FORM-I

For

PROPOSED BULK DRUGS AND BULK DRUG INTERMEDIATES IN EXISTING INORGANIC PRODUCTS UNIT

of

M/s. STRIDE INDUSTRIES PLOT NO. 7613/1, GIDC ESTATE, ANKLESHWAR, DIST: BHARUCH-393002 (GUJ.)

Consultant



NABL Accredited Testing Laboratory ISO 9001:2008 Certified Company

Aqua-Air Environmental Engineers P. Ltd. (Pollution Control Consultants & Engineers) 403, Centre Point, Nr. Kadiwala School, Ring Road, Surat – 395002

APPENDIX I

FORM 1

(I) Basic Information

Sr.	Item	Details		
No.	Name of the Project/s	NA/s Ctride Industries		
1.	Name of the Project/s S. No. in the Schedule	M/s. Stride Industries		
2.		5 (f)		
3.	Proposed	Existing Capacity: 240 MT/Month		
	capacity/area/length/tonnage to be	Additional Capacity: 10.5 MT/Month		
	handled/command area/lease area/number of wells to be drilled	Total: 250.5 MT/Month (Existing + Additional) Total Plot Area: 1,459 m ²		
	area/number of wells to be drilled			
4.	New/Expansion/Modernization	List of Products with their capacity as Annexure: 2 Expansion		
	· · ·	·		
5.	Existing capacity/area etc.	Existing capacity: Annexure:2		
-	Catagory of project is (A) or (D)	Existing Area: 1,459 m ² 'A'		
6. 7.	Category of project i.e. 'A' or 'B'			
/.	Does it attract the general condition? If yes, please specify.	, .		
8.	Does it attract the specific condition?	(Ankleshwar). N.A.		
0.	If yes, please specify.	N.A.		
9.	Location			
J.	Plot/Survey/Khasra No.	7613/1		
	Village	GIDC ESTATE		
	Tehsil	Ankleshwar		
	District	Bharuch		
	State	Gujarat		
10.	Nearest railway station/airport along	Nearest Railway Station: Ankleshwar: 2.5 km		
	with distance in kms.	·		
11.	Nearest Town, city, District	Nearest town: Ankleshwar: 1.5 km		
	Headquarters along with distance in			
	kms.			
12.	Village Panchayats, zilla parishad,	GIDC Notified area, Ankleshwar-393002		
	Municipal corporation, Local body			
	(Complete postal addresses with			
	telephone nos. to be given)			
13.	Name of the applicant	M/s. Stride Industries		
14.	Registered address	Plot No. 7613/1, GIDC Estate, Ankeslwar-393002		

15.	Address for correspondence:	
	Name	Mr. Mahesh Hadiya
	Designation (Owner/Partner/CEO)	Partner
	Address	M/s. Stride Industries
		Plot No. 7613/1, GIDC Estate, Ankeslwar-393002,
		Dist: Bharuch (Gujarat)
	Pin Code	393002
	E-Mail	strideindustries@gmail.com
	Telephone No.	+919879062252
	Fax No.	
16.	Details of Alternative Sites examined,	No
	if any location of these sites should be	
	shown on a topo sheet.	
17.	Interlinked Projects	No
18.	Whether separate application of	No
	interlinked project has been	
	submitted?	
19.	If Yes, date of submission	Not applicable
20.	If no., reason	Not applicable
21.	Whether the proposal involves	No
	approval/clearance under: If yes,	
	details of the same and their status to	
	be given.	
	(a) The Forest (Conservation) Act, 1980?	
	(b) The Wildlife (Protection) Act, 1972?	
	(c) The C.R.Z Notification, 1991?	
22.	Whether there is any Government	No
۷۷.	order/policy relevant/relating to the	
	site?	
23.	Forest land involved (hectares)	No
24.	Whether there is any litigation	No
	pending against the project and/or	
	land in which the project is propose to	
	be set up?	
	(a) Name of the Court	
	(b) Case No.	
	(c) Orders/directions of the Court,	
	if any and its relevance with the	
	proposed project.	

(II) Activity

1. Construction, operation or decommissioning of the Project involving actions, which will cause physical changes in the locality (topography, land use, changes in water bodies, etc.)

Sr. No.	Information/Checklist confirmation	Yes /No?	Details thereof (with approximate quantities / rates, wherever possible) with source of information data
1.1	Permanent or temporary change in land use, land cover or topography including increase in intensity of land use (with respect to local land use plan)	No	Proposed expansion is within Existing Premises.
1.2	Clearance of existing land, vegetation and buildings?	Yes	Minor site clearance activities shall be carried out to clear shrubs and weed.
1.3	Creation of new land uses?	No	
1.4	Pre-construction investigations e.g. bore houses, soil testing?	No	
1.5	Construction works?	Yes	Plant layout is attached as Annexure: 1.
1.6	Demolition works?	No	
1.7	Temporary sites used for construction workers or housing of construction workers?	No	
1.8	Above ground buildings, structures or Earthworks including linear structures, cut and fill or excavations	Yes	Plant layout is attached as Annexure: 1.
1.9	Underground works including mining or tunneling?	No	
1.10	Reclamation works?	No	
1.11	Dredging?	No	
1.12	Offshore structures?	No	
1.13	Production and manufacturing	Yes	List of Products & their capacity is attached as Annexure: 2 and manufacturing process is attached as Annexure: 3.
1.14	Facilities for storage of goods or materials?	Yes	Dedicated storage area for storage of Raw Materials and finished products, solvents, etc. shall be provided.
1.15	Facilities for treatment or disposal of solid waste or liquid effluents?	Yes	Details of proposed Effluent Treatment Plant are attached as Annexure: 5. Details of Hazardous waste generation and disposal is attached as Annexure: 6.
1.16	Facilities for long term housing of operational workers?	No	No housing facilities are required.

1.17	New road, rail or sea traffic during	No	
1.17	construction or operation?	NO	
1.18	•	No	
1.18	, ,	No	
1.10	other airports etc?	NI -	
1.19		No	
	transport routes or infrastructure		
	leading to changes in traffic		
1 20	movements?		
1.20		No	
	pipelines?		
1.21	, ,	No	
	realignment or other changes to the		
	hydrology of watercourses or		
1.00	aquifers?		
	<u> </u>	No	
1.23	Abstraction or transfers or the water	No	
	form ground or surface waters?		
1.24	9	No	
	surface affecting drainage or run-off?		
1.25	Transport of personnel or materials for	Yes	Transportation of personnel, raw material
	construction, operation or		and products will be primarily by road only.
	decommissioning?		
1.26	Long-term dismantling or	No	
	decommissioning or restoration		
	works?		
1.27	Ongoing activity during	No	
	decommissioning which could have		
	an impact on the environment?		
1.28	Influx of people to an area in either	Yes	Direct/Indirect employment shall be
	temporarily or permanently?		provided for proposed expansion operation.
1.29	Introduction of alien species?	No	
1.30	Loss of native species of genetic	No	
	diversity?		
1.31	Any other actions?	No	

2. Use of Natural resources for construction or operation of the Project (such as land, water, materials or energy, especially any resources which are non-renewable or in short supply):

Sr. No.	Information/checklist confirmation	Yes/ No?	Details there of (with approximate quantities/rates, wherever possible) with source of information data
2.1	Land especially undeveloped or agriculture land (ha)	No	
2.2	Water (expected source & competing users) unit: KLD	Yes	Water requirement will meet through GIDC Water supply. A detail of water balance is given as Annexure – 4.
2.3	Minerals (MT)	No	
2.4	Construction material -stone, aggregates, sand / soil (expected source MT)	Yes	Company shall use Sand, stone, Cement and Structural Steel for Construction as required.
2.5	Forests and timber (source - MT)	No	
2.6	Energy including electricity and fuels source, competing users Unit: fuel (MT), energy (MW)	Yes	Power Requirement: Existing: Power required from DGVCL is 30 KVA. Proposed: Power required from DGVCL will be 70 KVA. Fuel Requirement: Existing: Wood= 500 kg/Day or Natural Gas= 1000 m³/Month Proposed: Agro Waste/ coal= 1500 kg/Day Diesel= 100 Lit./Day (Only for emergency).
2.7	Any other natural resources (use appropriates standard units)	No	

3. Use, storage, transport, handling or production of substances or materials, which could be harmful to human health or the environment or raise concerns about actual or perceived risks to human health.

Sr. No.	Information / Checklist confirmation	Yes/ No?	Details thereof (with approximate quantities / rates wherever possible) with source of information data
3.1	Use of substances or materials, which are hazardous (as per MSIHC rules) to human health or the environment (flora, fauna, and water supplies)	Yes	Please refer Annexure: 8
3.2	Changes in occurrence of disease or affect disease vectors (e.g. insect or water borne diseases)	No	
3.3	Affect the welfare of people e.g. by changing living conditions?	No	
3.4	Vulnerable groups of people who could be affected by the project e.g. hospital patients, children, the elderly etc.,	No	
3.5	Any other causes	No	

4. Production of solid wastes during construction or operation or decommissioning MT/month)

Sr. No.	Information/Checklist confirmation	Yes/ No?	Details thereof (with approximate quantities / rates, wherever possible) with source of information data
4.1	Spoil, overburden or mine wastes	No	
4.2	Municipal waste (domestic and or commercial wastes)	No	
4.3	Hazardous wastes (as per Hazardous Waste Management Rules)	Yes	Please refer Annexure: 6
4.4	Other industrial process wastes	Yes	Please refer Annexure: 6
4.5	Surplus product	No	
4.6	Sewage sludge or other sludge from effluent treatment	Yes	Please refer Annexure: 6
4.7	Construction or demolition wastes	Yes	Construction waste shall be utilized for leveling, land filling in the premises.
4.8	Redundant machinery or equipment	No	
4.9	Contaminated soils or other materials	No	
4.10	Agricultural wastes	No	
4.11	Other solid wastes	Yes	Please refer Annexure: 6

5. Release of pollutants or any hazardous, toxic or noxious substances to air (Kg/hr)

Sr. No.	Information/Checklist confirmation	Yes/ No	Details there of (with approximate quantities/rates, wherever possible) with source of information data
5.1	Emissions from combustion of fossil fuels from stationary or mobile sources	Yes	Please refer Annexure: 7
5.2	Emissions from production processes	Yes	Please refer Annexure: 7
5.3	Emissions from materials handling storage or transport	Yes	All liquid raw materials shall be procured in tankers and shall be transferred through a closed circuit pipe lines. Solid raw materials shall be charged through close pipeline into reactors and the dust collection hopper shall be connected to a bag filter and ID fan. Also all hazardous chemicals storage tanks will be provided with flame arrestors &
5.4	Emissions from construction activities including plant and equipment	Yes	During construction work, only dust contamination will be there & water sprinklers shall be utilized whenever necessary.
5.5	Dust or odours from handling of materials including construction materials, sewage and waste		Dust from drying will be collected in to dust collector through cyclone separator & recovered powder will be recycled back to process. Air Handling Unit will be provided where ever applicable.
5.6	Emissions from incineration of waste	No	
5.7	Emissions from burning of waste in open air e.g. slash materials, construction debris)	ו ואוט	
5.8	Emissions from any other sources	Yes	Please refer Annexure: 7

6. Generation of Noise and Vibration, and Emissions of Light and Heat:

Sr. No.	Information/Checklist confirmation	Yes/ No?	Details there of (with approximate Quantities /rates, wherever possible) With source of source of information data
6.1	From operation of equipment e.g. engines, ventilation plant, crushers	Yes	There are few activities due to which noise would be generated. The equipments resulting in noise generation are machinery of plant and Diesel generator. Adequate noise control measures will be provided whenever required. Proper and timely oiling, lubrication and preventive maintenance will be carried out for the machineries & equipments to reduce noise generation. Use of PPE like ear plugs and ear muffs will be made compulsory near the high noise generating machines. Noise monitoring shall be done regularly in plant area. D.G. Set will be installed in a closed room and provided with acoustic enclosure. The unit will increase the plantation in the proposed greenbelt within the premises which will be prevent noise pollution in surrounding area.
6.2	From industrial or similar processes	Yes	All machinery / equipment shall be well maintained, shall have proper foundation with anti vibrating pads wherever applicable to keep noise levels within permissible limits. Acoustic enclosures shall be provided for DG set.
6.3	From construction or demolition	No	
6.4	From blasting or piling	No	
6.5	From construction or operational traffic	No	
6.6	From lighting or cooling systems	No	
6.7	From any other sources	No	

7. Risks of contamination of land or water from releases of pollutants into the ground or into sewers, surface waters, groundwater, coastal waters or the sea:

Sr. No	Information/Checklist confirmation	Yes/ No?	Details thereof (with approximate quantities / rates, wherever possible) with source of information data
7.1	From handling, storage, use or spillage of hazardous materials	Yes	All raw material shall be stored separately in designated storage area and safely. Bund walls shall be provided around raw materials storage tanks for containing any liquid spillage. Please refer Annexure: 8.
7.2	From discharge of sewage or other effluents to water or the land (expected mode and place of discharge)	Yes	Sewage shall be treated in Septic Tank & Soak Pit.
7.3	By deposition of pollutants emitted to air into the land or into water	No	
7.4	From any other sources	No	
7.5	Is there a risk of long term build up of pollution in the environment from these sources?	No	

8. Risks of accident during construction or operation of the Project, which could affect human health or the environment:

Sr. No.	Information/Checklist confirmation	Yes/ No?	Details thereof (with approximate quantities / rates, wherever possible) with source of information data
8.1	From explosions, spillages, fires etc from storage, handling, use or production of hazardous substances	Yes	Please refer Annexure: 8
8.2	From any other causes	No	
8.3	Could the project be affected by natural disasters causing environmental damage (e.g. floods, earthquakes, landslides, cloudburst etc)?	No	

9. Factors which should be considered (such as consequential development) which could lead to environmental effects or the potential for cumulative impacts with other existing or planned activities in the locality

Sr. No.	Information/Checklist confirmation	Yes/ No?	Details thereof (with approximate quantities / rates, wherever possible) with source of information data
9.1	Lead to development of supporting. laities, ancillary development or development stimulated by the project which could have impact on the environment e.g.: * Supporting infrastructure (roads, power supply, waste or waste water treatment, etc.) • housing development • extractive industries • supply industries • other	No	Site is having the entire required infrastructure. Existing road infrastructure & power supply are to be utilized. Local people will be employed and no housing is required. Please refer Annexure: 9.
9.2	Lead to after-use of the site, which could have an impact on the environment	No	
9.3	Set a precedent for later developments	No	
9.4	Have cumulative effects due to proximity to Other existing or planned projects with similar effects	No	

(III) Environmental Sensitivity

Sr.	Information/Checklist confirmation	Name /	Aerial distance (within 15 km). Proposed
No.		Identity	Project Location Boundary.
1	Areas protected under international conventions national or local legislation for their ecological, landscape, cultural or other related value	Yes	Proposed expansion project site is within the GIDC, Ankleshwar.
2	Areas which are important or sensitive for Ecological reasons - Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	No	Proposed expansion project site is within the GIDC, Ankleshwar.

3	Areas used by protected, important or sensitive species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	No	
4	Inland, coastal, marine or underground waters	Yes	River Narmada = 9 kms
5	State, National boundaries	No	
6	Routes or facilities used by the public for to recreation or other tourist, pilgrim areas.	No	
7	Defense installations	No	
8	Densely populated or built-up area	Yes	Bharuch city = 5 lakh population
9	Areas occupied by sensitive man-made land community facilities)	No	
10	Areas containing important, high quality or scarce resources (ground water resources, surface resources, forestry, agriculture, fisheries, tourism, tourism, minerals)	No	
11	Areas already subjected to pollution or environmental damage. (those where existing legal environmental standards are exceeded)	No	
12	Areas susceptible to natural hazard which could cause the project to present environmental problems (earthquake s, subsidence ,landslides, flooding erosion, or extreme or adverse climatic conditions)	No	

IV). Proposed Terms of Reference for EIA studies: Please refer Annexure: 10.

I hereby given undertaking that the data and information given in the application and enclosures are true to the best of my knowledge and belief and I am aware that if any part of the data and information submitted is found to be false or misleading at any stage, the project will be rejected and clearance given, if any to the project will be revoked at our risk and cost.

Date: February 13, 2017

Place: GIDC Ankleshwar

For Stride Industries

Mr. Mahesh Hadiya

(Partner)

NOTE:

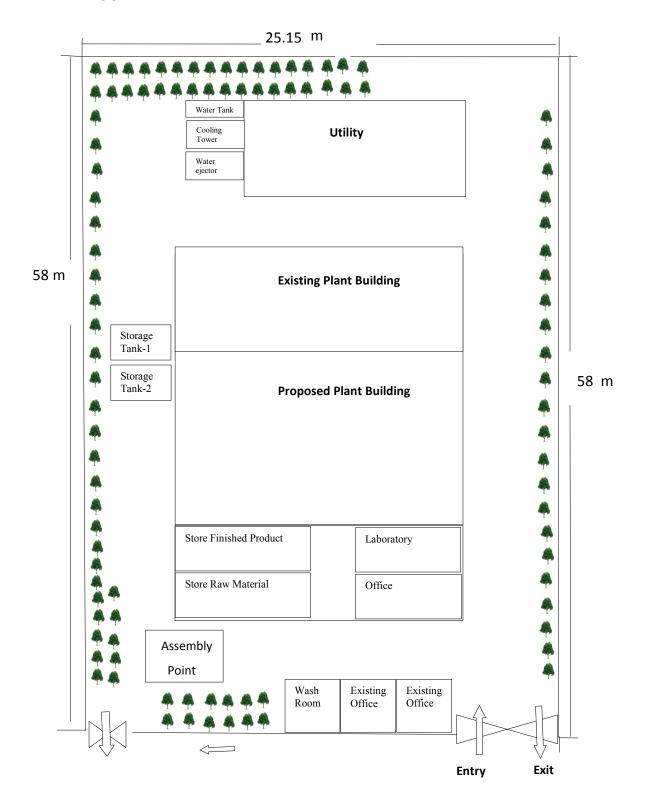
- The projects involving clearance under Coastal Regulation Zone Notification, 1991 shall submit with the application a C.R.Z. map duly demarcated by one of the authorized agencies, showing the project activities, w.r.t. C.R.Z. (at the stage of TOR) and the recommendations of the State Coastal Zone Management Authority (at the stage of EC). Simultaneous action shall also be taken to obtain the requisite clearance under the provisions of the C.R.Z. Notification, 1991 for the activities to be located in the CRZ.
- 2. The projects to be located within 10 km of the National Parks, Sanctuaries, Biosphere Reserves, Migratory Corridors of Wild Animals, the project proponent shall submit the map duly authenticated by Chief Wildlife Warden showing these features vis-à-vis the project location and the recommendations or comments of the Chief Wildlife Warden thereon (at the stage of EC).
- 3. All correspondence with the Ministry of Environment & Forests including submission of application for TOR/Environmental Clearance, subsequent clarifications, as may be required from time to time, participation in the EAC Meeting on behalf of the project proponent shall be made by the authorized signatory only. The authorized signatory should also submit a document in support of his claim of being an authorized signatory for the specific project.

ANNEXURES

1	PLANT LAYOUT
2	LIST OF PRODUCTS WITH PRODUCTION CAPACITY AND RAW MATERIALS
3	BRIEF MANUFACTRING PROCESS, CHEMICAL REACTION AND MASS BALANCE WITH
	FLOW DIAGRAM
4	WATER CONSUMPTION AND EFFLUENT GENERATION
5	DETAILS OF PROPOSED EFFLUENT TREATMENT PLANT
6	DETAILS OF HAZARDOUS SOLID WASTE MANAGEMENT AND DISPOSAL
7	DETAILS OF STACK & VENTS
8	DETAILS HAZARDOUS CHEMICAL STORAGE FACILITY
9	SOCIO - ECONOMIC IMPACTS
10	PROPOSED TERMS OF REFERENCES

ANNEXURE: 1

PLANT LAYOUT



ANNEXURE: 2
LIST OF PRODUCTS WITH PRODUCTION CAPACITY

Sr.	Product	Existing	Additional	Total
No.		Capacity	Capacity	Capacity
		(MT/Month)	(MT/Month)	(MT/Month)
1.	Potassium Sulphate	80		80
2.	Sodium Nitrate	80		80
3.	Tri Sodium Phosphate	80		80
Propo	osed			
4.	Doxofylline and its Intermediates			
5.	Acebrophylline and its intermediate			
6.	Levosulpride and its intermediate			
7.	Amisulpride and its intermediate			
8.	Duloxetine Hydrochloride			
9.	Celecoxib and its Intermediate			
10.	Lacosamide and its Intermediate		10	10
11.	Diclofenac Sodium and its Intermediate			
12.	Pantoprazole Sodium and its Intermediate			
13.	Venlafaxine Hydrochloride and Its			
	Intermediate			
14.	Sevelamar Hydrochloride and its			
	intermediates			
15.	R&D		0.5	0.5
Total		240	10.5	250.5

List of Raw Material

SR. NO.	RAW MATERIALS	QUANTITY (MT/MT)				
EXISTI	EXISTING					
Potass	sium sulphate					
1.	Potassium Hydroxide	1.73				
2.	Sulfuric acid	1.50				
Sodiu	m Nitrate					
3.	Sodium carbonate	1.66				
4.	Nitric acid	2.83				
Tri So	dium Phosphate					
5.	Phosphoric acid	1.60				
6.	Sodium Hydroxide	1.96				
PROP	OSED	·				
Doxof	ylline & its Intermediates					
1.	Vinyl acetate	0.75				
2.	Liquid Bromine	1.06				
3.	PTSA	0.01				
4.	Dichloromethene	1.50				
5.	Monoethylene glycol	0.41				
6.	Methanol	1.32				
7.	Dimethylformamide	0.95				
8.	Theofylline	0.75				
9.	Potassium carbonate	0.51				
10.	Activated Charcoal	0.05				
Acebr	ophylline & its Intermediates	•				
1.	Theophylline	0.31				
2.	Sodium Carbonate	0.16				
3.	Mono Chloro acetic acid	0.15				
4.	Hydrochloric acid	0.40				
5.	Acefylline	0.41				
6.	Ambroxol	0.63				
7.	Dimethylformamide	1.00				
8.	Toluene	3.95				
Levosi	Levosulpiride & its Intermediates					

1.	1-Ethyl 2-Pyrrolidinone	0.73
2.	Dimethysulfate	0.77
3.	Nitromethane	0.44
4.	Sodium methoxide	1.17
5.	Dichloromethane	2.20
6.	Toluene	1.10
7.	Methyl-2-methoxy-5-sulfamoyl	
	benzoate	0.73
8.	1-Ethyl-2-amino methyl	
	pyrrolidine	0.38
9.	Monoethylene glycol	2.17
10.	Methanol	16.13
11.	Activated carbon	0.03
Amisu	Ilpride & its Intermediates	T
1.	4-Amino-5-(ethylsulfonyl)-2-	0.70
_	methoxybenzoic acid	0.70
2.	1-Ethyl-2-aminomethyl pyrrolidine	0.35
3.	Ethyl chloroformate	0.30
4.	Triethyl amine	0.40
5.	Sodium hydroxide	0.72
6.	Acetone	3.15
7.	Amisulpride (crude)	1.00
8.	Isopropyl alchol	0.75
Dulox	etine Hydrochloride & its intermedia	
1.	(S)-3-(Methylamino)-1-(thiophen-	
	2-yl)propane-1-ol	1.35
2.	1-Fluoro Napthalene	2.00
3.	Sodium Hydride (60%) in Paraffin	
	oil	0.54
4.	Toluene	8.20
5.	Dimethyl Sulfoxide	4.50
6.	Ethyl acetate	24.20
7.	Potassium Acetate	0.07
8.	Ammonium Chloride	0.51
9.	Sodium Chloride	1.76
10.	Ethyl acetate	11.60
L	I	l

11.	IPA HCI (15-18%)	1.65		
12.	Activated carbon	0.05		
13.	Acetone	11.10		
14.	Methanol	1.00		
Celec	Celecoxib & its intermediates			
1.	Dione	0.90		
2.	Acetic acid	2.00		
3.	Sulphonamide Salt	1.36		
4.	Toluene	10.90		
5.	Activated Carbon	0.09		
6.	Isopropyl alcohol	14.09		
Lacos	amide and its Intermediate			
1.	D-Serine	0.770		
2.	NaOH	1.15		
3.	(BOC) ₂ O	1.38		
4.	1,4- dioxane	0.38		
5.	Citric acid	0.53		
6.	Ethyl acetate	7.15		
7.	Pet. Ether	0.53		
8.	Sodium sulphate	0.08		
9.	Toluene	2.30		
11.	T.B.A.B	0.10		
12.	Dimethyl sulphate	0.92		
13.	N-methyl morpholine	0.38		
14.	Isobutyl chloroformate	0.38		
15.	Benzyl amine	0.38		
16.	Sodium bicarbonate	0.38		
17.	Hydrochloric acid	0.85		
18.	Sodium hydroxide	0.38		
Diclo	fenac sodium and its Intermediate			
1.	2,6-Dichlorophenol	0.97		
2.	Potassium carbonate	0.43		
	MMCA (Monomethylchloro			
3.	acetate)	0.70		
4.	Toluene	3.10		
5.	Sodium methoxide	0.87		

6. Methanol 1.11 7. Aniline 0.53 8. Aluminium Chloride 0.81 9. Sodium Hydroxide 0.30 Pantoprazole Sodium and its Intermediate 1. 2-Chloromethyl-3,4-dimethoxypyridine HCl 0.68 2. 5-Difluoromethoxy 2-mercapto benzimidazole 0.67 3. Sodium hydroxide 0.53 4. Dichloromethane 4.13 5. Acetic acid 0.34 6. Sodium hypochlorite (6%) 0.80 7. Acetone 3.45 Venlafexine Hydrochloride and its Intermediate 1. PMPA (P-Methoxy phenyl acetonitrile) 0.90 2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formi			1
8. Aluminium Chloride 0.81 9. Sodium Hydroxide 0.30 Pantoprazole Sodium and its Intermediate 1. 2-Chloromethyl-3,4-dimethoxypyridine HCl 0.68 2. 5-Difluoromethoxy 2-mercapto benzimidazole 0.67 3. Sodium hydroxide 0.53 4. Dichloromethane 4.13 5. Acetic acid 0.34 6. Sodium hypochlorite (6%) 0.80 7. Acetone 3.45 Venlafexine Hydrochloride and its Intermediate 1. PMPA (P-Methoxy phenyl acetonitrile) 0.90 2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Seve	6.	Methanol	1.11
Sodium Hydroxide 0.30	7.	Aniline	0.53
Pantoprazole Sodium and its Intermediate 1. 2-Chloromethyl-3,4-dimethoxypyridine HCl 0.68 2. 5-Difluoromethoxy 2-mercapto benzimidazole 0.67 3. Sodium hydroxide 0.53 4. Dichloromethane 4.13 5. Acetic acid 0.34 6. Sodium hypochlorite (6%) 0.80 7. Acetone 3.45 Venlafexine Hydrochloride and its Intermediate 1. PMPA (P-Methoxy phenyl acetonitrile) 0.90 2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.18 3. Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3.	8.	Aluminium Chloride	0.81
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3. Sodium hydroxide 0.53 4. Dichloromethane 4.13 5. Acetic acid 0.34 6. Sodium hypochlorite (6%) 0.80 7. Acetone 3.45 Venlafexine Hydrochloride and its Intermediate 1. PMPA (P-Methoxy phenyl acetonitrile) 0.90 2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	2.		
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acetonitrile) 0.90 2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	Venlaf	exine Hydrochloride and its Interme	ediate
2. Sodium methoxide 0.45 3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	1.	PMPA (P-Methoxy phenyl	
3. Methanol 0.50 4. Cyclohexanone 0.85 5. IPA 2.30 6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41		acetonitrile)	0.90
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6. Acetic acid 4.44 7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	4.	Cyclohexanone	0.85
7. O-xylene 1.50 8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	5.	IPA	2.30
8. Ethyl acetate 10.77 9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	6.	Acetic acid	4.44
9. Formic acid 1.36 10. Formaldehyde 1.18 Sevelamer Hydrochloride and its Intermediate 1. Allylamine 1.00 2. Hydrochloric acid 2.10 3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	7.	O-xylene	1.50
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10.Formaldehyde1.18Sevelamer Hydrochloride and its Intermediate1.Allylamine1.002.Hydrochloric acid2.103.Polyallylamine Hydrochlride2.604.Sodium hydroxide0.41	9.	Formic acid	1.36
Sevelamer Hydrochloride and its Intermediate1.Allylamine1.002.Hydrochloric acid2.103.Polyallylamine Hydrochlride2.604.Sodium hydroxide0.41	10.	Formaldehyde	1 10
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3. Polyallylamine Hydrochlride 2.60 4. Sodium hydroxide 0.41	1.	Allylamine	1.00
4. Sodium hydroxide 0.41	2.	Hydrochloric acid	2.10
_	3.	Polyallylamine Hydrochlride	2.60
5. Epichlorohydrine 0.10	4.	Sodium hydroxide	0.41
	5.	Epichlorohydrine	0.10

ANNEXURE: 3

BRIEF MANUFACTRING PROCESS, CHEMICAL REACTION AND MASS BALANCE WITH FLOW DIAGRAM

Existing:

1. Potassium Sulphate

Process Description:

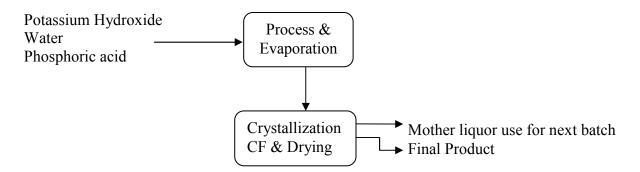
Charged Potassium hydroxide and sulphuric acid in reactor and heat to make the required temperature. After completed the reaction mass, cool the reaction mass to crystsallization and after crystallization, mass is cetrifuging to separates solids from mother liquor. The mother liquour collected from the centrifuge and use for next batch.

Route of Synthesis:

$$2KOH + H_2SO_4 \rightarrow K_2SO_4 + 2H_2O$$

MW 2(56.1) 98.0 174.3 2(18.0)

Flow Chart



2. Sodium Nitrate

Process Description:

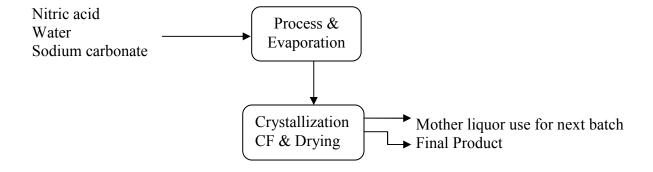
Charged Nitric acid and Sodium carbonate in reactor and heat to make the required temperature. After completed the reaction mass, cool the reaction mass to crystsallization and after crystallization, mass is cetrifuging to separates solids from mother liquor. The mother liquour collected from the centrifuge and use for next batch.

Route of Synthesis:

$$Na_2CO_3 + 2HNO_3 \Rightarrow 2NaNO_3 + H_2O + CO_2$$

MW 106.0 2(63.0) 2(85.0) 18.0 44

Flow Chart



3. Trisodium phosphate

Process Description:

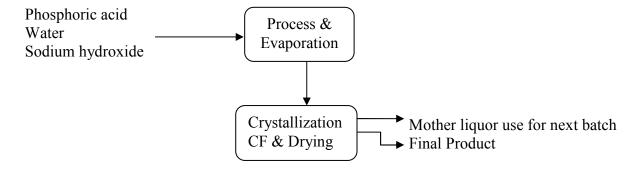
Charged Phosphoric acid and water in reactor and make up the pH about 11 to 14 with sodium hydroxide. Maintain the reaction to required temparature.. After completed the reaction mass, cool the reaction mass to crystsallization and after crystallization, mass is cetrifuging to separates solids from mother liquor. The mother liquour collected from the centrifuge and use for next batch.

Route of Synthesis:

$$H_3PO_4 + 3NaOH \rightarrow Na_3PO_4 + 3H_2O$$

MW 98.0 3(40.0) 163.9 3(18.0)

Flow Chart



Proposed:

4. Doxofylline and its Intermediates

Process Description:

Stage-1:

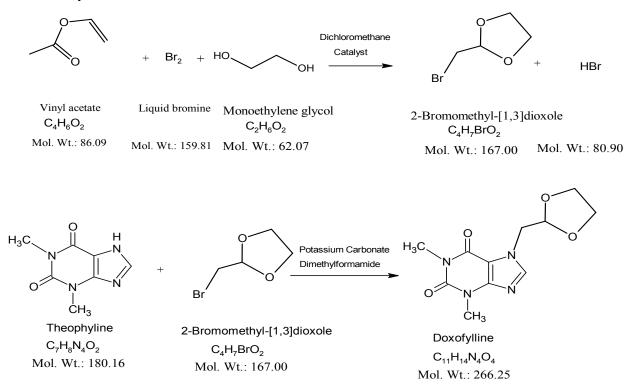
Starting raw materials Vinyl acetate, Liquid bromine, & dichloro methane are charged into the reaction vessel.MDC layer is then distilled to obtain MDC wherein vapor loss occurs during the operation.Further Mono ethelene glycol is added into the reaction mass and entire reaction mass is then distilled out through vacuum.

Stage-2:

Starting raw materials Theophylline, Potassium carbonate, Stage-1, Dimethylformamide are charged into the reaction vessel. & are stirred till reaction is completed.

Dimethylformamide is then distilled to obtain Dimethylformamide wherein vapor loss occurs during the operation. Finally water is added into the reaction mass & entire reaction mass is filtered through sparkler filtration than cool and centrifugal. Wet cake is then dried to obtain Final product.

Route of Synthesis:



Material Balance:

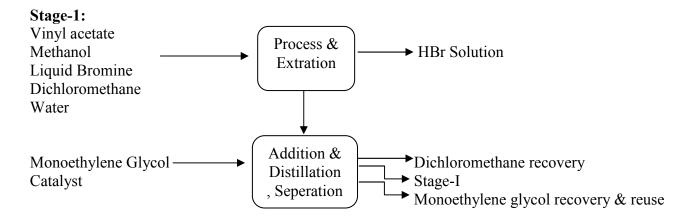
Stage:-1

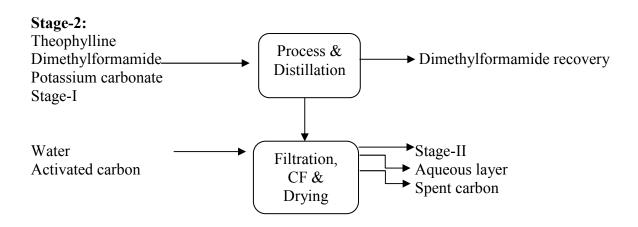
Sr. No	Input Material	MT	Output Material	MT
1	Vinyl acetate	0.91	Stage- I	1.36
2	Liquid Bromine	1.28	HBR Solution	6.75
3	Dichloromethane	1.80	Dichloromethane recovery	1.75
4	Methanol	1.59	Dichloromethane loss	0.09
5	Catalyst	0.02	Monoethylene glycol recovery & reuse	0.10
6	Monoethylene glycol	0.50	Distillation Residue	0.05
7	Water	4.00		
	Total	10.10	Total	10.10

Stage:- 2

Sr. No	Input Material	MT	Output Material	MT
1	Theophylline	0.91	Doxofylline	1.20
2	Stage-I	1.36	DMF Recovery	1.10
3	DMF	1.15	DMF Loss	0.05
4	Potassium carbonate	0.62	Aqueous layer	4.20
5	Activated charcoal	0.06	Solid waste	0.10
6	Water	2.75	Drying Evaporation	0.20
	Total	6.85	Total	6.85

Flow Chart:





5. Acebrophylline & it's intermediates

Process Description:

Stage-1:

Charge Water and Mono Chloro Acetic acid then chill the mass. Charge Sodium Carbonate till pH comes within limit. Then unload solution. Charge Water, Sodium Carbonate and Theophylline. Heat the reaction mass and maintain it. Slowly add solution of Mono Chloro acetic acid. After addition maintain the reaction mass till reaction complies. Cool the mass and filter it and Collect clear filtrate. Charge Hydrochloric acid till ph comes within limit. Collect wet material and charge in Water. Filter the mass and wash the wet material with Water. Collect wet material and dry it to get Pure Acefylline.

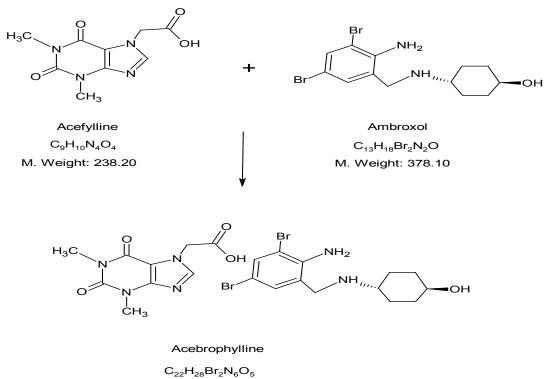
Stage-2:

Charge Toluene and Acefylline and heat it. Start addition of AXB solution (Charge Dimethyl formamide and Ambroxol Base and stir it till clear solution. Charge Activated Carbon slurry and filter it. Collect clear filtrate into charging pot). Again heat it and Distill water till completely removal. Cool it and filter it. Dry wet material to give pure dry Acebrophylline.

Route of Synthesis:

Stage-1:

Stage-2:



M. Weight: 616.30

Material Balance:

Stage-1:

Sr.				
No	Input Material	MT	Output Material	MT
1	Theophylline	2.00	Acefylline	2.65
2	Sodium carbonate	1.05	Aqueous layer	8.20
3	Mono Chloro acetic acid	1.00	Drying loss	0.75
4	Hydrochloric acid	2.55		
5	Water	5.00		
	Total	11.6	Total	11.6

Sr.				
No	Input Material	MT	Output Material	MT
1	Acefylline	2.65	Acebrophylline	6.33
2	Ambroxol	4.00	Dimethylformamide Recovery	5.82
3	Dimethylformamide	6.27	Dimethylformamide Loss	0.35
4	Toluene	25.00	Toluene recovery	23.45
5	Activated carbon	0.04	Toluene Loss	1.25
6			Drying and condensation loss	0.72
7			Spent Carbon	0.04
	Total	37.96	Total	37.96

6. Levosulpride & it's intermediates

Process Description:

Stage-1:

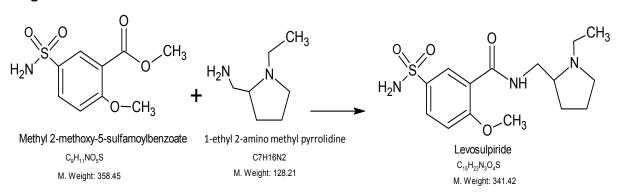
1-Ethyl-2-pyrrolidinone react with nitromethane in presence of sodium methoxide, dimethylsulphate, dichloromethane, toluene to give 1-ethyl-2(nitrotethyl)pyrrolidine. Further products reduced using palladium carbon catalyst.

Stage-2:

Methyl 2-methoxy-5-sulfamoylbenzoate is reacted with 1-ethyl 2-amino methyl pyrrolidine in ethylene glycol, methanol and active carbon to give Levosulpride as product.

Route of Synthesis:

Stage-1:



Material Balance

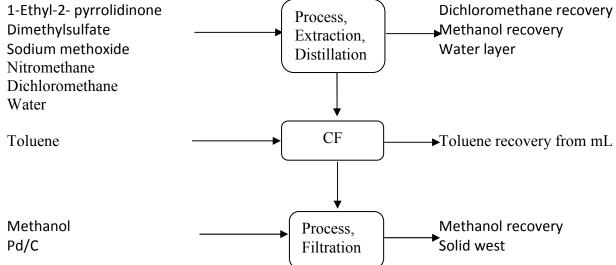
Stage-1:

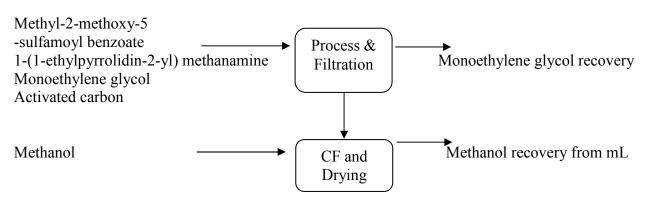
Sr.				
No.	Input Material	MT	Output Material	MT
1	1-Ethyl-2- pyrrolidinone	1.00	Stage-1	1.05
2	Dimethylsulfate	1.05	Methanol Recovery	3.45
3	Nitromethane	0.60	Methanol Loss	0.65
4	Sodium methoxide	1.60	Dichloromethane recovery	2.85
5	Dichlormethane	3.00	Dichloromethane loss	0.15
6	Toluene	1.50	Toluene recovery	1.43
7	Pd/C	0.01	Toluene loss	0.08
8	Methanol	2.50	Water layer	3.08
7	Water	1.50	Solid west	0.02
	Total	12.76	Total	12.76

Sr.				
No.	Input Material	MT	Output Material	MT
1	Methyl-2-methoxy-5-sulfamoyl	1.00	Levosulpiride	1.36
	benzoate			
2	1-Ethyl-2-amino methyl pyrrolidine	0.52	Monoethylene glycol Recovery	2.81
3	Monoethylene glycol	2.96	Monoethylene glycol Loss	0.32
4	Methanol	19.45	Methanol recovery	18.48
5	Activated carbon	0.05	Methanol Loss	0.97
6			Spent Carbon	0.04
	Total	23.98	Total	23.98

Flow Chart:







7. Amisulpride & it's intermediates

Process Description:

Stage-1:

4-Amino-5-(ethyl sulfonyl)-2-methoxybenzoic acid is reacted with 1-ethyl 2-amino methyl pyrrolidine in presence of Ethyl chloroformate, Triethyl amine in acetone Sodium hydroxide and water to yield Amisulpride (crude).

Stage-2:

Amisulpride(Crude) is recrystallised from isopropyl alcohol and carbon to yield Amisulpride.

Route of Synthesis:

Stage-1:

Material Balance:

Stage-1:

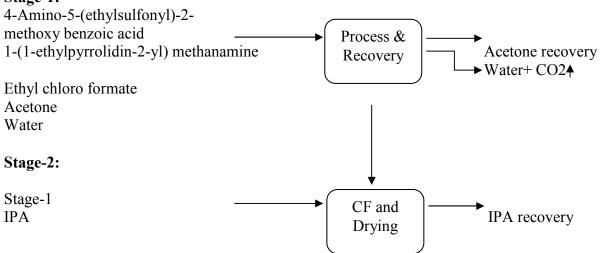
- Cage				
Sr.				
No.	Input Material	MT	Output Material	MT
1	4-Amino-5-(ethylsulfonyl)-2-	1.40	Amisulpride (crude)	2.00
1	methoxybenzoic acid			2.00
2	1-Ethyl-2-amino methyl pyrrolidine	0.75	Acetone Recovery	5.97
3	Ethyl chloroformate	0.59	Acetone Loss	0.33
4	Triethyl amine	0.80	Water layer	9.60
5	Sodium hydroxide	1.45	Carbon Dioxide	0.28
6	Acetone	6.30	Residue	1.11
7	Water	8.00		
	Total	19.29	Total	19.29

Stage-2:

Sr.				
No.	Input Material	MT	Output Material	MT
1	Amisulpride (crude)	2.00	Amisulpride	2.00
2	Isopropyl alchol	1.50	Isopropyl alchol recovery	1.43
3	Activated Carbon	0.05	Isopropyl alchol loss	0.07
4			Spent Carbon	0.05
	Total	3.55	Total	3.55

Flow Chart:

Stage-1:



8. Duloxetine Hydrochloride and its Intermediate

Process Description:

Stage-1:

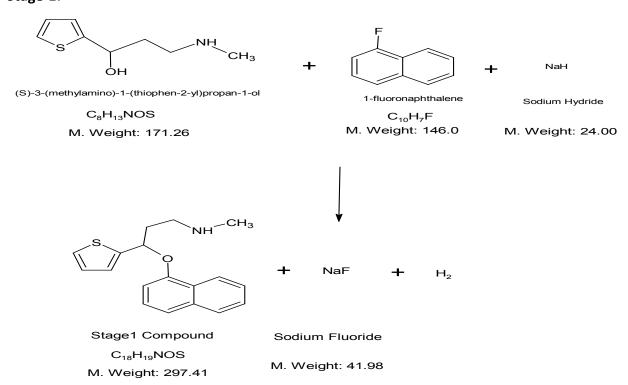
A Mixture of Dimethyl sulfoxide, Toluene, (S)-3-(Methylamino)-1-(thiophen-2-yl)propane-1-ol, Potassium acetate and Sodium hydride is heated to 90-100°C till completion of reaction. Reaction is cooled and quenched with aqueous solution of Ammonium chloride with Ethyl acetate. Extract reaction mass in ethyl acetate, washed with saturated sodium chloride solution and evaporated to get Duloxetine free base.

Stage-2:

Duloxetine free base dissolved in Ethyl acetate, charcolised and treated with IPA-HCl at below 10°C, centrifuged to get crude product that is purified in Acetone ,methanol to get pure Duloxetine Hydrochloride.

Route of Synthesis:

Stage-1:



Stage-2:

Stage1 Compound

 $C_{18}H_{19}NOS$

M. Weight: 297.41

Duloxetine Hydrochloride

 $C_{18}H_{19}NOS$

M. Weight: 333.86

Material Balance:

Stage:-1

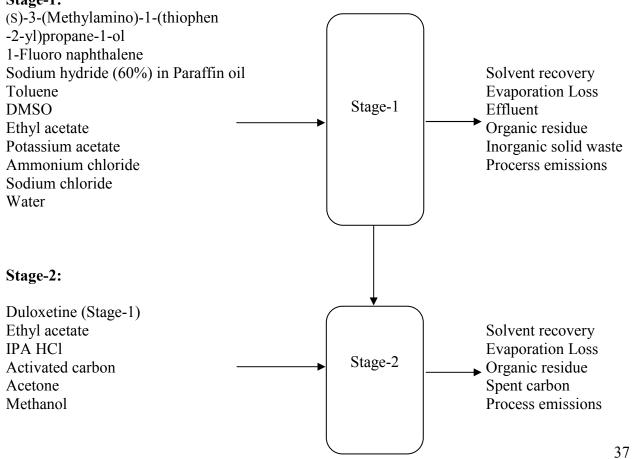
Sr.				
No.	Input Material	MT	Output Material	MT
1	(S)-3-(Methylamino)-1-(thiophen-2-yl)propane-1-ol	1.35	Stage-I compound	2.00
2	1-Fluoro Napthalene	2.00	Toluene recovery	7.71
3	Sodium Hydride (60%) in Paraffin oil	0.54	Toluene loss	0.33
4	Toluene	8.20	Dimethyl Sulfoxide recovery	4.23
5	Dimethyl Sulfoxide	4.50	Dimethyl Sulfoxide loss	0.18
6	Ethyl acetate	24.40	Ethyl acetate recovery	22.69
7	Potassium Acetate	0.07	Ethyl acetate loss	1.22
8	Ammonium Chloride	0.51	Aqueous layer	9.60
9	Sodium Chloride	1.76	Organic residue	2.76
10	Water	9.50	Inorganic solid waste	1.57
11			Process Emissions	0.54
	Total	52.83	Total	52.83

Stage:-2

Sr.				
No.	Input Material	MT	Output Material	MT
1	Stage-I compound	2.00	Duloxetine Hydrochloride	1.00
2	Ethyl acetate	11.60	Ethyl acetate recovery	10.79
3	IPA HCl (15-18%)	1.65	Ethyl acetate loss	0.58
4	Activated carbon	0.05	IPA recovery	1.30
5	Acetone	11.10	IPA loss	0.07
6	Methanol	1.00	Methanol recovery	0.93
7			Methanol Loss	0.05
8			Acetone recovery	10.32
9			Acetone Loss	0.56
10			Organic residue	1.51
11			Spent Carbon	0.05
12			Process Emissions	0.02
13			Drying loss	0.22
	Total	27.40	Total	27. 40

Flow Chart:

Stage-1:

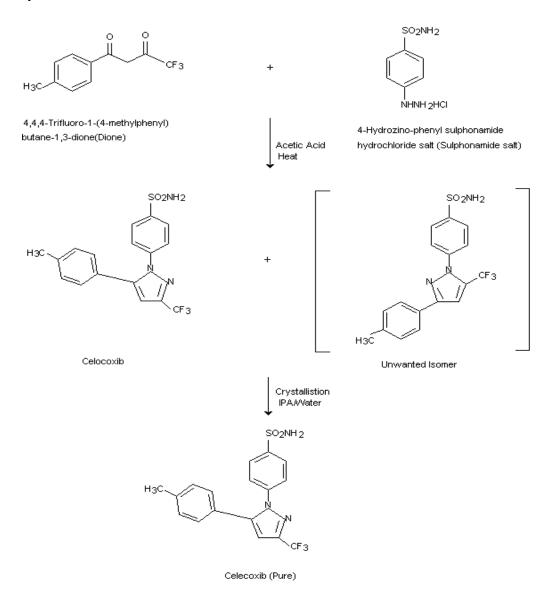


9. Celecoxib and its Intermediates

Process Description:

4,4,4-Trifluoro-1-(4-methylphenyl) butane-1, 3-dione, which is cyclised with 4-hydrizin-ophenyl sulphonamide to give Celecoxib.

Route of Synthesis:



Material Balance:

Stage:-1

Sr. No.	Input Material	MT	Output Material	MT
1	Dione	1.00	Stage- I	1.10
2	Acetic acid	2.20	Water layer	8.43
3	Sulphonamide Salt	1.50	Toluene recovery	11.40
4	Toluene	12.0	Toluene loss	0.60
5	Water	5.00	Drying loss	0.17
6	Activated Carbon	0.05	Spent carbon	0.05
	Total	21.75	Total	21.75

Sr. No.	Input Material	MT	Output Material	MT
1	Stage-1	1.10	Celecoxib	1.10
2	Isopropyl alcohol	15.50	Isopropyl alcohol Recovery	14.72
4	Water	0.80	Isopropyl alcohol Loss	0.78
5	Activated carbon	0.05	Drying loss	0.45
6			Water leyer	0.35
7			Spent carbon	0.05
	Total	17.45	Total	17.45

10. Lacosamide and its Intermediates

Process Description:

Stage -1:

Stir D- serine, NaOH and water at 10 °C. Add (BOC) $_2$ O and 1, 4 –Dioxane to the reaction mass at 10 °C & stir for 2 hours. Check TLC of the reaction then add citric acid to the R.M. extract with ethyl acetate. Concentrate the organic layer & solidify with pet. Ether. Filter the solid product and dry it.

Stage -2:

Stir suspension of TBAB, toluene & Stage -1 at ambient temp. Add aqueous NaOH solution dropwise & stir reaction mass for 1 hr. After that Dimethyl sulphate was added drop wise and stir the reaction mass for 5 hrs. Check TLC for completion of reaction. After that separate the aqueous layer & wash with toluene. Combined organic layer and wash with 5% citric acid & with brine. On concentrate org. layer crude Stage -# 2 obtained which was purified with ethyl acetate to give Stage -# 2.

Stage -3:

Stir a suspension of Stage -2, N-methyl morpholine and ethyl acetate at ambient temp. Add dropwise iso-butylchloroformate and stir reaction mass for 2 hrs. After that add benzyl amine & further stir the reaction mixture for one hour. Check TLC for completion of reaction, then charge water & separate the layer. Organic layer wash with bi-carbonate and brine. Dried the organic layer and concentrate it to obtain a crude Stage - # 3, which recrystallised from ethyl acetate and hexane.

Stage -4:

Stir a solution of Stage -#3 and toluene; add dropwise concentrated HCl & stir reaction mass for 2 hrs. Check TLC for completion of reaction. After that separate the aqueous layer & wash with toluene, then aqueous layer was basified with aqueous NaOH and extracted with Dichloromethane. Organic layer was concentrated to obtain crude Stage- 4.

Route of Synthesis:

Material Balance:

Stage -1

Sr. No.	Input Material	MT	Output Material	MT
1	D-Serine	1.00	Stage - 1	1.80
2	Sodium hydroxide	1.50	Ethyl acetate recovery	2.20
3	(BOC)2O	1.80	ethyl acetate loss	0.10
4	1,4- dioxane	0.50	Pet. Eather recovery	0.66
5	citric acid	0.70	Pet. Eather loss	0.04
6	ethyl acetate	2.30	Aqueous	4.50
7	pet. Ether	0.70	Solid waste	1.20
8	Sodium sulphate	0.10	Organic Residue	1.00
9	water	2.90		
Total		11.50	Total	11.50
Stage - 2	2	<u> </u>		
Sr. No.	Input Material	MT	Output Material	MT
1	Stage - 1	1.80	Stage - 2	1.70
2	Sodium hydroxide	1.10	Toluene Recovery	1.30
3	Toluene	1.40	Toluene Loss	0.10
4	T.B.A.B	0.10	Ethyl acetate recovery	0.40
5	Dimethyl sulphate	1.20	Ethyl acetate loss	0.10
6	citric acid	0.30	Aqueous	1.60
7	ethyl acetate	0.50	Organic Residue	0.90
8	water	1.10	Solid Waste	1.40
Total		7.50	Total	7.50
Stage - 3	3			
Sr. No.	Input Material	MT	Output Material	MT
1	Stage - 2	1.70	Stage - 3	2.10
2	N-methyl morpholine	0.50	Ethyl acetate recovery	6.15
3	Isobutyl chloroformate	0.50	Ethyl acetate loss	0.35
4	Benzyl amine	0.50	Aqueous layer	2.10
5	Ethyl acetate	6.50	Solid waste	0.60
6	Sodium bicarbonate	0.50	Organic Residue	0.80
7	Citric acid	0.40		
8	water	1.30		
9	Sodium sulphate	0.20		
Total		12.10	Total	12.10

Stage - 4	Stage - 4				
Sr. No.	Input Material	MT	Output Material	MT	
1	Stage - 3	2.10	Lacosamide	1.30	
2	Hydrochloric acid	1.10	Toluene Recovery	1.52	
3	Toluene	1.60	Toluene Loss	0.08	
4	Sodium hydroxide	0.50	Dichloromethane Recovery	2.85	
5	Dichloromethane	3.00	Dichloromethane Loss	0.15	
6	water	1.00	Aqueous Layer	1.30	
			Organic Residue	0.80	
			Solid Waste	1.30	
Total		9.30	Total	9.30	

11. Diclofenac Sodium and its Intermediates

Process Description:

Stage -1:

Stir 2,6-Dichlorophenol, Potassium carbonate and Toluene at ambient temperature. Heat to reflux for hydrolysis & cool to ambient temperature. Charge MMCA in the reaction mass then heat to110°C and maintain for 12 hrs. Recovered the Toluene U/V than charge Aniline and Sodium methoxide solution in reaction mass and stir for 3 hrs. Recovered Methanol than charge water and CF.

Stage -2:

Stir suspension toluene & Stage -1 at ambient temp. Distilled out water through Azeotropic distillation. Cool to 50°C than slowly add Chloroacetyl chloride & stir reaction mass for 8 hr. Check TLC for completion of reaction. Distilled out Toluene. Charge water and cool to ambient temperature than CF and dry the product.

Stage -3:

Stir a suspension of Stage -2, Aluminum chloride at ambient temp. Heat to 180°C and maintain for 4 hrs. Charge water and cool to ambient temperature than CF and dry the product.

Stage -4:

Stir a solution of Stage -#3 and Water and Sodium hydroxide in reactor & stir reaction mass for 8 hrs at 100°C. Check TLC for completion of reaction. Cool to ambient temperature and CF.

Route of Synthesis:

Stage-1:

Stage-2:

Stage-3:

$$\begin{array}{c} O \\ CI \\ + AICI_3 \\ 2\text{-chloro-}N\text{-}(2,6\text{-dichlorophenyl})\text{-}N\text{-phenylacetamide} \\ C_{14}H_{10}CI_3NO \\ M.Weight: 314.59 \\ \end{array}$$

Stage-4:

Material Balance:

Stage:-1

Sr. No	Input Material	MT	Output Material	MT
1	2,6-Dichlorophenol	1.00	Stage- I (Amine compound)	1.35
2	Potassium carbonate	0.45	Toluene recovery	1.91
3	MMCA (Monomethylchloro acetate)	0.72	Toluene loss	0.09
4	Toluene	2.00	Methanol recovery	1.94
5	Sodium methoxide	0.90	Methanol loss	0.11
6	Methanol	1.15	Water layer	2.32
7	Aniline	0.55	Solid waste	0.55
8	Water	1.50		
	Total	8.27	Total	8.27

Sr. No	Input Material	MT	Output Material	MT
1	Stage- I (Amine compound)	1.00	Stage- II (Chloro compound)	1.20
2	Chloroacetyl chloride	0.54	Toluene Recovery	1.14
4	Toluene	1.20	Toluene Loss	0.06
5	Water	1.00	Water layer	1.34
	Total	3.74	Total	3.74

Stage:- 3

Sr. No	Input Material	MT	Output Material	MT
1	Stage- II (Chloro compound)	1.20	Stage- III (Indo compound)	1.04
2	Aluminum chloride	0.84	Water leyer	2.34
4	Water	2.00	Solid waste	0.66
	Total	4.04	Total	4.04

Sr. No	Input Material	MT	Output Material	MT
1	Stage- III (Indo compound)	1.00	Diclofenac Sodium	1.03
2	Sodium hydroxide	0.30	Water leyer	2.17
4	Water	1.90	Solid waste	0.05
5	Activated carbon	0.05		
	Total	3.25	Total	3.25

12. Pantoprazole Sodium and its Intermediate

Process Description:

Stage-1:

2-Chloromethyl-3,4-dimethoxypyridine HCl and 5-Difluoromethoxy 2-mercapto benzimidazole is suspended in a mixure of water and dichloromethane in presence of Sodium hydroxide at ambient temperature till completion of reaction. Pantoprazole sulphide is extracted in dichloromethane.

Stage-2:

Pantoprazole sulphide in dichloromethane is chilled to 0 to 5°C and slowly in reaction vessel. Add mixture of Sodium hypochlorite and Sodium hydroxide in it with control temperature. After completion of reaction sodium thiosulfate is charge to the reaction vessel then Separate out dichloromethane layer at 7 to 7.5 pH with acetic acid. Distilled out Dichloromethane wherein vapor loss occurs during the operation. Charge Acetone, Sodium hydroxide solution and Activated carbon at ambient temperature. Finally entire reaction mass is filtered through sparkler filtration than cool and centrifugal. Wet cake is then dried to obtain Final product.

Route of Synthesis:

Stage-1:

Stage-2:

$$F = \begin{pmatrix} CH_3 & C$$

Material Balance:

Stage:-1

Sr. No.	Input Material	MT	Output Material	MT
1	2-Chloromethyl-3,4-	1.00	Pantoprazole sulphide in	7.69
1	dimethoxypyridine HCl	1.00	MDC	
2	5-Difluoromethoxy 2-mercapto	0.98	Water laver	4.10
2	benzimidazole	0.98	Water layer	4.10
3	Sodium hydroxide	0.45	Organic Residue	0.64
4	Dichloromethane	6.00		
5	Water	4.00		
	Total	12.43	Total	12.43

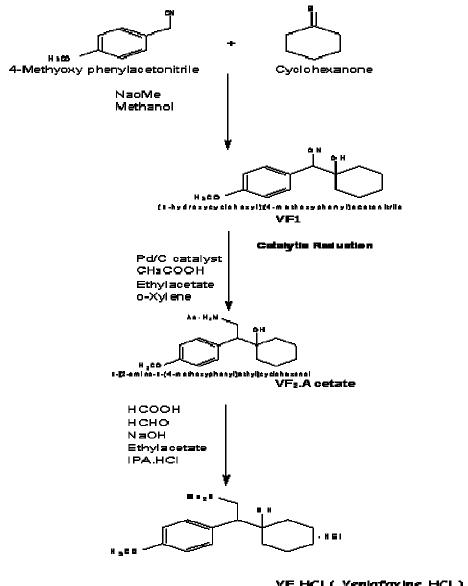
Sr. No	Input Material	MT	Output Material	MT
1	Pantoprazole sulphide in MDC	7.69	Pantoprazole Sodium	1.45
2	Acetic acid	0.50	Dichloromethane Recovery	5.67
4	Sodium hypochlorite (6%)	1.15	Dichloromethane Loss	0.52
5	Sodium hydroxide	0.32	Acetone recovery	4.10
6	Acetone	5.00	Acetone Loss in distillation	0.35
7	Water	1.35	Acetone loss in Drying	0.55
8	Sodium thiosulfate	0.14	Acetic Acid Recovery	0.40
9	Activated carbon	0.08	Acetic Acid Recovery	0.10
			Water layer (Effluent)	2.50
			Solid waste	0.59
	Total	16.23	Total	16.23

13. Venlafaxine and its Intermediate

Process Description:

Cyclohexanone is condensed with Para Methoxy Phenyl acetonitrile to give VF1. This VF1 is reduced using palladium charcoal as catalyst. Acetic acid is used to get VF2 during this step. This VF2 is reacted with Formic Acid & formaldehyde to Venlaflaxine base. Venlaflaxine Hydrochloride is obtained by condensation of this base with IPA HCl.

Route of Synthesis:



VF.HCI (Veniafaxine.HCI)

Material Balance:

Stage:-1

Sr. No.	Input Material	MT	Output Material	MT
1	PMPA (P-Methoxy phenyl acetonitrile)	1.00	Stage-I (VF-1)	1.31
2	Sodium methoxide	0.50	Methanol recovery	0.89
3	Methanol	0.56	Methanol loss	0.17
4	Cyclohexanone	0.93	IPA recovery	2.43
5	IPA	2.54	IPA loss	0.11
6	Water	4.00	Aqueous layer	4.52
7			Drying Loss	0.10
	Total	9.53	Total	9.53

Stage:-2

Sr. No.	Input Material	MT	Output Material	MT
1	Stage-I (VF-1)	1.00	Stage-II (VF-2 Acetate)	0.99
2	Paladium Charcol	0.01	O-Xylene recovery	1.49
3	Acetic acid	4.89	O-Xylene loss	0.17
4	O-Xylene	1.66	Ethyl acetate recovery	0.41
5	Ethyl acetate	0.60	Ethyl acetate loss	0.09
6			Acetic acid recovery	4.69
7			Drying Loss	0.22
8			Spent Paladium Carbon	0.10
	Total	8.16	Total	8.16

Sr. No.	Input Material	MT	Output Material	MT
1	Stage-II (VF-2 Acetate)	1.25	Venlafexine Hydrochloride	1.10
2	Formic acid	1.50	Ethyl acetate recovery	11.60
3	Formaldehyde	1.30	Ethyl acetate Loss	0.90
4	Sodium hydroxide	1.26	Water Layer	4.90
5	Water	3.50	Drying Loss	0.26
6	Ethyl acetate	11.25	Spent carbon	0.04
7	Ethyl acetate HCl	1.50	Organic Residue	2.80
7	Activated carbon	0.04		
	Total	21.60	Total	21.60

14. Sevelamer Hydrochloride and its Intermediate

Process Description:

Stage-1:

A Mixture of Allylamine and Hydrochloric acid in low temperature with pressure of Nitrogen gas to get Allylamine Hydrochloride. A Mixture of Allyamine Hydrochloride Catalyst A, B and C and with controlled nitrogen gas to process of polymerization to get Plolyallyl amine Hydrochloride.

Stage-2:

A Mixture of Sodium hydroxide, DM water and Polyallyamine Hydrochloride in the reaction vessel at ambient temprature. Slowly add Epichlorohydrine to get gel formation at low tempreture. Charge DM water and stir for 24 hrs to get final product.

Route of Synthesis:

Stage-1:

$$H_2N$$
 CH_2 + HCI H_2N CH_2 .HCI H_2N CH_2 .HCI H_2N CH_3 .HCI H_2N CH_3 .HCI

Stage-2:

Polyallylamine Hydrochloride

Epichlorohydrine

$$C_3H_5CIO$$

M. Weight: 92.52

Method

Sevelamer Hydrochloride

 $C_8H_{12}Cl_2NO$

M. Weight: 186.08

Material Balance:

Stage:-1

Sr.				
No	Input Material	MT	Output Material	MT
1	Allylamina	1.00	Polyallylamine	2.60
1	Allylamine	1.00	Hydrochlride	2.60
2	Hydrochloric acid	2.10	Water effluent	0.58
3	Catalyst-A	0.01		
4	Catalyst-B	0.01		
5	Catalyst-C	0.01		
6	Nitrogen gas			
7	Water	0.05		
	Total	3.18	Total	3.18

Sr.				
No	Input Material	MT	Output Material	MT
1	Polyallylamine Hydrochloride	2.60	Sevelemer Hydrochloride	1.00
2	Sodium hydroxide	0.41	Water effluent	8.09
3	Epichlorohydrine	0.10	Drying loss	0.25
4	Nitrogen gas		Process emission	0.10
5	Water	6.33		
	Total	9.44	Total	9.44

ANNEXURE: 4
WATER CONSUMPTION AND WASTEWATER GENERATION

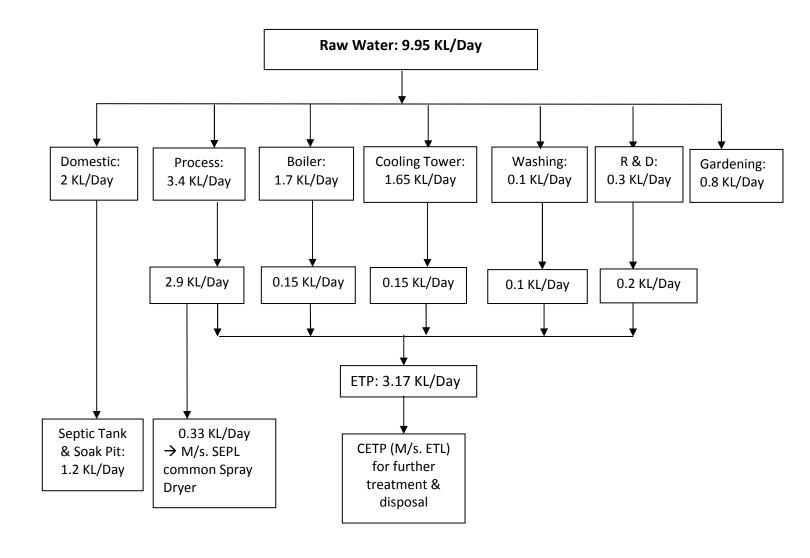
WATER CONSUMPTION

Sr.	Category	Wate	r Consumption (K	L/day)			
No.		Existing	Additional	Total			
1. Ir	1. Industrial						
	Process	0.30	3.10	3.40			
	Boiler	0.20	1.50	1.70			
	Cooling Tower	0.15	1.50	1.65			
	Washing	NIL	0.10	0.10			
	Total (Industrial)	0.65	6.20	6.85			
2.	R & D	NIL	0.30	0.30			
3.	Gardening	0.30	0.50	0.80			
4.	Domestic	1.00	1.00	2.00			
Total		1.95	8.00	9.95			

WASTEWATER GENERATION

Sr.	Category	Wastew	Wastewater Consumption (KL/day)			
No.		Existing	Additional	Total		
1.	L. Industrial					
	Process	NIL	2.90	2.90		
	Boiler	NIL	0.15	0.15		
	Cooling Tower	NIL	0.15	0.15		
	Washing	NIL	0.10	0.10		
	Total (Industrial)	NIL	3.30	3.30		
2.	R & D	NIL	0.20	0.20		
3.	Gardening	NIL	NIL	NIL		
4.	Domestic	0.40	0.80	1.20		
Total		0.40	4.30	4.70		

WATER BALANCE DIAGRAM (TOTAL)



ANNEXURE: 5

DETAILS OF EFFLUENT TREATMENT PLANT (ETP)

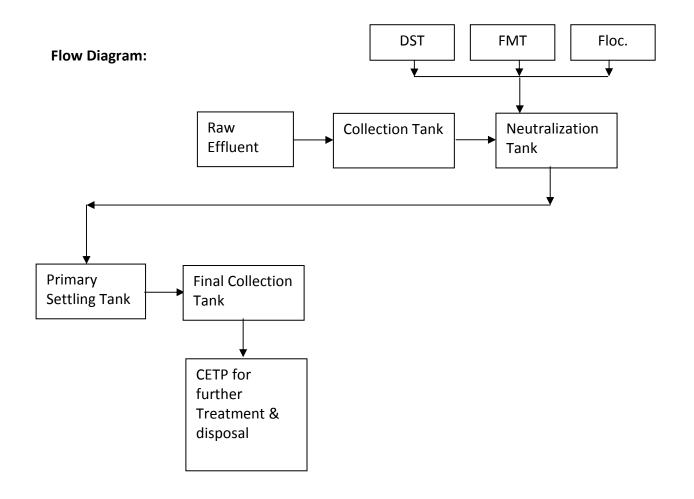
1) Primary Treatment:

The waste water from unit will be brought to the treatment plant via a series of underground pipelines. The waste water will be collected in the equalization tank. Two numbers of tanks are proposed. One will in filling mode for equalization of waste water while the other will be in pumping mode. The equalized wastewater is pumped to the flash mixer for addition of chemicals like lime. From the flash mixer the waste water flows into the flocculator where chemical flocs are formed by coagulation and flocculation by addition of Alum/Ferrous sulphate and polyelectrolyte. These flocs are removed in the primary settling tank. Treated effluent will be sent to CETP for further treatment. The underflow (sludge) from the primary settling tank is taken to sludge dewatering unit (Sludge Drying Bed).

The Domestic wastewater is disposed of through septic tank / soak pit.

Effluent Treatment Plant (Dimension):

Sr. No.	Name of the Unit	Dimension	Volume (m³)	МОС
1.	Collection Tank (2 Nos.)	1.5(m) x 2.0(m)x 1.0(m)	3.0 m ³	RCC
2.	Dosing Tank (1 Nos.)	1.0(m) x 1.0(m)x 1.0(m)	1.0 m ³	RCC
3.	Flash Mixer	1.0(m) x 1.0(m)x 1.0(m)	1.0 m ³	RCC
4.	Flocculator	1.0(m) x 1.0(m)x 1.0(m)	1.0 m ³	RCC
5.	Neutralization Tank	1.5(m) x 2.0(m)x 1.0(m)	3.0 m ³	RCC
6.	Primary Settling Tank	1.5(m) x 2.0(m)x 1.0(m)	3.0 m ³	RCC



EXPECTED CHARACTERISTICS OF WASTEWATER BEFORE & AFTER TREATMENT

Sr.	Parameter	Characteristic	CETP Inlet Norms	
No.		Untreated	Treated	(mg/L)
1.	рН	3-9	6.5-8.5	5-9
2.	TDS	2000	1900	2100
3.	COD	3000	950	1000
4.	BOD ₃	950	280	300
5.	Ammonical Nitrogen	10	6	50

ANNEXURE: 6
DETAILS OF HAZARDOUS WASTE MANAGEMENT AND DISPOSAL

Sr.	Type of Waste	Schedule		Quantity		Disposal Method
No.		Category	Existing	Additional	Total	
1	Used Oil	5.1	1	0.20	1.20	Collection, Storage,
			MT/Month	MT/Month	MT/Month	Transportation & sale to
						GPCB authorized recycler
2	Discarded	33.1	1.024	1.0	2.024	Collection, storage,
	Containers/ Bags/		MT/Month	MT/Month	MT/Month	transportation,
	Carboys					decontamination & sell to
						GPCB authorized vendors
3	ETP sludge	35.3		5	5	Collection, Storage,
				MT/Month	MT/Month	Transportation & Disposal to
						TSDF site
4	Distillation	20.3		5	5	Collection, Storage,
	Residue			MT/Month	MT/Month	Transportation & given to
5	Organic Residue			25	25	cement industries for co-
	_			MT/Month	MT/Month	processing or Disposal at
						common incineration site
6	Inorganic Solid			30	30	Collection, Storage,
	Waste			MT/Month	MT/Month	Transportation & Disposal at
						nearest TSDF site
7	Spent Carbon	36.2		0.5	0.5	Collection, Storage,
				MT/Month	MT/Month	Transportation & given to cement industries for co-
						processing or Disposal at
						TSDF site

ANNEXURE: 7

DETAILS OF STACK & VENTS

Existing:

1. Details of Flue Gas Stack; Stack Attached To Non IBR Boiler

SOURCES OF GASESOUS EMISSIONS	STACK		
Fuel Used	Wood		
Capacity	600 kg/hr		
Type of Emissions	SO ₂	NOx	SPM
Permissible Limits	100 ppm	50 ppm	150 mg/Nm ³
Stack Height	11 meter		

Proposed:

1. Details of Flue Gas Stack; Stack Attached To Steam Boiler

SOURCES OF GASESOUS EMISSIONS	STACK				
Fuel Used	Agro Waste/ coal				
Capacity	1.5 T/Hr				
Type of Emissions	SO ₂	NOx	SPM		
Permissible Limits	100 ppm 50 ppm 150 mg/Nm ³				
Stack Height	30 meter				
Stack Diameter at the Top	1.0 meter				
Air Pollution Control Measures	Multicyclone Se	eparator, Bag Fil	ter & Scrubber		

2. Details of Flue Gas Stack; Stack Attached To D.G. Set

Sources of Gaseous Emissions	D.G. Set (150 K	D.G. Set (150 KVA)			
Fuel Used	Diesel				
Stack Height	11 meter				
Stack Diameter at The Top	0.2 meter				
Type of Emissions	SO ₂ NOx SPM				
Permissible Limits	100 ppm	50 ppm	150 mg/Nm ³		

3. Details of Process Vent

Sr.	Stack attached	Stack	Air Pollution	Parameter	Permissible	
No.	to	Height	Control System		Limit	
1	Process Vent - 1	15 m	Two Stage Scrubber	HCI	20 mg/Nm ³	
2	Process Vent - 2	15 m	Two Stage Scrubber	Br ₂	5 mg/Nm ³	

ANNEXURE: 8
DETAILS HAZARDOUS CHEMICAL STORAGE FACILITY

Sr.	Name of the Hazardous	Type of	Maximum	MOC of	Actual
No.	Chemicals	Hazard	Storage	Storage	Storage
1	Sulphuric Acid	Corrosive	5 MT	Tank	5 MT
2	Hydrochloric Acid	Corrosive	5 MT	Tank	5 MT
3	Liquid Bromine	Toxic	36 kg	Carrat Pack	18 kg
				(2 Nos.)	
4	Toluene	Flammable	5 MT	Drum	1000 kg
				(5 Nos.)	
5	Nitric Acid	Corrosive	5 MT	Tank	5 MT
6	Acetic Acid	Corrosive	5 MT	Tank	5 MT
7	Methanol	Flammable	2 MT	Drums	200 Liters
				(10 Nos.)	
8	Isopropyl Alcohol	Flammable	2 MT	Drums	200 Liters
				(10 Nos.)	
9	Monoethylene glycol	Corrosive	2 MT	Drums	200 Liters
				(10 Nos.)	

ANNEXURE: 9

SOCIO - ECONOMIC IMPACTS

1) EMPLOYMENT OPPORTUNITIES

The manpower requirement for the proposed project is expected to generate some permanent jobs and secondary jobs for the operation and maintenance of plant. This will increase direct / indirect employment opportunities and ancillary business development to some extent for the local population. This phase is expected to create a beneficial impact on the local socio-economic environment.

2) INDUSTRIES

Required raw materials and skilled and unskilled laborers will be utilized maximum from the local area. The increasing industrial activity will boost the commercial and economical status of the locality, to some extent.

3) PUBLIC HEALTH

The company regularly examines, inspects and tests its emission from sources to make sure that the emission is below the permissible limit. Hence, there will not be any significant change in the status of sanitation and the community health of the area, as sufficient measures have been taken and proposed under the EMP.

4) TRANSPORTATION AND COMMUNICATION

Since the existing factory is having proper linkage for the transport and communication, the development of this project will not cause any additional impact.

In brief, as a result of the proposed project there will be no adverse impact on sanitation, communication and community health, as sufficient measures have been proposed to be taken under the EMP. The proposed project is not expected to make any significant change in the existing status of the socio - economic environment of this region.

ANNEXURE: 10

PROPOSED DRAFT TERMS OF REFERENCE

1. Project Description

- Justification of project.
- · Promoters and their back ground
- Project site location along with site map of 5 km area and site details providing various industries, surface water bodies, forests etc.
- Project cost
- Project location and Plant layout.
- Water source and utilization including proposed water balance.
- Product spectrum (proposed products along with production capacity) and process
- List of hazardous chemicals.
- Mass balance of each product
- Storage and Transportation of raw materials and products.

2. Description of the Environment and Baseline Data Collection

- Micrometeorological data for wind speed, direction, temperature, humidity and rainfall in 5 km area.
- Existing environmental status Vis a Vis air, water, noise, soil in 5 km area from the project site. For SPM, RSPM, SO₂, NOx.
- Ground water quality at 5 locations within 5 km.
- Complete water balance

3. Socio Economic Data

• Existing socio-economic status, land use pattern and infrastructure facilities available in the study area were surveyed.

4. Impacts Identification And Mitigatory Measures

- Identification of impacting activities from the proposed project during construction and operational phase.
- Impact on air and mitigation measures including green belt
- Impact on water environment and mitigation measures
- Soil pollution source and mitigation measures
- Noise generation and control.
- Solid waste quantification and disposal.

5. Environmental Management Plan

- Details of pollution control measures
- Environment management team
- Proposed schedule for environmental monitoring including post project

6. Risk Assessment

- Objectives and methodology of risk assessment
- Details on storage facilities
- Process safety, transportation, fire fighting systems, safety features and emergency capabilities to be adopted.
- Identification of hazards
- Consequence analysis through occurrence & evaluation of incidents
- Disaster Management Plan.
- 7. Information for Control of Fugitive Emissions
- 8. Post Project Monitoring Plan for Air, Water, Soil and Noise.
- 9. Information on Rain Water Harvesting
- 10. Green Belt Development plan