine	=	120	30
Diisopropylethylamine	=	82	20.50
Dimethylformamide	=	2080	520.00
Hydroxybenzotriazole	=	84	21
Isopropyl Alcohol	=	1040	260.00
Methylene Dichloride	=	1040	260.00
Phosphoric acid	=	171	42.75

No of Batches per day=0.33

PRODUCT : Prasugrel Hydrochloride

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
Acetic Anhydride	=	85	21.25
Ammonium Chlolride	=	43	10.75
Chloroform	=	800	200.00
Cyclopropyl-2-(2-fluorophenyl) ethanone	=	183	45.75
Dimethylformamide	=	3735	933.75
Ethyl Acetate	=	2940	735
Hexane	=	1590	397.5
Hydrochloric acid (35%)	=	92	23.00
Methylene Dichloride	=	1350	337.5
N-Bromosuccinimide	=	183	45.75
Sodium Bicarbonate	=	87	21.75
Sodium Hydride (60%) in Paraffin oil	=	35	8.75
Thienohydropyridone	=	159	39.75

PRODUCT : Pregabalin

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
3-Methylbutanal	=	206	51.50
Ethyl Acetate	=	2000	500.00
Ethyl-2-Bromoacetate	=	400	100.00
Hydrogen	=	20	5.00
Nitromethane	=	147	36.75
Potassium tert-Butoxide	=	269	67.25
Sodium Hydroxide	=	96	24
Tetrahydrofuran	=	2000	500.00
Toluene	=	2000	500.00
Tripheylphosphine	=	628	157.00

PRODUCT : Diacerein

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
Acetic Anhydride	=	1410	352.5
Acetonitrile	=	1440	360
Dibenzyl Aloe-Emodin	=	288	72
Dimethylformamide	=	1440	360
Ethyl Acetate	=	3450	862.5
Ferric Chloride	=	98	24.50
Sodium Chlorite	=	58	14.50
Sodium Dihydrogen Phosphate	=	77	19.25
Tempo	=	200	50.00

PRODUCT : Linezolid

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
(R)-Epichlorhydrin	=	80	20.00
3-Fluoro-4-Morpholino benzenamine	=	167	41.75
Acetic Anhydride	=	87	21.75
Carbonyldiimidazole	=	140	35.00
Dimethylformamide	=	835	208.75
Hydrazine	=	28	7.00
Isopropyl Alcohol	=	835	208.75
Methanol	=	500	125.00
Methylene Dichloride	=	835	208.75
Potassium Phthalimide	=	158	39.50

PRODUCT : Ropinirole Hydrochloride

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-(2-(2-(Dipropylamino) ethyl) phenyl)-N-hydroxyacetamide	=	235	58.75
Acetyl Chloride	=	67	16.75
Ethyl Acetate	=	1175	293.75
Ferric Chloride	=	137	34.25
Hydrochloric acid (35%)	=	94	23.50
Isopropyl Alcohol	=	1175	293.75
Methylene Dichloride	=	2350	587.50

PRODUCT : D-Cycloserine

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
Hydroxylamine Hydrochloride	=	172	43.00
Methylene Dichloride	=	5580	1395
N-Benzyloxycarbonyl-D-Serine	=	588	147
Sodium Bicarbonate	=	210	52.5
Sodium Hydride (60%) in Paraffin oil	=	100	25.00
Tetrahydrofuran	=	4120	1030.00
Thionyl Chloride	=	300	75

PRODUCT : Clopidogrel Hydrogen Sulfate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
4,5,6,7-Tetrahydrothieno[3,2-c] pyridine Hydrochloride	=	105	26.25
Acetone	=	1570	392.50
Chloroform	=	800	200.00
Methanol	=	800	200.00
Methyl-2-bromo-2-(2-chlorophenyl)acetate	=	157	39.25
Sodium Bicarbonate	=	101	25.25
Sulfuric acid	=	60	15

PRODUCT : Bosentan

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
4-(tert-Butyl)benzene-1-sulfonamide	=	102	25.5
5-(2-Methoxyphenoxy)-4,6-dichloro-2-(pyrimidin-2-yl) pyrimidine	=	167	41.75
Ethylene glycol	=	30	7.5
Methylene Dichloride	=	835	208.75
Sodium Bicarbonate	=	41	10.25
Sodium Methoxide	=	26	6.50
Toluene	=	1670	417.50

PRODUCT : Candesartan Cilexitil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
1-Chloroethyl cyclohexyl carbonate	=	86	21.50
Acetone	=	2820	705
Cyclohexane	=	1970	492.50
Dimethylformamide	=	1410	352.5
Hydrochloric acid (35%)	=	46	11.50
Sodium Bicarbonate	=	40	10.00
Trityl Candesartan	=	282	70.5

PRODUCT : Febuxostat

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
3-Cyano-4-isobutoxy benzothioamide	=	400	100.00
Acetone	=	6000	1500
Ethyl Acetate	=	4000	1000.00
Ethyl-2-chloro-3-oxobutanoate	=	282	70.5
Hydrochloric acid (35%)	=	190	47.50
Isopropyl Alcohol	=	1000	250.00
Sodium Hydroxide	=	70	17.50

PRODUCT : Azilsartan medoxomil

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
4-(Hydroxymethyl)-5-methyl-1,3-dioxol-2-one	=	58	14.50
Azilsartan	=	200	50.00
Dimethylformamide	=	2200	550.00
Methylene Dichloride	=	1000	250.00
p -Toluenesulfonyl Chloride	=	85	21.25
Pyridine	=	36	9
Triethylamine	=	46	11.50

PRODUCT : Solifenacin Succinate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
1-(S)-phenyl-1,2,3,4-tetrahydro-2-Isoquinoline carboxylate	=	200	50.00
3-Quinolidinol	=	91	22.75
Acetone	=	2000	500.00
Succinic acid	=	85	21.25
Toluene	=	1400	350.00

PRODUCT : Darifenacin Hydrobromide

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2,2-Diphenyl-2-((S)-pyrrolidin-3-yl) acetamide	=	138	34.5
5-(2-Bromoethyl)-2,3-dihydrobenzofuran	=	112	28.00
Acetone	=	1380	345
Hydrogen Bromide	=	40	10.00
Methylene Dichloride	=	1380	345
Sodium Bicarbonate	=	42	10.5
Tetrahydrofuran	=	690	172.5

PRODUCT : Trospium Chloride

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
2-Hydroxy-2,2-diphenylacetic acid	=	140	35.00
Carbonyldiimidazole	=	100	25.00
Cyclohexane	=	1330	332.50
Methylene Dichloride	=	665	166.25
Spiro[bicyclo[3.2.1]octane-8,1'-pyrrolidin]-1'-ium chloride	=	133	33.25

PRODUCT : Tolterodine Tartrate

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
3-(2-methoxy-5-methyl phenyl)-3-phenylpropan-1-ol	=	133	33.25
Acetonitrile	=	665	166.25
Diisopropylamine	=	53	13.25
Hydrobromic acid (48%)	=	43	10.75
L-(-)Tartaric acid	=	80	20.00
Methanol	=	665	166.25
Methylene Dichloride	=	1330	332.50
p-Toluenesulfonyl Chloride	=	100	25.00
Sodium Bicarbonate	=	65	16.25

PRODUCT : Valsartan

LIST OF RAW MATERIALS

Raw Material		Consumption of Raw Material / Batch of Product	Daily Consumption of Raw Material
		Kg	**Kg**
Biphenyl bromomethyl-1H- tetrazole	=	194	48.50
Diisopropylethylamine	=	82	20.50
Dimethylformamide	=	360	90
L-Valine	=	72	18
Methanol	=	360	90
Methylene Dichloride	=	720	180
Pentanoyl Chloride	=	75	18.75
Sodium Bicarbonate	=	52	13.00

LIST OF HAZARDOUS RAW MATERIALS

Porposed Products

Raw Material
(R)-Epichlorhydrin
Acetaldeyde
Acetic Acid
Acetic Anhydride
Acetone
Acetonitrile
Ammonia Solution (16%)
Benzoyl Chloride
Chloroform
Cyclohexane
Cyclohexanone
Diethylamine
Ethanol
Ethyl Acetate
Ethylene glycol
Formaldehyde (40%)
Formic acid
Hexane
Hydrazine
Hydrobromic acid (48%)
Hydrochloric acid (35%)
Hydrogen
Hydrogen Bromide
Isopropyl Alcohol
Methanol
Methyl Isobutyl Ketone
Methylene Dichloride
Phenol
Phosphorous Oxychloride
Phosphorous Pentachloride
Piperdine
Pyridine
Sulfuric acid
Tetrahydrofuran
Thionyl Chloride
Toluene
Triethylamine

Topographical map of 10 km study area