FORM-1

for

PROPOSED EXPANSION OF API & API INTERMEDITES IN EXISTING UNIT

of

M/s. ALEMBIC PHARMACUETICALS LIMITED
(API UNIT-II)
SURVEY NO.: 137, 144P & 145P,
AT: PANELAV, POST: TAJPURA, TAL: HALOL,
DIST: - PANCHMAHAL-389 350 (GUJ)

Prepared by:

NABL Accredited Testing Laboratory
ISO 9001:2008 Certified Company

Aqua-Air Environmental Engineers P. Ltd.
403, Centre Point, Nr. Kadiwala School, Ring Road, Surat - 395002

APPENDIX I

(See paragraph - 6)

FORM 1

(I) Basic Information

Sr. No.	Item	Details
1.	Name of the project/s	Alembic Pharmaceuticals Limited(API Unit-II)
2.	S. No. in the schedule	5(f)
3.	Proposed capacity/area/length/tonnage to be handled/command area/lease area/number of wells to be drilled	For detail Please refer **Annexure – I**
4.	New/Expansion/Modernization	Expansion
5.	Existing Capacity/Area etc.	--
6.	Category of Project i.e. 'A' or 'B'	'A'
7.	Does it attract the general condition? If yes, please specify.	No
8.	Does it attract the specific condition? If yes, please specify.	No
9.	Location	
	Plot/Survey/Khasra No.	Survey No.137, 144P & 145P.
	Village	Panelav
	Tehsil	Halol
	District	Panchmahal
	State	Gujarat
10.	Nearest railway station/airport along with distance in kms.	Vadodara – 45 Km
11.	Nearest Town, city, District Headquarters along with distance in kms.	Halol - 10 km
12.	Village Panchayats, Zilla Parishad, Municipal Corporation, local body (complete postal address with telephone nos. to be given)	Not applicable
13.	Name of the applicant	M/s. Alembic Pharmaceuticals Limited (API Unit-II)
14.	Registered Address	M/s. Alembic Pharmaceuticals Limited (API Unit-II) Survey No.: 137, 144P & 145P, At: Panelav, Post: Tajpura, Tal: Halol, Dist.: Panchmahal-389 350, Gujarat
15.	Address for correspondence:	M/s. Alembic Pharmaceuticals Limited (API Unit-II) Survey No.: 137, 144P & 145P, At: Panelav, Post: Tajpura, Tal: Halol, Dist.: Panchmahal-389 350, Gujarat
	Name	Mr. Ashok Tulankar
	Designation (Owner/Partner/CEO)	Vice President (Mfg.)
	Address	M/s. Alembic Pharmaceuticals Limited (API Unit-II) Survey No.: 137, 144P & 145P, At: Panelav, Post: Tajpura, Tal: Halol, Dist: Panchmahal-389 350, Gujarat
	Pin Code	389 350

	E-mail	ashok.tulankar@alembic.co.in agua_eia@yahoo.com
	Telephone No.	(02676) 664301
	Fax No.	(02676) 247255
16.	Details of Alternative Sites examined, if any. Location of these sites should be shown on a topo sheet.	NA
17.	Interlinked Projects	NA
18.	Whether separate application of interlinked project has been submitted?	NA
19.	If yes, date of submission	NA
20.	If no, reason	NA
21.	Whether the proposal involves 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?	No
22.	Whether there is any Government Order/Policy relevant/relating to the site?	No
23.	Forest land involved (hectares)	NA
24.	Whether there is any litigation 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.	NA

- Capacity corresponding to sectoral activity (such as production capacity for manufacturing, mining lease area and production capacity for mineral production, area for mineral exploration, length for linear transport infrastructure, generation capacity for power generation etc.,)

(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 there of with approximate quantities fraters, wherever possible) with source of information data
1.1	Permanent or temporary change in land use, land cover or topography including increase intensity of land use (with respect to local land use plan)	No	Proposed Expansion within existing unit.
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	The project site is located on level

			ground, which does not require any major land filling for area grading work.
1.4	Pre-construction investigations e.g. bore Houses, soil testing?	No	
1.5	Construction works?	Yes	For detail Please refer **Annexure – II**
1.6	Demolition works?	No	There will not be Demolition work at the site.
1.7	Temporary sites used for construction works or housing of construction workers?	Yes	
1.8	Above ground buildings, structures or earthworks including linear structures, cut and fill or excavations	Yes	For detail Please refer **Annexure – II**
1.9	Underground works mining or tunneling?	No	
1.10	Reclamation works?	No	
1.11	Dredging?	No	
1.12	Off shore structures?	No	
1.13	Production and manufacturing processes?	Yes	For detail Please refer **Annexure -III**
1.14	Facilities for storage of goods or materials?	Yes	Areas for storage tank farm, raw materials and finished products will be developed for the proposed Expansion project.
1.15	Facilities for treatment or disposal of solid waste or liquid effluents?	Yes	For detail please refer **Annexure – IV & V.**
1.16	Facilities for long term housing of operational workers?	No	
1.17	New road, rail or sea traffic during Construction or Operation?	No	
1.18	New road, rail, air waterborne or other transport infrastructure including new or altered routes and stations, ports, airports etc?	No	
1.19	Closure or diversion of existing transport routes or infrastructure leading to changes in traffic movements?	No	
1.20	New or diverted transmission lines or Pipelines?	No	There will not be said work at the site.
1.21	Impoundment, damming, culverting,	No	

	realignment or other changes to the hydrology of watercourses or aquifers?		
1.22	Stream crossings?	No	
1.23	Abstraction or transfers of water form ground or surface waters?	Yes	Water requirement will be met through ground water.
1.24	Changes in water bodies or the land surface Affecting drainage or run-off?	No	
1.25	Transport of personnel or materials for construction, operation or decommissioning?	Yes	By road only.
1.26	Long-term dismantling or decommissioning or restoration works?	No	
1.27	Ongoing activity during decommissioning which could have an impact on the environment?	No	
1.28	Influx of people to an area either temporarily or permanently?	No	
1.29	Introduction of alien species?	No	
1.30	Loss of native species or genetic diversity?	No	
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 frates, wherever possible) with source of information data
2.1	Land especially undeveloped or agricultural land (ha)	No	
2.2	Water (expected source & competing users) unit: KLD	Yes	Water requirement will meet through the ground water. For detail water balance please refer **Annexure – IV**
2.3	Minerals (MT)	No	
2.4	Construction material - stone, aggregates, and / soil (expected source - MT)	Yes	Construction materials, like steel, cement, crushed stones, sand, rubble, etc. required for the project shall be procured from the

			local market of the region.
2.5	Forests and timber (source - MT)	No.	
2.6	Energy including electricity and fuels (source, competing users) Unit: fuel (MT), energy (MW)	Yes	**Fuel** Furnace Oil : 0.120 Lit/Hrs (Existing) HSD : 0.130 kl/hr (Proposed for DG Set) **Energy :** 600 KVA from MGVCL D.G. Set 750 KVA Stand by
2.7	Any other natural resources (use appropriate 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 there of (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	For details please refer **Annexure – VII**
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?	Yes	Direct/Indirect employment
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 there of (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 –V**
4.4	Other industrial process wastes	No	
4.5	Surplus product	No	
4.6	Sewage sludge or other sludge from effluent treatment	Yes	Please refer **Annexure – V**
4.7	Construction or demolition wastes	No	
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 –V**

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	For details Please refer **Annexure – VI**
5.2	Emissions from production processes	Yes	For details Please refer **Annexure – VI**
5.3	Emissions from materials handling storage or transport	Yes	For details Please refer **Annexure – VI**
5.4	Emissions from construction activities including plant and equipment	No	
5.5	Dust or odors from handling of materials including construction materials, sewage and waste	No	
5.6	Emissions from incineration of waste	No	
5.7	Emissions from burning of waste in open air (e.g. slash materials, construction debris)	No	
5.8	Emissions from any other sources	No	

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 information data with source of information data
6.1	From operation of equipment e.g. engines, ventilation plant, crushers	Yes	The Noise level will be within the prescribed limit. At noisy areas adequate preventive & control measures will be taken. No significant noise, vibration or emission of light & heat from the unit.
6.2	From industrial or similar processes	Yes	-do-
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	Yes	Adequate Lighting is provided in unit and also local ventilation system is provided.
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 there of (with approximate quantities/rates, wherever possible) with source of information data
7.1	From handling, storage, use or spillage of hazardous materials	Yes	For details please refer **Annexure – VII**
7.2	From discharge of sewage or other effluents to water or the land (expected mode and place of discharge)	Yes	For details please refer **Annexure – IV**
7.3	By deposition of pollutants emitted to air into the and or into water	No	
7.4	From any other sources	No	
7.5	Is there a risk of long term build up of pollutants in the environment from these sources?	No	

8. Risk of accidents during construction or operation of the Project, which could affect human health or the environment

Sr. No.	Information/Checklist confirmation	Yes/No	Details there of (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	For detail please refer **Annexure – VII**
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 there of (with approximate quantities/rates, wherever possible) with source of information data
9.1	Lead to development of supporting. lities, 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 industry • supply industry • other	Yes	For detail please refer **Annexure – VIII**
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	

(II) Environmental Sensitivity

Sr. No.	Areas	Name/ Identity	Aerial distance (within 15km.) Proposed project location boundary
1	Areas protected under international conventions, national or local legislation for their ecological, landscape, cultural or other related value	-	No protected area within 5 km from the proposed expansion project boundary
2	Areas which important for are or sensitive Ecol logical reasons - Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	Vishwamitri river Pawagadh Mountain	Vishwamitri river is around 1 Km away from the project site. Pawagadh Mountain is around 5 Km away from the project site.
3	Area used by protected, important or sensitive Species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	-	No protected area or sensitive species within 5 km from the proposed expansion project boundary
4	Inland, coastal, marine or underground waters	-	Vishwamitri river is around 1 Km away from the project site.
5	State, National boundaries	-	N.A.
6	Routes or facilities used by the public for access to recreation or other tourist, pilgrim areas	-	N.A.
7	Defense installations	-	N.A.
8	Densely populated or built-up area	Halol	Halol is around 10 km from the proposed expansion project site.
9	Area occupied by sensitive man-made land uses Hospitals, schools, places of worship, community facilities)	-	N.A.
10	Areas containing important, high quality or scarce resources (ground water resources, surface resources, forestry, agriculture, fisheries, tourism, minerals)	-	N.A.
11	Areas already subjected to pollution environmental damage. (those where existing legal environmental standards are exceeded)or	-	N.A.
12	Are as 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)	-	N.A.

IV). Proposed Terms of Reference for EIA studies: For detail please refer **Annexure – IX**

I hereby give an 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 give, if any to the project will be revoked at our risk and cost.

Date: 03.06.2014
Place: Panelav, Halol, Panchmahal

FOR **ALEMBIC PHARMACUETICALS LIMITED (API UNIT-II)**

Tulankar

ASHOK TULANKAR
SR. VICE PRESIDENT MFG.

ANNEXURE – I

LIST OF PRODUCTS

Sr. No.	Product	Existing (MT/Annum)	Total after Proposed Expansion (MT/Annum)
1	Candesartan Cilexetil	5	300
2	Celecoxib	12	
3	Irbesartan	2	
4	Losartan Potassium	12	
5	MEM Chloride	6	
6	Moclobemide	2	
7	Olmesartan	2	
8	Ropinorole	3	
9	Valsartan	3	
10	Bupropion Hydrochloride	-	
11	Etoricoxib	-	
12	O Des Venlafaxine	-	
	Total	**47**	**300**

LIST OF RAW MATERIALS

SR. NO.	NAME OF RAW MATERIAL	QUANTITY (Kg/Kg PRODUCT)
1	**Candesartan Cilexetil**	
	EBC-III	2.383
	Acetone	25.425
	Anhydrous Potassium Carbonate	0.445
	Candesartan Cilexetil-I	1.833
	Candesartan Cilexetil-II	2.200
	Cyclohexane	9.243
	Cyclohexyl 1-Chloro Ethyl Carbonate	0.672
	D M Water	92.414
	Dichloromethane	29.040
	Dimethyl-Formamide	3.153
	Ethyl Alcohol	1.041
	Hydrochloric Acid	1.111
	Hyflow	0.060
	Methanol	8.800
	Sodium Bicarbonate	1.100
	Sodium Chloride	0.550
	Triethyl Amine	3.163
2	**Celecoxib**	
	1-(4-Methylphenyl)-4,4,4 Trifluorobutane 1,3-dione	0.754
	4-Methylacetophenon	0.443
	D M water	12.282
	Ethyl Alcohol	0.237
	Ethyl Trifluro Acetate	0.562
	Isopropyl Alcohol	8.447
	Methanol	0.019
	Sodium Methoxide	0.356
	Sulphuric Acid	0.515
	Toluene	2.113
	Trifluoro Acetic Acid	0.396
	4-Sulphonamino Phenyl Hydrazine	0.769
3	**Irbesartan**	
	2-Butyl-1,3-Diaziaspiro[4,4]non-1-en-4-one Hydrochloride	1.145
	4-Bromomethyl 2-Cyno Biphenyl(4 BMCP)	1.316
	Acetone	4.648
	D M Water	27.027
	Hydrochloric Acid	0.699
	Irbesartan-I	1.250
	Methyl T-Butyl Ether	1.879
	O-Xylene	0.009
	Sodium Azide	0.538
	Sodium Chloride	0.263
	Sodium Hydroxide	0.858
	Sodium Nitrate	0.175
	Toluene	4.335
	Triethyl Amine Hydrochloride	1.750
4	**Losartan Potassium**	
	2-Butyl-1,3-Diaziaspiro[4,4]non-1-en-4-one Hydrochloride	0.964
	4-Bromomethyl 2-Cyno Biphenyl(4 BMCP)	1.108

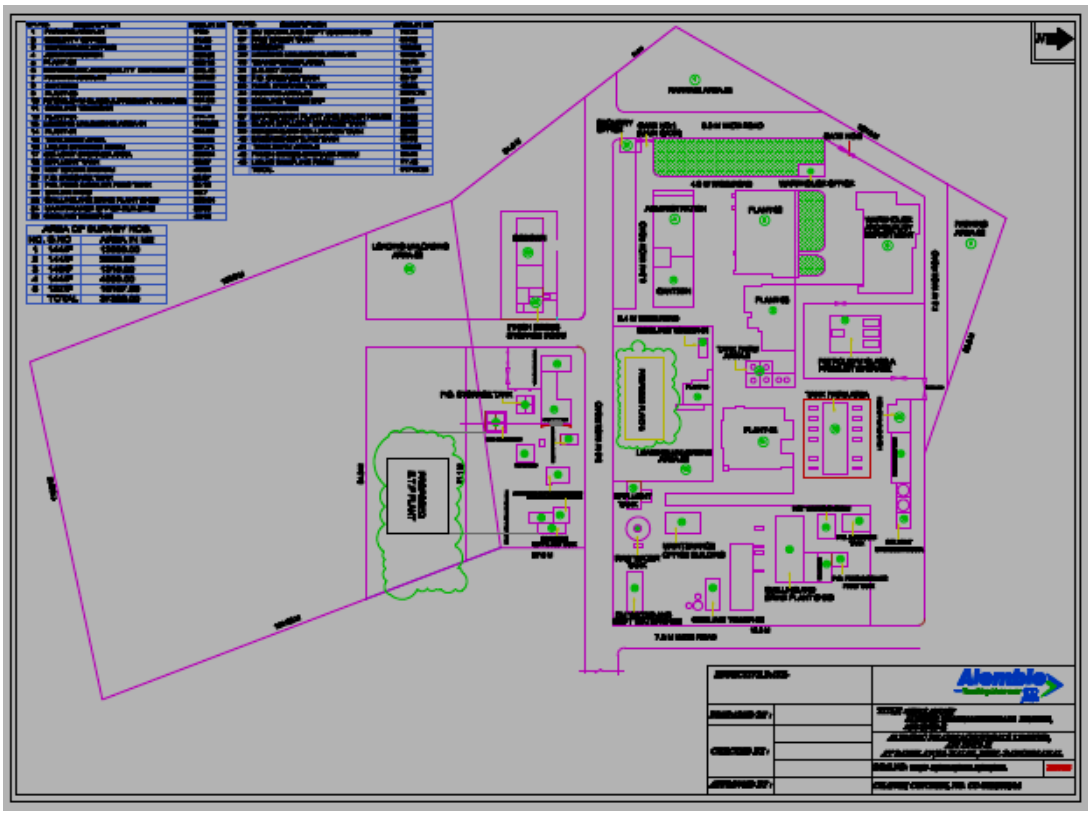
	Acetone	9.287
	Activated Carbon	0.105
	D M Water	8.202
	Hyflow	0.012
	Losartan Potassium-I	1.053
	Methanol	4.597
	Potassium Hydroxide	0.184
	Sodium Chloride	0.222
	Sodium Hydroxide	0.554
5	**Methoxy Ethoxy Methyl Chloride**	
	Para Formaldehyde	0.333
	Methyl Cellosove	0.867
	Thionyl Chloride	1.433
	D M Water	22.222
	Sodium Hydroxide Lye (50%)	1.667
6	**Moclobemide**	
	2-Chloro Ethylamine Hydrochloride	1.613
	4- Chloro Benzoyl Chloride	1.115
	Activated Charcoal	0.045
	D M Water	8.073
	Dichloromethane	5.913
	Hyflow	0.033
	Isopropyl Alcohol	1.099
	Moclobemide Stage-I	0.981
	Moclobemide Stage-II	1.128
	Moclobemide Stage-III	1.083
	Morpholine	1.560
	Sodium bicarbonate	0.223
	Sodium Carbonate	0.989
	Sodium Hydroxide	0.186
	Toluene	14.293
7	**Olmesartan**	
	5-[4'-(Bromomethyl)[1,1'-biphenyl]-2-yl]- 2-(triphenylmethyl)-2H-tetrazole(TTBB) (Lot-I)	4.271
	Acetic Acid	0.420
	Acetone	13.299
	Activated Carbon	0.133
	Anhydrous Potassium Carbonate	4.085
	D M Water	119.673
	Di Methyl Formamide	26.171
	Dichloromethane	77.657
	Dimethyl2-Propyl 1-H Imedazole-4, 5-Diccarboxylate	41.262
	DIPE	1.571
	Ethyl 4-(1-Hydroxyl -1-Methylethyl)-2-Propylimidazole -5-Carboxylate	1.841
	Ethyl Acetate	59.922
	Hydrochloric Acid	0.922
	Hyflow	4.668
	Medoxomil	0.596
	Methanol	13.710
	N N-Dimethyl Formamide	10.161
	Olmesartan-I Stage	1.922
	Olmesartan-II Stage	1.826
	Olmesartan-III Stage	1.059
	Sodium Carbonate	0.913

	Sodium Chloride	1.802
	Sodium Hydroxide	0.160
8	**Ropinorole**	
	2-Methyl -3-Nitro phenyl acetic acid	0.909
	Cyclohexane	3.187
	Dichloromethane	23.188
	Di-n-propyl-amine	1.312
	DM Water	6.545
	Ethyl Acetate	15.785
	Hydrochloric acid	5.837
	Methane sulphonic Acid	0.444
	Methanol	2.122
	Oxalic Acid Dihydrate	0.473
	p-Toluene Sulfonyl chloride	1.245
	Sodium bicarbonate	0.227
	Sodium Borohydride	0.445
	Sodium Chloride	0.182
	Tetrahydrofuran	3.147
	Toluene	1.180
	Triethyl amine	4.745
9	**Valsartan**	
	Acetone	0.001
	Activated Carbon	0.107
	Biphenyl Valine	1.429
	D M Water	60.256
	Dichloromethane	37.581
	Hydrochloric Acid	1.220
	Hyflow	0.063
	O-Xylene	6.403
	Potassium Carbonate	1.671
	Sodium Azide	0.676
	Sodium Bicarbonate	0.200
	Sodium Chloride	0.429
	Sodium Hydroxide	0.829
	Tetra butyl Ammonium Bromide	0.071
	Tri-n-butyl tin Chloride	2.821
	Valeroyl Chloride	0.627
10	**Bupropion Hydrochloride**	
	3" Chloropropiophenone	0.703
	Activated Carbon	0.051
	Bromine	0.735
	Bupropion Hydrochloride-I	1.054
	D M Water	22.134
	Hyflow	0.014
	Iso Propyl Alcohol HCL	1.013
	Iso Propyl Alcohol	6.171
	Methanol	3.336
	Sodium Chloride	0.703
	Sodium Thiosulphate	0.054
	T-Butyl Amine	1.527
	Toluene	9.138
11	**Etoricoxib**	
	Acetic Acid	2.283
	Acetone	2.781

	Activated Carbon	0.022
	Ammonia Solution	10.871
	D M Water	45.343
	Etoricoxib-I	1.107
	Hexane	0.260
	Hyflow	0.230
	Isopropyl Alcohol	25.054
	Ketosulfone	1.574
	Methanol	9.706
	Tri Hydrofuron	22.273
	Trifluro Acetic Acid	0.465
12	**O Des Venlafaxine**	
	Acetic Acid	1.018
	Activated Carbon	0.141
	D M Water	39.287
	Dimethyl Formamide	5.713
	Ethanethiol	1.051
	Hyflow	0.078
	Methanol	34.523
	O-Desmethyl Venlafaxine	1.087
	Sodium Hydroxide	0.690
	Toluene	4.607
	Venlafaxine Hydrochloride	1.327

ANNEXURE – II

PLANT LAYOUT



ANNEXURE – III

BRIEF MANUFACTURING PROCESS

1. CANDESARTAN CILEXETIL

Manufacturing Process

Stage-1

EBC-III is reacted with Cyclohexyl 1-chloro ethyl carbonate Dimethyl Formamide react with Potassium carbonate & then reaction mass goes in to acetone.

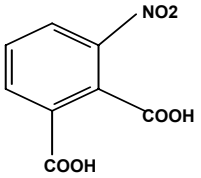
Stage – 2:

Charge in Dichloromethane reacts with sodium bicarbonate & then add methanolic hydrochloric acid then separate and add in ethanol for reaction mass centrifugation.

Stage – 3:

Candesartan Cilexetil crude is purified with mixture of Acetone and D M Water to get for purification for Candesartan Cilexetil pure.

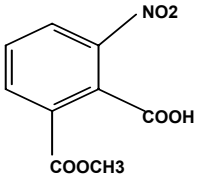
Chemical Reaction



3-Nitro phalic acid

METHANOL
D.M.WATER
CONC.SULPHUIRIC ACID

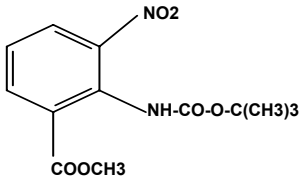
D.M.WATER
CONC.SULPHURIC ACID



METHYL 2-CARBOXY 3-NITROBENZOATE

Thionyl chloride
Toluene
Dimethylformamide
Sodium azide
t-Butanol
Sodium bicarbonate
D.M.Water
Methanol

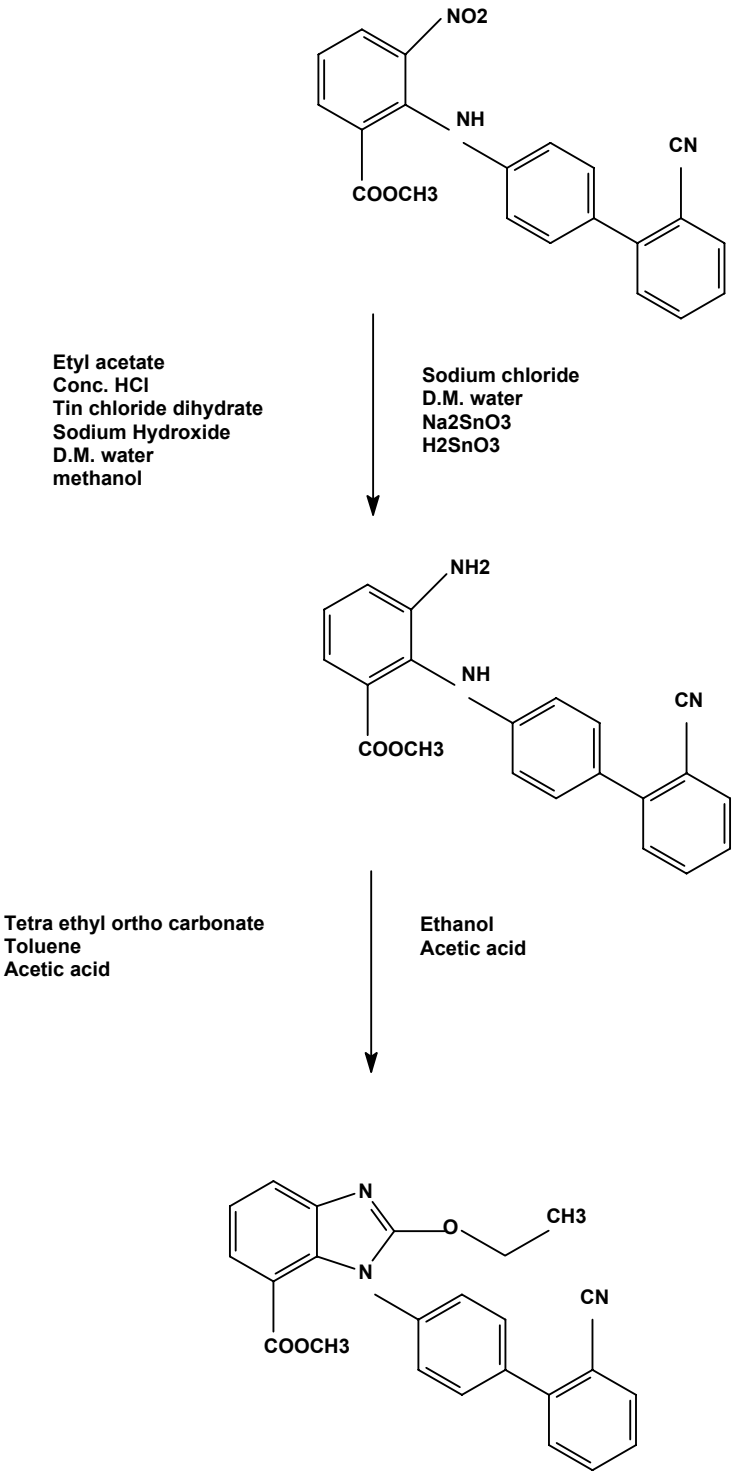
Sodium chloride
Nitrogen
SO2
HCl



Methyl 2-t-butoxycarbonylamino-3-nitrobenzoate

4-(2-cynophenyl)benzyl bromide
Potassium carbonate
Potassium iodide
Acetonitrile
Conc. HCl
Sodium bicarbonate
D.M. water
Methanol

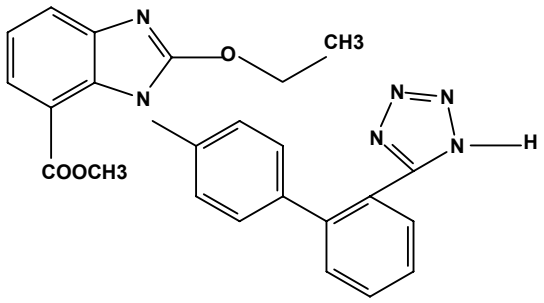
Potassium Bromide
t-Butanol
Potassium carbonate
Potassium iodide



Methyl 1[(2'-cyanobiphenyl-4yl)methyl]-2-ethoxy-benzimidazole-7-carboxylate

O-xylene
Tri butyl tin chloride
Sodium azide
D.M. water
Sodium hydroxide
Conc. HCl

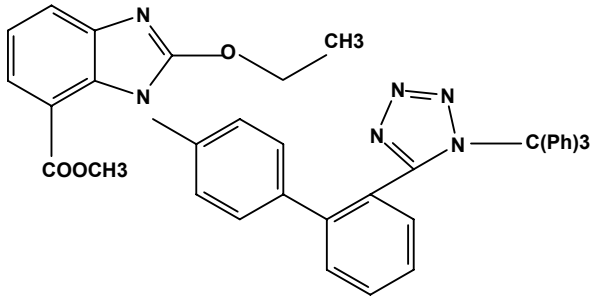
Sodium chloride
Tri butyl tin hydroxide
Methanol



2-Ethoxy-1[2'-{1h-tetrazole-5-yl}biphenyl-4yl)-methyl]benzimidazole-7carboxylic acid

Dichloromethane
Trityl phenyl chloride
Triethyl amine
Acetonitrile

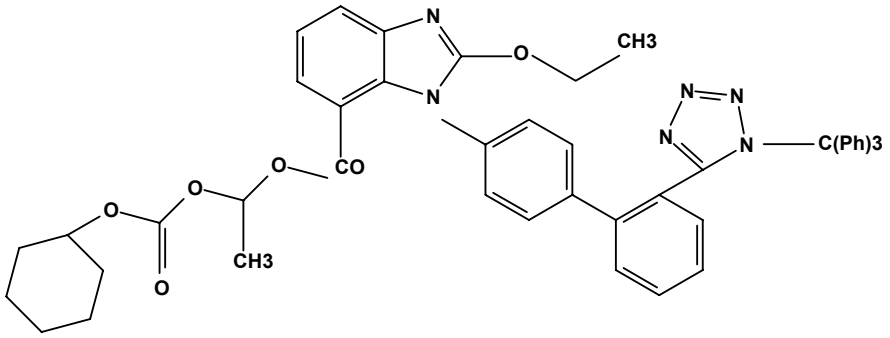
Triethyl amine hydrochloride



2-Ethoxy-1[2'-{N-tri phenyl methyl tetrazole-5-yl}biphenyl-4yl)-methyl]benzimidazole-7carboxylic acid

Cyclohexyl 1-chloroethyl carbonate
Potassium carbonate
Potassium iodide
Dimethyl sulphoxide
Acetonitrile
D.M. water

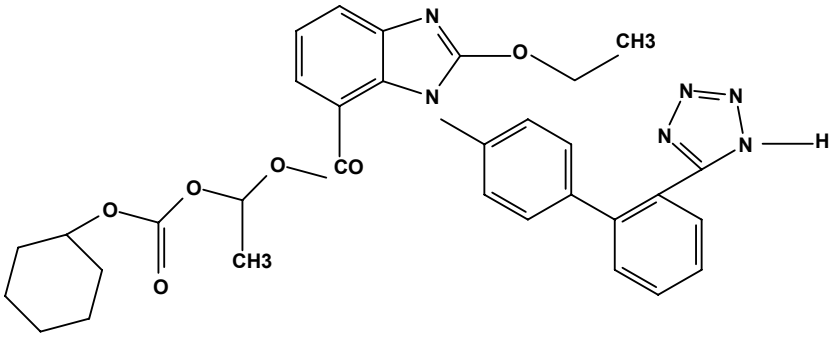
Potassium chloride
CO2
Potassium carbonate
Potassium iodide



1-(Cyclohexaloxycarbonyloxy)ethyl-2-ethoxy-1[2'-{N-tri phenyl methyl tetrazole-5-yl biphenyl-4-yl)-methyl] benzimidazole-7-carboxylate

Conc.HCl
Methanol
Dichloromethane
Sodium bicarbonate
D.M.Water
Ethanol
Cyclohexane
D.M. water
Aceton

Tritanol
CO2
Sodium chloride



Canadesatan Cilexitil

Material Balance

Stage – 1

Total input Kgs.	Starting Material	Product output Candesartan Cilexetil-I	Quantity Kgs.	Output details
2.383	EBC-III	**1.830Kgs**	-	
11.988	Acetone		10.000	Acetone Recovery
24.732	D M Water		1.988	Acetone Recovery Loss
2.423	Triethyl Amine			
			0.171	Evaporation Loss
			27.537	Aqueous Effluent
41.526	**Total**		**39.696**	**Total**

Stage – 2

Total input Kgs.	Starting Material	Product output Candesartan Cilexetil-II	Quantity Kgs.	Output details
3.153	Dimethyl-Formamide	**2.200Kgs**	-	
1.833	Candesartan Cilexetil-I		10.927	Acetone Recovery
0.445	Anhydrous Potassium Carbonate		0.587	Acetone Recovery Loss
0.672	Cyclohexyl 1-Chloro Ethyl Carbonate		2.988	Dimethyl-Formamide Recovery
33.000	D M Water		0.165	Dimethyl-Formamide Recovery Loss
11.513	Acetone			
			0.385	Evaporation Loss
			33.365	Aqueous Effluent
50.617	**Total**		**48.417**	**Total**

Stage – 3

Total input Kgs.	Starting Material	Product output Candesartan Cilexetil	Quantity Kgs.	Output details
1.923	Acetone		-	
2.200	Candesartan Cilexetil-II		23.840	Dichloromethane Recovery
9.243	Cyclohexane		1.680	Dichloromethane Recovery Loss
34.682	D M Water		8.360	Methanol Recovery
29.040	Dichloromethane		0.440	Methanol Recovery Loss
1.041	Ethyl Alcohol	**1.00Kgs**	8.800	Cyclohexane Recovery
1.111	Hydrochloric Acid		0.443	Cyclohexane Recovery Loss
0.060	Hyflow			
8.800	Methanol			
1.100	Sodium Bicarbonate		45.788	Aqueous Effluent
0.550	Sodium Chloride		0.140	Evaporation Loss
0.740	Triethyl Amine			
90.490	**Total**		**89.490**	**Total**

2. CELECOXIB

Manufacturing Process

Stage-1 & 2

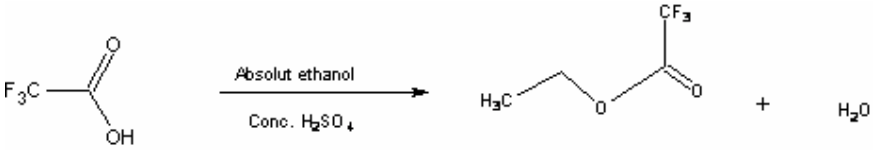
A mixture of ethyl trifluoroacetate and 4 methyl acetophenone is reacted with Sodium methoxide in solvent media toluene at a under temperature. The reaction mass is then heated and maintained. The completion of the reaction is monitored on GC after which the reaction mass is subjected to work up in acidic medium of sulphuric acid solution. The product is thereafter washed with water and the resultant Toluene layer is distilled off and the residual oil is unloaded. This is stage-I which is further analyzed before use.

Stage-II

The stage obtained as above is then reacted with 4-Sulfamoyl phenyl hydrazine hydrochloride in 12.5 % Aqueous Isopropyl alcohol followed maintaining of reaction mixture temp. The end point is monitored on GC and then the reaction mass is cooled and precipitated by addition of water. This precipitated mass is then centrifuged. The wet cake is then further purified in Aqueous Isopropyl alcohol and chilled then centrifuged and dried and packed.

Chemical Reaction

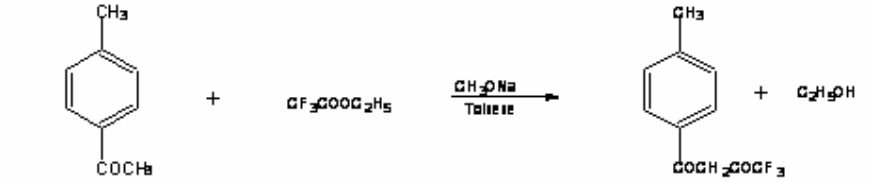
Stage-I: Preparation of Ethyl trifluoroacetate



Trifluoroacetic acid
Mol Wt.: 114. 02
Mol For.: $C_2HF_3O_2$
CAS No. 76-05-1

Ethyltrifluoro acetate
Mol. Wt. : 142 . 08
Mol For.: $C_4H_5F_3O_2$
CAS: 383- 63 - 1

Stage-II: Preparation of 1- (4-methylphenyl) 4, 4, 4-trifluro butane 1, 3-dione

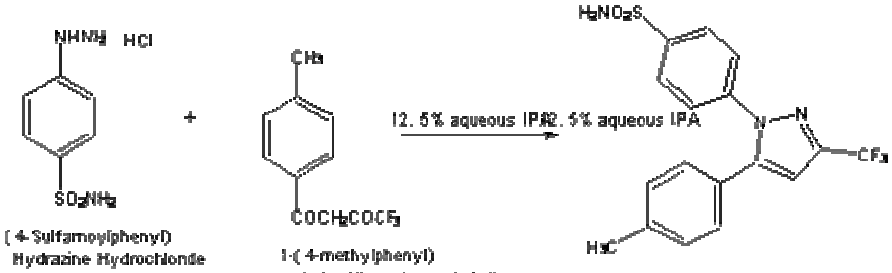


4-Methylacetophenone
Mol.wt: 134 . 18
Mol For.: $C_9H_{10}O$
CAS No.: 122-00-9

Ethyltrifluoroacetate
Mol. Wt. : 142 . 08
Mol For.: $C_4H_5F_3O_2$
CAS: 383 - 63 - 1

1-(4-methylphenyl)
4, 4, 4- trifluorobutane 1, 3-dione
Mol.wt: 230
Mol For.: $C_{11}H_9F_3O_2$
CAS No.: 720-94-5

Stage-III: Preparation of Celecoxib

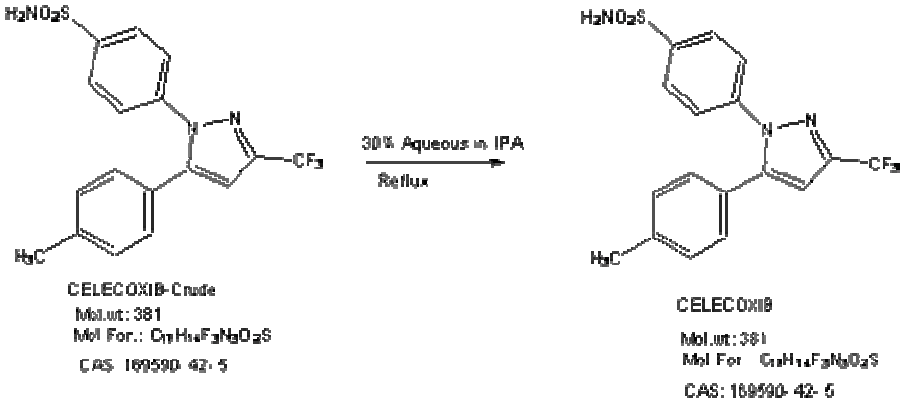


(4- Sulfamoylphenyl)
Hydrazine Hydrochloride
Mol. Wt. 223.5
Mol For.: $C_6H_{10}ClN_3O_2S$
CAS: 17852- 52- 7

1-(4-methylphenyl)
4, 4, 4- trifluoro butane1, 3-dione
Mol.wt: 230
Mol For : $C_{11}H_9F_3O_2$
CAS No.: 720-94-5 **CAS No.: 720-94-5**

CELECOXIB-Crude
Mol.wt: 38 Mol.wt: 381
Mol For $C_{17}H_{14}F_3N_3O_2S$
CAS: 169590- 42- **CAS: 16**

Stage-IV: Purification of Celecoxib



CELECOXIB-Crude
Mol.wt: 381
Mol For.: $C_{17}H_{14}F_3N_3O_2S$
CAS: 169590- 42- 5

CELECOXIB
Mol.wt: 381
Mol For: $C_{17}H_{14}F_3N_3O_2S$
CAS: 169590- 42- 5

Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Celecoxib-I 0.443 Kgs	Quantity Kgs	Output details
0.396	Trifluoro Acetic Acid		-	
0.237	Ethyl Alcohol		0.225	Ethyl Trifluoro Acetate Recovery
0.190	Sulphuric Acid		0.013	Ethyl Trifluoro Acetate Recovery Loss
			0.142	Aqueous Effluent
0.823	**Total**		**0.380**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Celecoxib-II 0.754 Kgs	Quantity Kgs	Output details
2.113	Toluene		-	
0.356	Sodium Methoxide		2.071	Toluene Recovery
0.325	Sulphuric Acid		0.042	Toluene Recovery Loss
0.019	Methanol			
0.562	Ethyl Trifluoro Acetate			
3.468	D M water			
0.012	Acetic Acid		4.431	Aqueous Effluent
0.443	4-Methylacetophenon			
7.298			**6.544**	**Total**

Stage – 3

Total input Kgs	Starting Material	Product output Celecoxib 1 Kgs	Quantity Kgs	Output details
0.754	1-(4-Methylphenyl)-4,4,4 Trifluorobutane 1,3-dione		-	
8.813	D M Water		8.033	Isopropyl Alcohol Recovery
8.447	Isopropyl Alcohol		0.414	Isopropyl Alcohol Recovery Loss
0.769	4-Sulphonamino Phenyl Hydrazine			
			9.336	Aqueous Effluent
18.783	**Total**		**17.783**	**Total**

3. IRBESARTAN

Manufacturing Process

A mixture of 1-(2-Cyanobiphenyl-4-yl)-methyl-2-n-butyl-4-spirocyclopentane-imidazoline-5-one, Sodium Azide, Triethyl Amine hydrochloride and Toluene were heated for formation of Tetrazole. Caustic solution was added to it and the product layers were separated and washed with Toluene and methyl-tert butyl ether. Hydrochloric acid was added to the product layer and pH was adjusted. The product was filtered and solid washed with water. The solid was dried to give the crude product. The crude product is crystallized from Ethyl Alcohol to give Irbesartan.

Chemical Reaction

Cyclopentanone

Methanol
D.M. Water
Sodium Cyanide
Ammonium Chloride
Ammonium Hydroxide
Dichloromethane

D.M. Water
Sodium Chloride
Methanol
Dichloromethane

1 - Aminocyclopentanenitrile

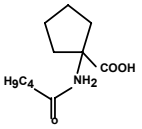
Hydrochloric Acid
D.m. Water

Ammonium Chloride
D.M. Water
Hydrochloric Acid

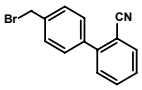
1 - Aminocyclopentanecarboxylic acid hydrochloride

Hydrochloric Acid
D.m. Water
Pyridine
Valeroyl Chloride

Valeric Acid
Pyridine Hydrochloride
D.M. Water
Hydrochloric Acid

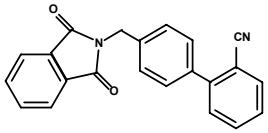


1 - Valeramidocyclopentanecarboxylic acid



Dimethylformamide
D.M. Water
Phthalimide
Potassium Carbonate

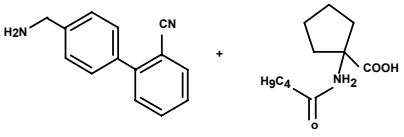
D.M. Water
Potassium Bromide
Carbon Dioxide
Dimethylformamide
Phthalimide



4' - (Phthalimidomethyl) - 2 - cyanobiphenyl

Hydrazine hydrate
D.M. Water
Sodium hydroxide

D.M. Water
Sodium hydroxide
Hydrazine hydrate
Sodium phthalate

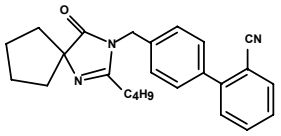


4' - (Aminomethyl) - 2 - cyanobiphenyl

1 - Valeramidocyclopentanecarboxylic acid

Methane Sulphonic Acid
D.M. Water
Toluene
Sodium Hydroxide

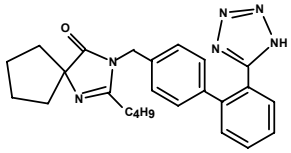
D.M. Water
Methane Sulphonic Acid Sodium Salt
Toluene
1 - Valeramidocyclopentanecarboxylic acid sodium salt



2 - (n-Butyl)-3-(2'-cyanobiphenyl-4-yimethyl)-4-oxo-1,3 diazaspiro [4,4] non-1-ene

Tributyl tin chloride
D.M. Water
Sodium azide
Sodium Hydroxide
Hydrochloric Acid
Water
Xylene
Ethanol
Methyl t. butyl ether

Water
Sodium Chloride
Potassium Bromide
Carbon Dioxide
Tributyl tin hydroxide
Xylene
Ethanol
Methyl t. butyl ether



Irbesartan

Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Irbesartan-I 1.250 Kgs	Quantity Kgs	Output details
4.648	Acetone		-	
0.263	Sodium Chloride		4.408	Acetone Recovery
0.658	Sodium Hydroxide		0.240	Acetone Recovery Loss
1.145	2-Butyl-1,3-Diaziaspiro[4,4]non-1-en-4-one Hydrochloride			
1.316	4-Bromomethyl 2-Cyno Biphenyl (4 BMCP)			
9.737	D M Water		0.138	Evaporation Loss
			11.731	Aqueous Effluent
17.767	**Total**		**16.517**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Irbesartan 1.000 Kgs	Quantity Kgs	Output details
17.290	D M Water		-	
0.699	Hydrochloric Acid		4.120	Toluene Recovery
1.250	Irbesartan-I		0.215	Toluene Recovery Loss
1.879	Methyl T-Butyl Ether		1.785	Methyl T-Butyl Ether Recovery
0.009	O-Xylene		0.094	Methyl T-Butyl Ether Recovery Loss
0.538	Sodium Azide			
0.200	Sodium Hydroxide		0.110	Evaporation Loss
0.175	Sodium Nitrate		20.801	Aqueous Effluent
4.335	Toluene			
1.750	Triethyl Amine Hydrochloride			
28.125	**Total**		**27.125**	**Total**

4. LOSARTAN POTASSIUM

Manufacturing Process

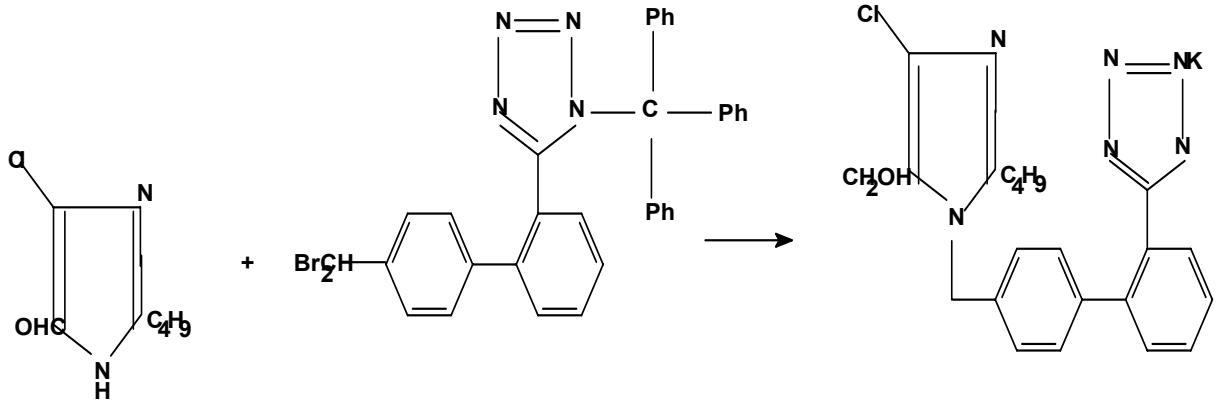
Stage-1

The raw materials N Methyl pyrolidine,Sodium azide, Triethyl amine hydrochloride and Cyno alcohol are reacted in Toluene as a solvent medium at a reflux temperature and then the completion is monitored on HPLC. After the reaction is completed the reaction mass is subjected to work up and precipitation. The precipitated intermediate is filtered in centrifuge and dried and analyzed.

Stage-2

The stage -1 is then subjected to salt formation by treating it with potassium hydroxide solution to attain alkaline pH. After the pH adjustment is over it is charcoalised filtered and precipitated by distilling off excess of Methanol and centrifuging the precipitated mass. The wet cake is further dried and packed. This is Losartan Potassium.

Chemical Reaction



Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Losartan Potassium 1.053 Kgs	Quantity Kgs	Output details
3.915	Acetone		-	
0.222	Sodium Chloride		3.713	Acetone Recovery
0.554	Sodium Hydroxide		0.202	Acetone Recovery Loss
0.964	2-Butyl-1,3-Diaziaspiro[4,4]non-1-en-4-one Hydrochloride			
1.108	4-Bromomethyl 2-Cyno Biphenyl (4 BMCP)			
8.202	D M Water		0.116	Evaporation Loss
			9.881	Aqueous Effluent
14.965	**Total**		**13.912**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Losartan Potassium 1.00 Kgs	Quantity Kgs	Output details
5.371	Acetone		-	
0.105	Activated Carbon		5.102	Acetone Recovery
0.012	Hyflow		0.269	Acetone Recovery Loss
1.053	Losartan Potassium-I		4.386	Methanol Recovery
4.597	Methanol		0.211	Methanol Recovery Loss
0.184	Potassium Hydroxide			
			0.123	Spent Carbon
			0.231	Aqueous Effluent
11.322	**Total**		**10.322**	**Total**

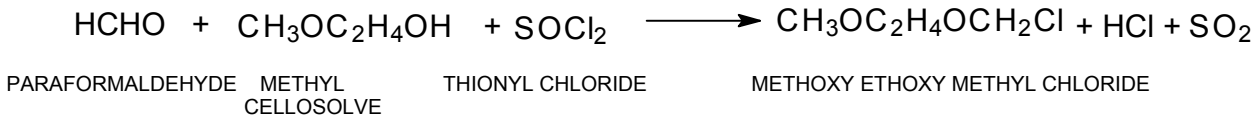
5. MEM CHLORIDE

Manufacturing Process

Hydrogen Chloride gas is generated and reacted with the reaction mixture of Paraformaldehyde/1,3,5 Trioxane and Methyl Cellulose to give Methoxyethoxymethyl Chloride.

Chemical Reaction

PRODUCT : METHOXY ETHOXY METHYL CHLORIDE (MEM Cl)



Material Balance

Total input Kgs.	Starting Material	Product output MEM Chloride 1.00 Kgs	Quantity Kgs.	Output details
0.333	Para Formaldehyde			
0.867	Methyl Cellosove		25.522	Aqueous Effluent
1.433	Thionyl Chloride			
22.222	D M Water			
1.667	Sodium Hydroxide Lye (50%)			
26.522	**Total**		**25.522**	**Total**

11. MOCLOBEMIDE

Manufacturing Process

Stage-I

Charging of DM water, followed by sodium carbonate, cooling of solution to 0-5°C 4-Chlorobenzoyl Chloride, 2-Chloroethylamin hydrochloride thereby by condensation reaction formation of Moclobemide stage-I . After formation of the material centrifugation, drying & packing of the material.

Stage-II

Charging of Stage-I followed by Morpholine thereby formation of Moclobemide stage-II by exothermic reaction. Further by workup material is being taken in Methylene chloride & after distillation of Methylene chloride material is isolated in Toluene. Finally filtration & drying of the material & packing.

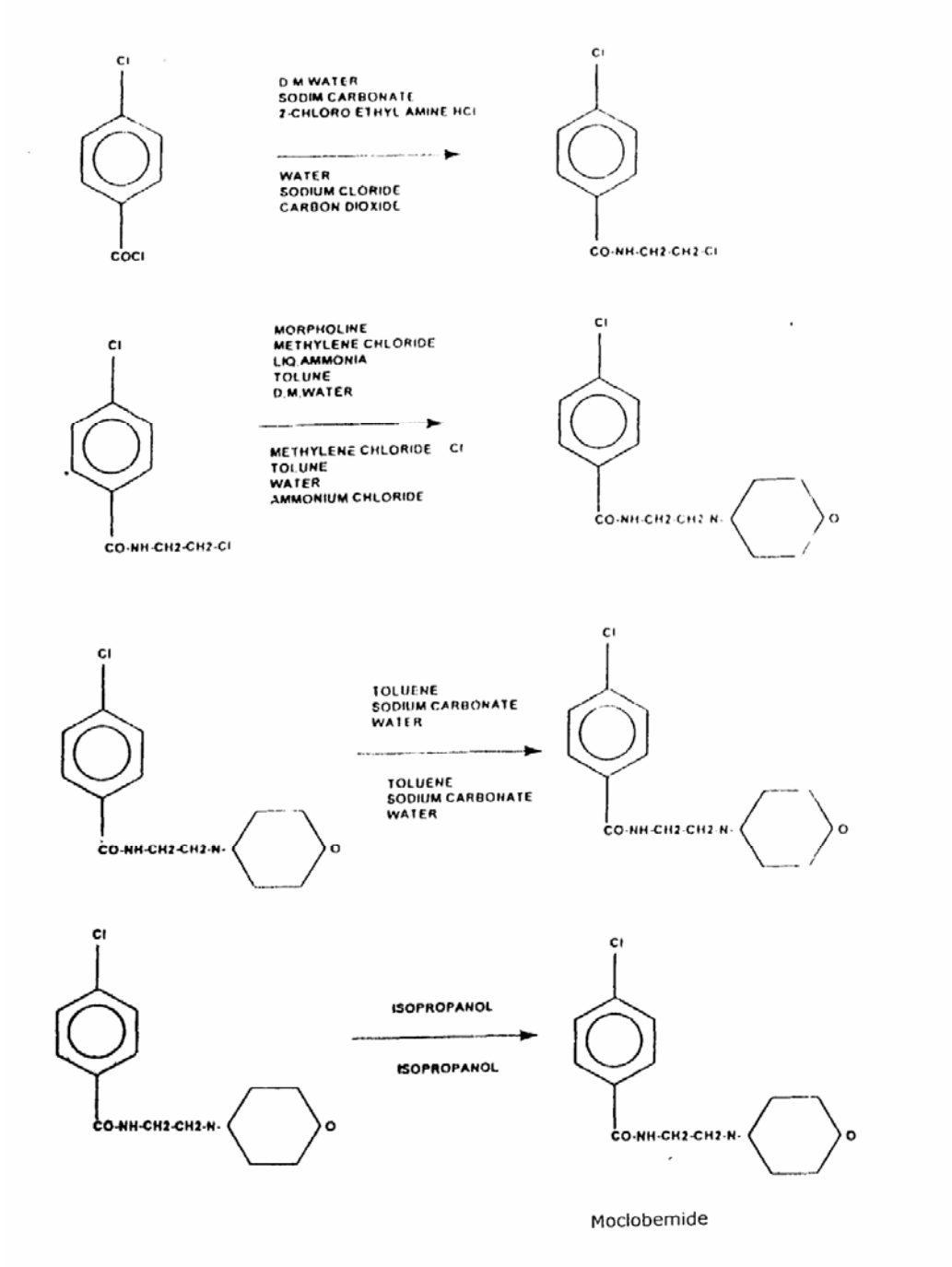
Stage-III

Charging of Toluene followed by Moclobemide stage-III. Dissolution of the material by heating then sodium carbonate solution addition & two water washing. Distillation of the Toluene & finally gradual cooling, centrifugation, drying & packing of the material.

Stage-IV

Charging of Isopropyl alcohol followed by stage-III, dissolution, Charcoalisation of the material. Distillation of the Isopropyl alcohol, gradual cooling centrifugation of the material. Finally material is dried in FBD followed by milling, sifting, blending again micronizarion, sifting & finally packing of the material.

Chemical Reaction



Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Moclobemide-I 0.981 Kgs	Quantity Kgs	Total output Kgs
1.115	4- Chloro Benzoyl Chloride			
1.613	2-Chloro Ethylamine Hydrochloride		4.459	Aqueous Effluent
0.820	Sodium Carbonate			
0.186	Sodium Hydroxide		0.211	Vapour Loss
1.917	D M Water			
5.651	**Total**		**4.670**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Moclobemide-II 1.128 Kgs	Quantity Kgs.	Total output Kgs
1.917	D M Water			
0.223	Sodium bicarbonate		5.322	Dichloromethane recovery
1.560	Morpholine		0.591	Dichloromethane recovery Loss
0.981	Moclobemide Stage-I		3.703	Toluene recovery & reuse
5.913	Dichloromethane		0.411	Toluene recovery Loss
2.888	D M Water			
4.115	Toluene		6.216	Aqueous Effluent
			0.226	Vapour Loss
17.597	**Total**		**16.469**	**Total**

Stage – 3

Total input Kgs	Starting Material	Product output Moclobemide-III 1.083 Kgs	Quantity Kgs	Total output Kgs
1.351	D M Water			
0.169	Sodium carbonate		8.782	Toluene recovery
9.758	Toluene		0.976	Toluene recovery Loss
1.128	Moclobemide Stage-II			
0.420	Toluene		1.816	Aqueous Effluent
			0.169	Vapour Loss
12.826	**Total**		**11.743**	**Total**

Stage – 4

Total input Kgs	Starting Material	Product output Moclobemide-IV 1.000 Kgs	Quantity Kgs	Total output Kgs
5.155	Isopropyl Alcohol			
1.083	Moclobemide Stage-III		5.462	Isopropyl Alcohol recovery
0.045	Activated Charcoal		0.790	Isopropyl Alcohol recovery Loss
0.033	Hyflow			
1.099	Isopropyl Alcohol		0.080	Spent Carbon
			0.083	Vapour Loss
7.415	**Total**		**6.415**	**Total**

7. OLMESARTAN

Manufacturing Process

Stage-1

3.0M Methyl Magnesium Chloride Solution is reaction in Dimethyl2-Propyl 1-H Imedazole-4, 5-Diccarboxylate with Dichloromethane in the solution sodium chloride and Acetic Acid in present of Methanol then layer separation, filtration, distillation and the precipitated mass. The wet cake is further dried and packed.

Stage-2

TTBB is treated with Ethyl 4-(1-Hydroxyl -1-Methylethyl)-2-Propylimidazole -5-Carboxylatein presence of potassium carbonate powder and DMF as a solvent.

Stage-3

Hydrolysis of stage-2 with sodium Hydroxide powder condensation with Medoxomil to get Trityl Olmesartan Medoxomil.

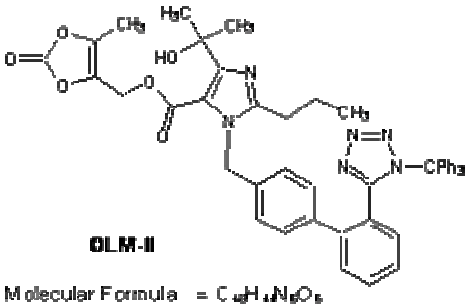
Stage-4

Detritylation of stage-3 using dichloromethane, methanol & hydrochloride acid gives Olmesartan Medoxomil (Technical).

Stage-5

Crystallization of Olmesartan Medoxomil (Technical) in acetone gives Olmesartan Medoxomil.

Chemical Reaction

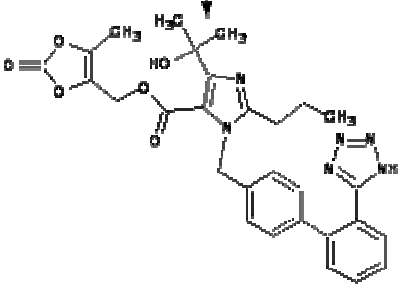


OLM-II

Molecular Formula = $C_{41}H_{44}N_6O_6$
Molecular weight: 800.89

\+ Aqueous HCl
Molecular Formula = HCl
Molecular weight: 36.5

MDC / Methanol / Ethyl acetate



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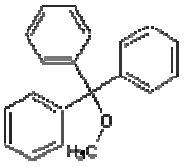
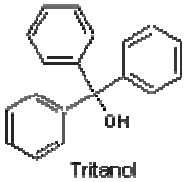


Triphenyl methyl ether
Molecular Formula = $C_{25}H_{18}O$
Molecular weight: 274.35

\+

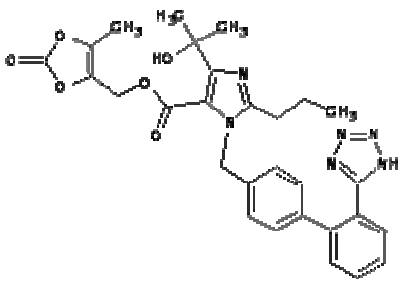


Tritanol
Molecular Formula = $C_{19}H_{16}O$
Molecular weight: 260.32

Olmesartan medoxomil stage-III (Technical)

Molecular Formula = $C_{29}H_{30}N_6O_6$
Molecular weight: 558.58

Acetone



OLMESARTAN MEDOXOMIL

Molecular Formula = $C_{29}H_{30}N_6O_6$
Molecular weight: 558.58

Material Balance

Stage – 1

Total input Kgs.	Starting Material	Product output Olmesartan	Quantity Kgs.	Output details
2.401	3.0M Methyl Magnésium Chloride Solution	**1.841Kgs**		-
0.420	Acetic Acid		8.004	Dichloromethane Recovery
0.010	Activated Carbon		0.448	Dichloromethane Recovery Loss
30.817	D M Water		1.481	DIPE Recovery
8.453	Dichloromethane		0.090	DIPE Recovery Loss
41.262	Dimethyl2-Propyl 1-H Imedazole-4, 5-Diccarboxylate			
1.571	DIPE		1.001	Spent Carbon
0.800	Hyflow		79.637	Aqueous Effluent
6.407	Methanol			
0.360	Sodium Chloride			
92.502	**Total**		**90.661**	**Total**

Stage – 2

Total input Kgs.	Starting Material	Product output Olmesartan-I	Quantity Kgs.	Output details
26.171	Di Methyl Formamide		25.093	Di Methyl Formamide Recovery
3.701	Anhydrous Potassium Carbonate		1.078	Di Methyl Formamide Recovery Loss
4.271	5-[4'-(Bromomethyl)[1,1'-biphenyl]-2-yl]-2-(triphenylmethyl)-2H-tetrazole(TTBB) (Lot-I)	**1.922Kgs**	42.845	Dichloromethane Recovery
29.898	D M Water		2.258	Dichloromethane Recovery Loss
45.103	Dichloromethane		15.750	Ethyl Acetate Recovery
1.841	Ethyl 4-(1-Hydroxyl -1-Methylethyl)-2-Propylimidazole -5-Carboxylate		0.779	Ethyl Acetate Recovery Loss
16.529	Ethyl Acetate		37.789	Aqueous Effluent
127.514	**Total**		**125.592**	**Total**

Stage – 3

Total input Kgs.	Starting Material	Product output Olmesartan-II	Quantity Kgs.	Output details
0.096	Activated Carbon			-
0.384	Anhydrous Potassium Carbonate	**1.826Kgs**	28.832	Ethyl Acetate Recovery
28.832	D M Water		1.999	Ethyl Acetate Recovery Loss
30.831	Ethyl Acetate		9.611	N N Dimethyl Formamide Recovery
3.844	Hyflow		0.550	N N Dimethyl Formamide Recovery Loss
0.596	Medoxomil			
10.161	N N-Dimethyl Formamide		4.805	Spent Carbon
1.922	Olmesartan-I Stage		30.645	Aqueous Effluent
1.442	Sodium Chloride			-
0.160	Sodium Hydroxide			-
78.267	**Total**		**76.441**	**Total**

Stage – 4

Total input Kgs.	Starting Material	Product output Olmesartan-III	Quantity Kgs.	Output details
30.127	D M Water			
24.101	Dichloromethane		22.823	Dichloromethane Recovery
12.562	Ethyl Acetate	**1.059Kgs**	1.278	Dichloromethane Recovery Loss
0.922	Hydrochloric Acid		11.868	Dimethyl-Formamide Recovery
7.303	Methanol		0.694	Dimethyl-Formamide Recovery Loss
1.826	Olmesartan-II Stage		6.847	Methanol Recovery
0.913	Sodium Carbonate		0.456	Methanol Recovery Loss
			32.728	Aqueous Effluent
77.754	**Total**		**76.695**	**Total**

Stage – 5

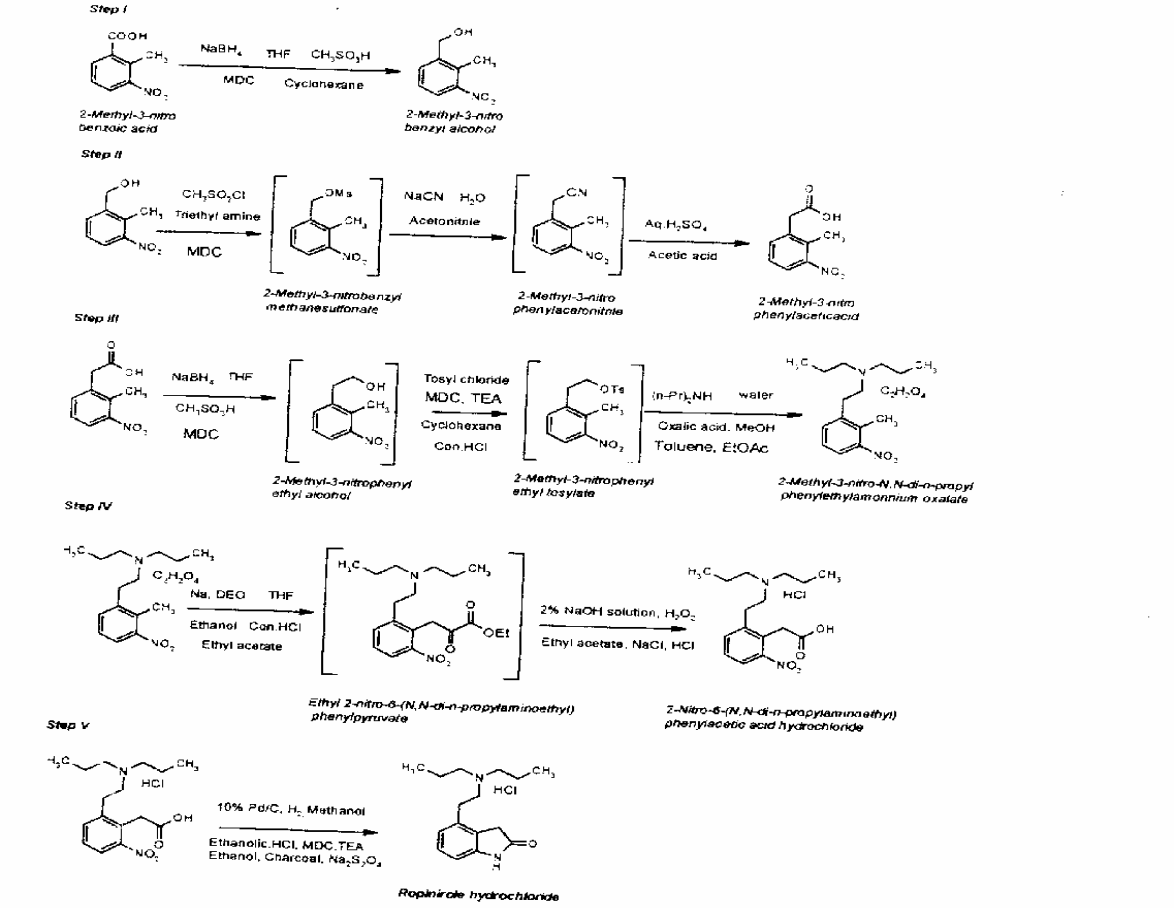
Total input Kgs	Starting Material	Product output Olmesartan	Quantity Kgs	Output details
13.299	Acetone	**1.00 Kgs**	11.000	Acetone Recovery
1.059	Olmesartan-III Stage		0.308	Acetone Recovery Loss
0.026	Activated Carbon			
0.024	Hyflow		1.267	Spent Carbon
			0.833	Aqueous Effluent
14.408	**Total**		**13.408**	**Total**

8. ROPINOROLE

Manufacturing Process

Key starting material 2-Methyl -3-Nitro phenyl acetic acid reacts with Methane sulphonic Acid in presence of Sodium Borohydride and Hydrochloric Acid its separate by Sodium Bicarbonate & Chloride then again reacts with p-Toluene Sulfonyl chloride of Hydrochloric Acid and again separate by Sodium Chloride and finally reacts with Oxalic Acid Dihydrate in presence of Ethyl Acetate to give the product.

Chemical Reaction



Material Balance

Total input Kgs.	Starting Material	Product output Ropinorole-III 1.000 Kgs	Quantity Kgs.	Total output Kgs.
3.147	Tetrahydrofuran			Solvent Recovery
0.445	Sodium Borohydride		20.869	Dichloromethane recovery
0.909	2-Methyl -3-Nitro phenyl acetic acid		2.319	Dichloromethane recovery Loss
0.444	Methane sulphonic Acid		0.534	Methanol recovery
0.873	Hydrochloric acid		0.059	Methanol recovery Loss
2.091	DM Water		1.062	Toluene recovery
1.091	DM Water		0.118	Toluene recovery Loss
0.227	Sodium bicarbonate		2.868	Cyclohexane recovery
0.091	Sodium Chloride		0.319	Cyclohexane recovery Loss
4.745	Triethyl amine		14.2065	Ethyl Acetate recovery
1.245	p-Toluene Sulfonyl chloride		1.579	Ethyl Acetate recovery Loss
23.188	Dichloromethane			
4.964	Hydrochloric acid		25.846	Aqueous Effluent
0.818	DM Water		0.193	Vapour Loss
0.091	Sodium Chloride			
0.180	Methanol			
0.827	Methanol			
3.187	Cyclohexane			
0.136	DM Water			
2.409	DM Water			
1.312	Di-n-propyl-amine			
1.180	Toluene			
14.555	Ethyl Acetate			
0.473	Oxalic Acid Dihydrate			
1.115	Methanol			
1.230	Ethyl Acetate			
70.973	**Total**		**69.973**	**Total**

9. VALSARTAN

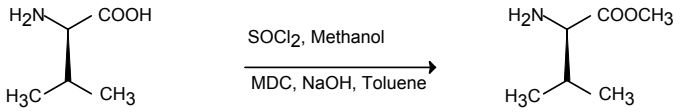
Manufacturing Process

Biphenyl Valine is reacted with Valeroyl Chloride in presence of potassium carbonate in O-Xylene and Acetone to form Valeroyl Valsartan which is reacted with sodium azide and tri-n-butyl tin chloride to form Tetrazole Valeroyl Valsartan which is reacted with sodium hydroxide in presence of TBAB to form Valsartan. The Valsartan so formed is precipitated from MDC by distilling off excess of MDC and then centrifuging the precipitated slurry. The wet cake so obtained is further purified in Methylene dichloride by further reflux and maintaining. This mass is further centrifuged and washed. The wet cake is dried and after the necessary in process checks it is packed.

Chemical Reaction

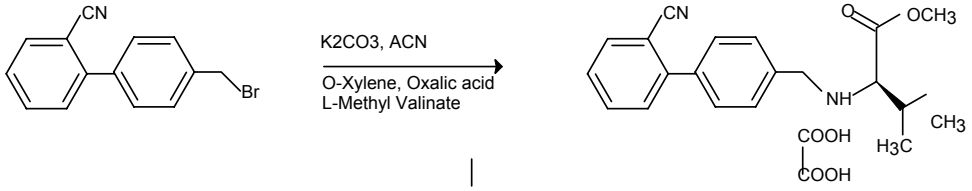
VALSARTAN

STEP-1



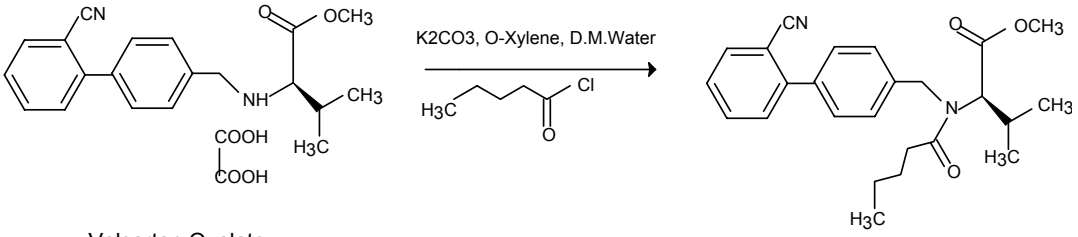
L-VALINE L-VALINE VALINATE

STEP-2



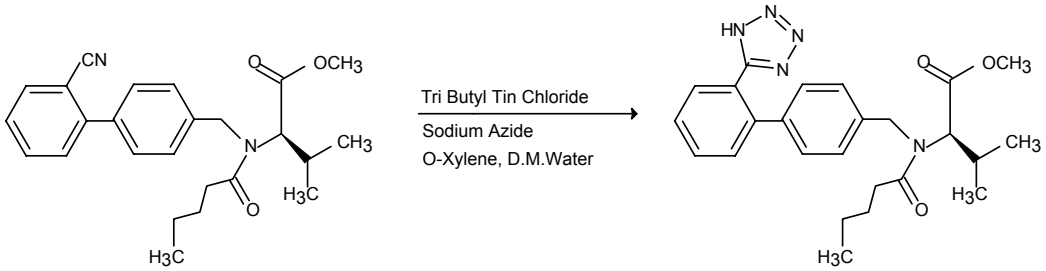
4-Bromomethyl -2'-Cycnobiphenyl Valsartan Oxalate

STEP-3A



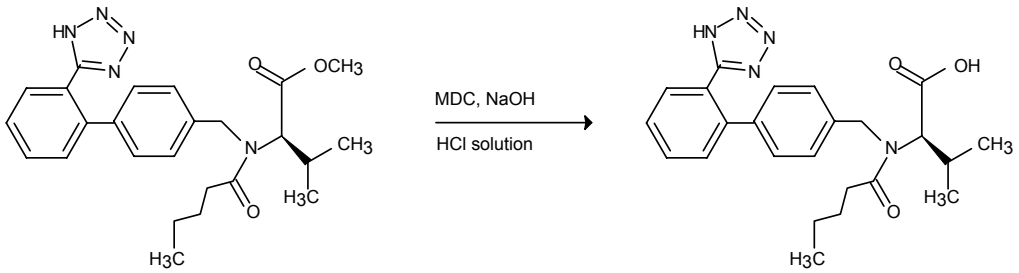
Valsartan Oxalate ValeroyValsartan

STEP-3B



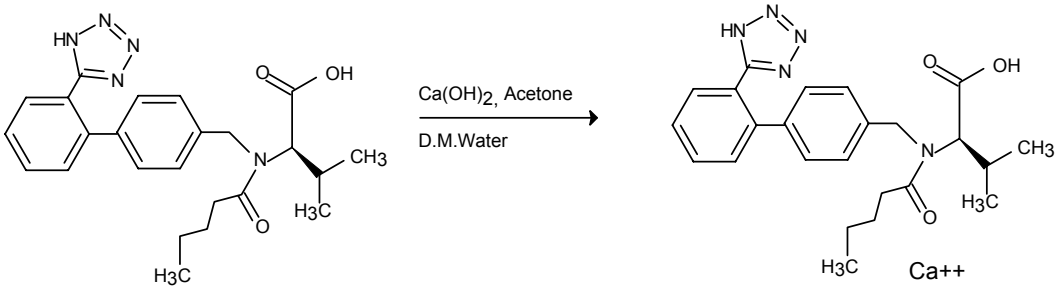
ValeroyValsartan Metyl Valsartan

STEP-3C



Metyl Valsartan Crude Valsartan

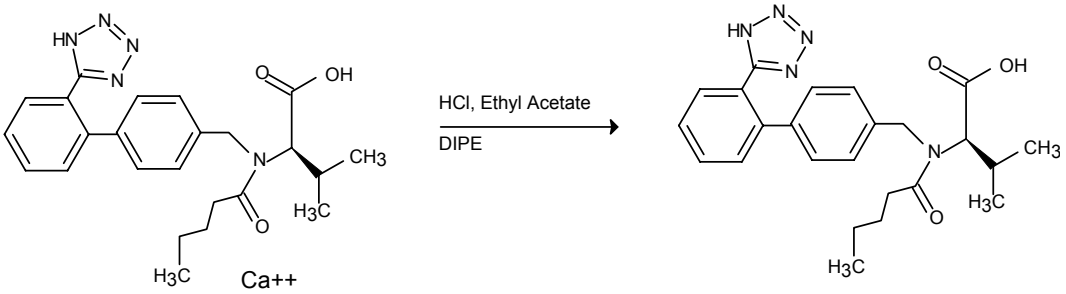
STEP-4



Crude Valsartan

Calcium Valsartan

STEP-5



Calcium Valsartan

Valsartan

Material Balance

Total input Kgs	Starting Material	Product output Valsartan 1.000 Kgs	Quantity Kgs	Output details
0.001	Acetone			
0.063	Hyflow		35.714	Dichloromethane Recovery
0.071	Tetra butyl Ammonium Bromide		1.866	Dichloromethane Recovery Loss
0.107	Activated Carbon		6.071	O-Xylene Recovery
60.256	D M Water		0.331	O-Xylene Recovery Loss
0.200	Sodium Bicarbonate		2.679	Tri-n-butyl tin Chloride Recovery
0.429	Sodium Chloride		0.143	Tri-n-butyl tin Chloride Recovery Loss
0.627	Valeroyl Chloride			
0.676	Sodium Azide			
0.829	Sodium Hydroxide		0.214	Spent Carbon
1.220	Hydrochloric Acid		0.161	Evaporation Loss
1.429	Biphenyl Valine		66.205	Aqueous Effluent
1.671	Potassium Carbonate			
2.821	Tri-n-butyl tin Chloride			
6.403	O-Xylene			
37.581	Dichloromethane			
114.384	**Total**		**113.384**	**Total**

10. BUPROPION HYDROCHLORIDE

Manufacturing Process

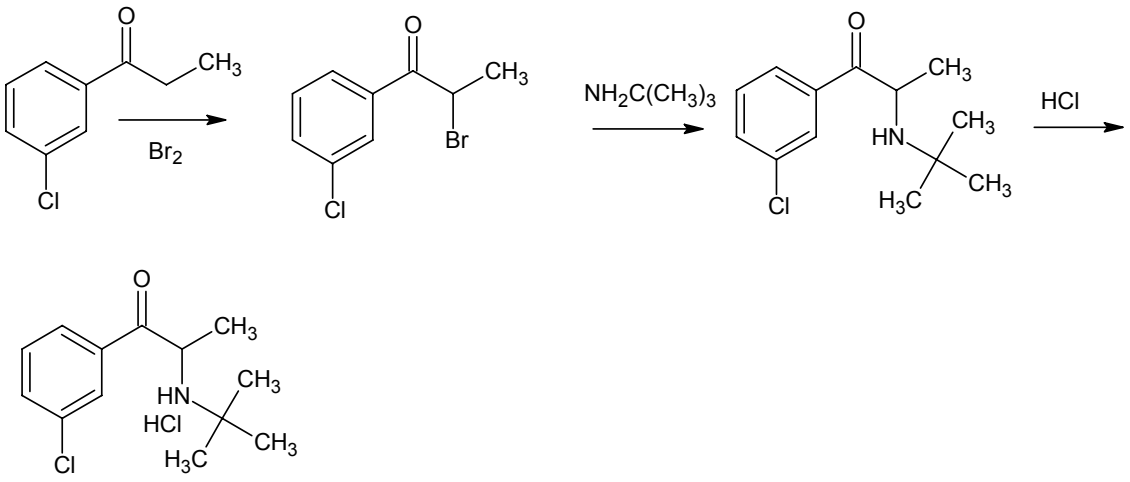
Stage-1

3'Chloropropiophenone and Bromine are reacted in water as a solvent media and progress of the reaction is monitored on HPLC. After the completion of the reaction the mass is treated with sodium thiosulphate solution and then subjected to work up. The organic layer containing product is then again reacted with tertiary butyl amine and again the reaction is monitored on HPLC. After the completion of reaction excess of the tertiary butyl amine is distilled off and the residual mass is then washed with water, precipitated with IPA HCL and centrifuged. This is stage-1 which is further used after analysis.

Stage-2

Bupropion Hydrochloride Stage-I is dissolved in methanol, purified by means of Charcoalisation followed by filtration & finally crystallized in Iso propanol to yield pure Bupropion Hydrochloride

Chemical Reaction



Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Bupropion Hydrochloride-I 1.054 Kgs	Quantity Kgs	Output details
0.703	3" Chloropropiophenone			-
0.735	Bromine		8.688	Toluene Recovery
22.134	D M Water		0.451	Toluene Recovery Loss
1.013	Iso Propyl Alcohol HCL		1.469	T-Butyl Amine Recovery
0.703	Sodium Chloride		0.057	T-Butyl Amine Recovery Loss
0.054	Sodium Thiosulphate		0.958	Iso Propyl Alcohol Recovery
1.527	T-Butyl Amine		0.055	Iso Propyl Alcohol Recovery Loss
9.138	Toluene			
			0.109	Evaporation Loss
			23.166	Aqueous Effluent
36.007	**Total**		**34.953**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Bupropion Hydrochloride 1.00 Kgs	Quantity Kgs	Output details
3.336	Methanol			-
1.054	Bupropion Hydrochloride-I		3.163	Methanol Recovery
0.051	Activated Carbon		0.173	Methanol Recovery Loss
0.014	Hyflow		5.857	Iso Propyl Alcohol Recovery
6.171	Iso Propyl Alcohol		0.314	Iso Propyl Alcohol Recovery Loss
			0.095	Evaporation Loss
			0.024	Aqueous Effluent
10.626	**Total**		**9.626**	**Total**

11. ETORICOXIB

Manufacturing Process

Stage-1

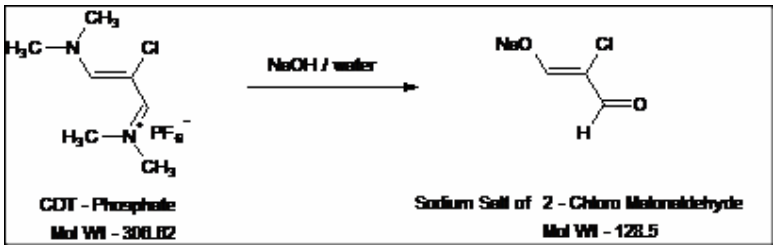
Ketosulfone is reacted with CPT-Phosphate in presence of Potassium tert-Butoxide in Tetra hydrofurane to give Etoricoxib crude.

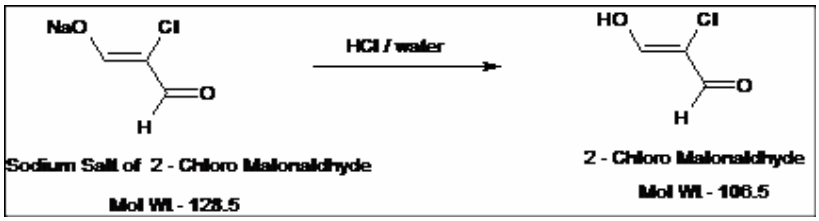
Stage-2

1- Etoricoxib crude recrystallized from IPA-Hexane to give Etoricoxib

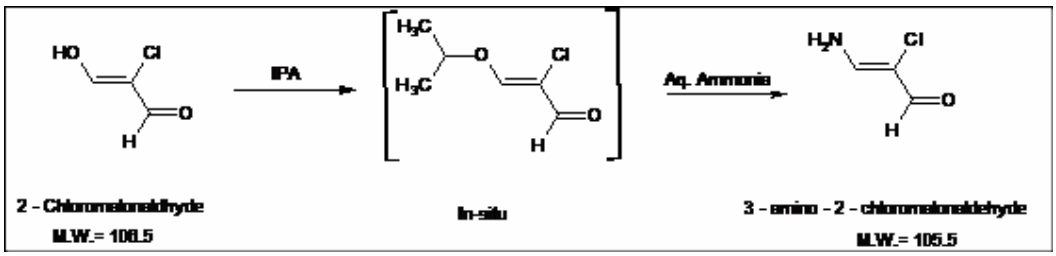
Chemical Reaction

Stage-I: Preparation 2-chloro malonaldehyde from sodium salt of 2-chloromalonaldehyde

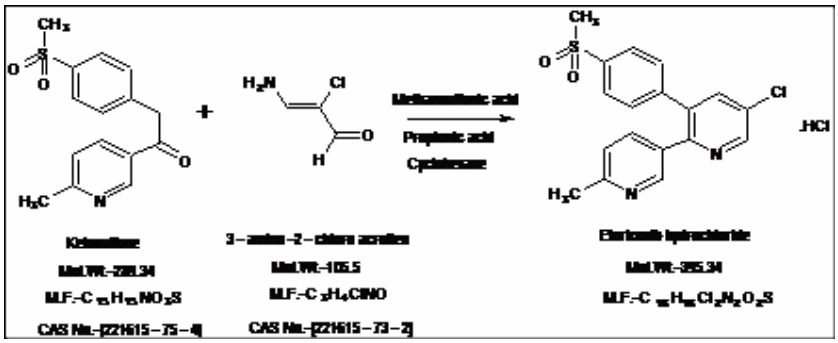




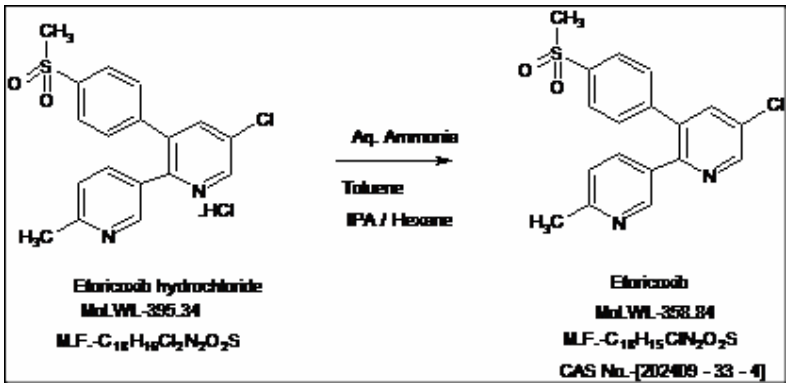
<u>Stage-II:</u> Preparation 3-amino-2- chloroacrolien from 2-chloro-malonaldehyde.



<u>Stage-III</u>: Preparation of Etoricoxib hydrochloride



<u>Stage-IV</u>: Preparation of Etoricoxib (API)



Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output Etoricoxib-I 1.107 Kgs	Quantity Kgs	Output details
2.283	Acetic Acid			-
2.781	Acetone		2.657	Acetone Recovery
10.871	Ammonia Solution		0.124	Acetone Recovery Loss
2.520	CPT-Phosphate		9.299	Isopropyl Alcohol Recovery
45.343	D M Water		0.469	Isopropyl Alcohol Recovery Loss
0.115	Hydroxylamine Hydrochloride		9.255	Methanol Recovery
0.177	Hyflow		0.452	Methanol Recovery Loss
9.768	Isopropyl Alcohol		50.546	Toluene Recovery
1.574	Ketosulfone		2.664	Toluene Recovery Loss
9.706	Methanol			-
0.664	Potassium Tertrabutoxide (KTB)			-
0.297	Sodium Acetate		88.627	Aqueous Effluent
3.153	Sodium Hydroxide			
53.210	Toluene			
22.273	Tri Hydrofuron			
0.465	Trifluro Acetic Acid			
165.200	**Total**		**164.093**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output Etoricoxib 1.00 Kgs	Quantity Kgs	Output details
0.022	Activated Carbon			-
1.107	Etoricoxib-I		14.474	Isopropyl Alcohol Recovery
0.260	Hexane		0.813	Isopropyl Alcohol Recovery Loss
0.053	Hyflow			
15.287	Isopropyl Alcohol		0.093	Spent Carbon
			0.349	Aqueous Effluent
16.729	**Total**		**15.729**	**Total**

12. O DES VENLAFEXINE

Manufacturing Process

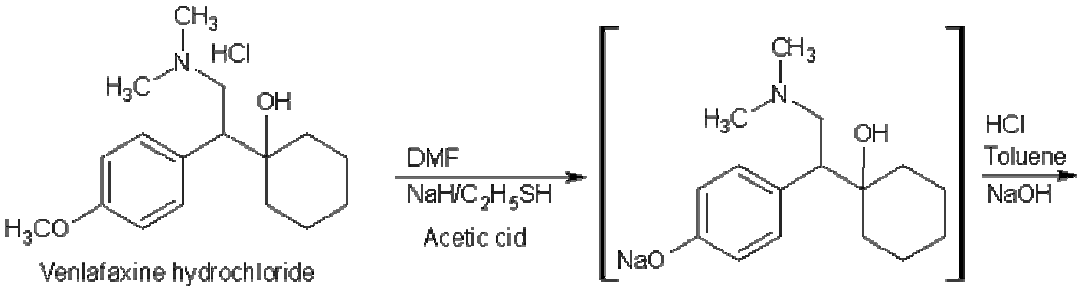
Stage-1

Venlafaxine hydrochloride is reaction in mixture of DMF with sodium hydroxide and MTL with Acetic Acid then separation, filtration and the precipitated mass. The wet cake is further dried and packed.

Stage-2

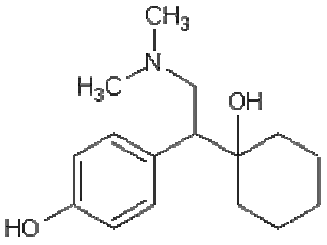
O Desmethyl Venlafaxine is dissolved in methanol and stirred to reflux and filter through hyflow. The methanol is distilled at atmospheric pressure. The reaction mixture is chilled, crystallized and filtered. The wet cake obtained is dried.

Chemical Reaction



Venlafaxine hydrochloride
Mol.For.:$C_{17}H_{28}ClNO_2$
Mol.Wt:313.86

Sodium salt of o desmethyl venlafaxine
In-situ intermediate
Mol.For.:$C_{16}H_{24}NNaO_2$



O DesmethylVenlafaxine
Mol.For.:$C_{15}H_{25}NO_2$
Mol.Wt: 263.37

Material Balance

Stage – 1

Total input Kgs	Starting Material	Product output	Quantity Kgs	Output details
1.018	Acetic Acid	O Des Venlafaxine-I 1.087Kgs	-	
0.069	Activated Carbon		1.984	Methanol Recovery
39.287	D M Water		0.086	Methanol Recovery Loss
5.713	Dimethyl Formamide		4.383	Toluene Recovery
1.051	Ethyl Alcohol		0.225	Toluene Recovery Loss
0.035	Hyflow		-	
2.070	Methanol		48.102	Aqueous Effluent
0.690	Sodium Hydroxide			
4.607	Toluene			
1.327	Venlafaxine Hydrochloride			
55.867	**Total**		**54.780**	**Total**

Stage – 2

Total input Kgs	Starting Material	Product output	Quantity Kgs	Output details
32.452	Methanol	O Des Venlafaxine 1.00 Kgs	-	
1.087	O-Desmethyl Venlafaxine		30.870	Methanol Recovery
0.072	Activated Carbon		1.666	Methanol Recovery Loss
0.043	Hyflow			
			0.120	Spent Carbon
33.654	**Total**		**32.656**	**Total**

ANNEXURE – IV

WATER CONSUMPTION & WASTEWATER GENERATION (EXISTING)

Sr. No.	Usages	Water Consumption (m^3/day)	Wastewater Generation (m^3/day)
1	Domestic	6	6
2	**Industrial**		
	Process	21	19
	Cooling	20 (Recycled)	0.2
	Boiler	10 (Fresh) + 8.3 (Recycled)	0.3
	DM Water	5.5	5
	Total (Industrial)	**36.5 (Fresh) + 28.3 (Recycled)**	**24.5**
	Grand Total	**70.8** **42.5 (Fresh) + 28.3 (Recycled)**	**30.5**

Note:

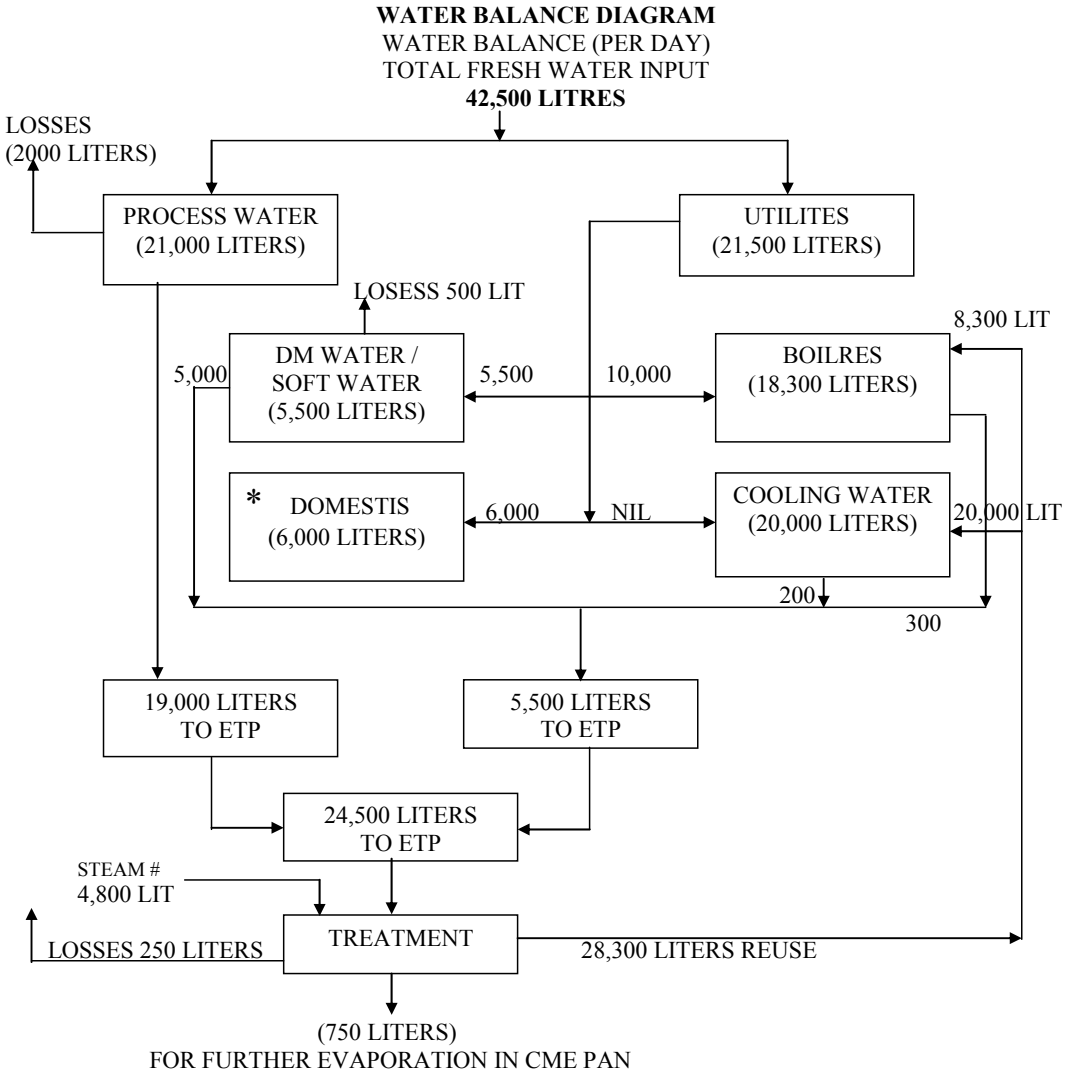
1. Domestic Wastewater is disposed off by Septic Tank and Soak Pit.
2. 4.8 m^3/day is Steam Purge of MEE which is added to 24.5 m^3/day of Wastewater to ETP so ultimately it becomes **24.5 + 4.8 = 29.3 m^3/day**, out of which 28.3 m^3/day is recycled back, 0.25 m^3/day is loss and 0.75 m^3/day is sent for further evaporation.

WATER CONSUMPTION & WASTEWATER GENERATION
(AFTER PROPOSED EXPANSION)

Sr. No.	Usages	Water Consumption (m^3/day)	Wastewater Generation (m^3/day)
1	Domestic	20	15
2	Gardening	15 (Recycled*)	-
3	**Industrial**		
	Process	20	20
	Cooling	41 [Recycled (18*+23#)]	10
	Utility	10	10
	Total (Industrial)	**71** **30 (Fresh) + 41 (Recycled)**	**40 + 5@ = 45**
	Grand Total	**106** **50 (Fresh) + 56 (Recycled)**	**55 + 5@ = 60**

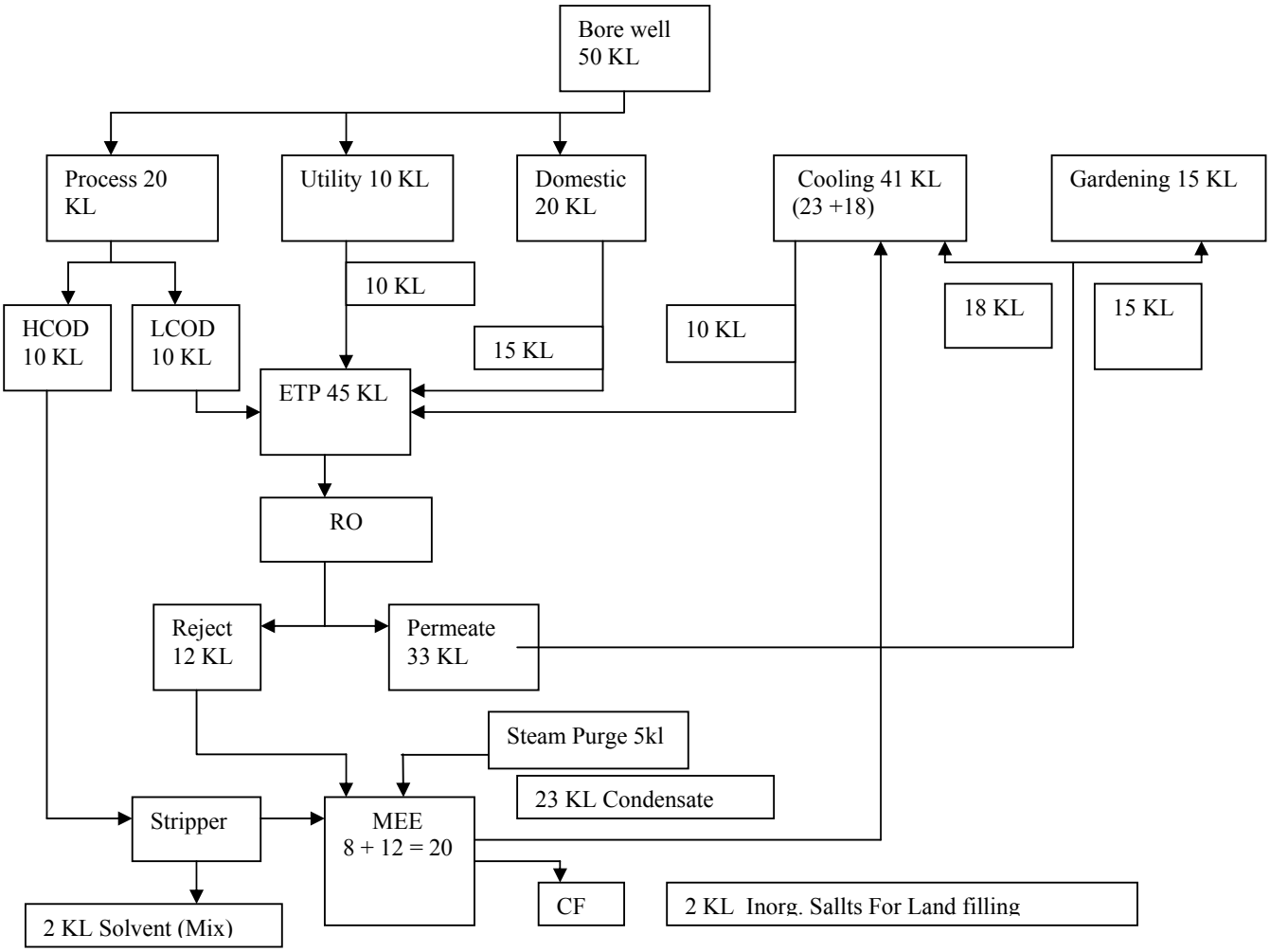
* RO Permeate
# MEE Condensate
@ MEE steam purge

WATER BALANCE DIAGRAM (EXISTING)



* DOMESTIC WASTEWATER IS DISPOSED OFF BY SEPTICTANK AND SOAK PIT.
# STEAM PURGING MEE.

WATER BALANCE DIAGRAM (AFTER PROPOSED EXPANSION)



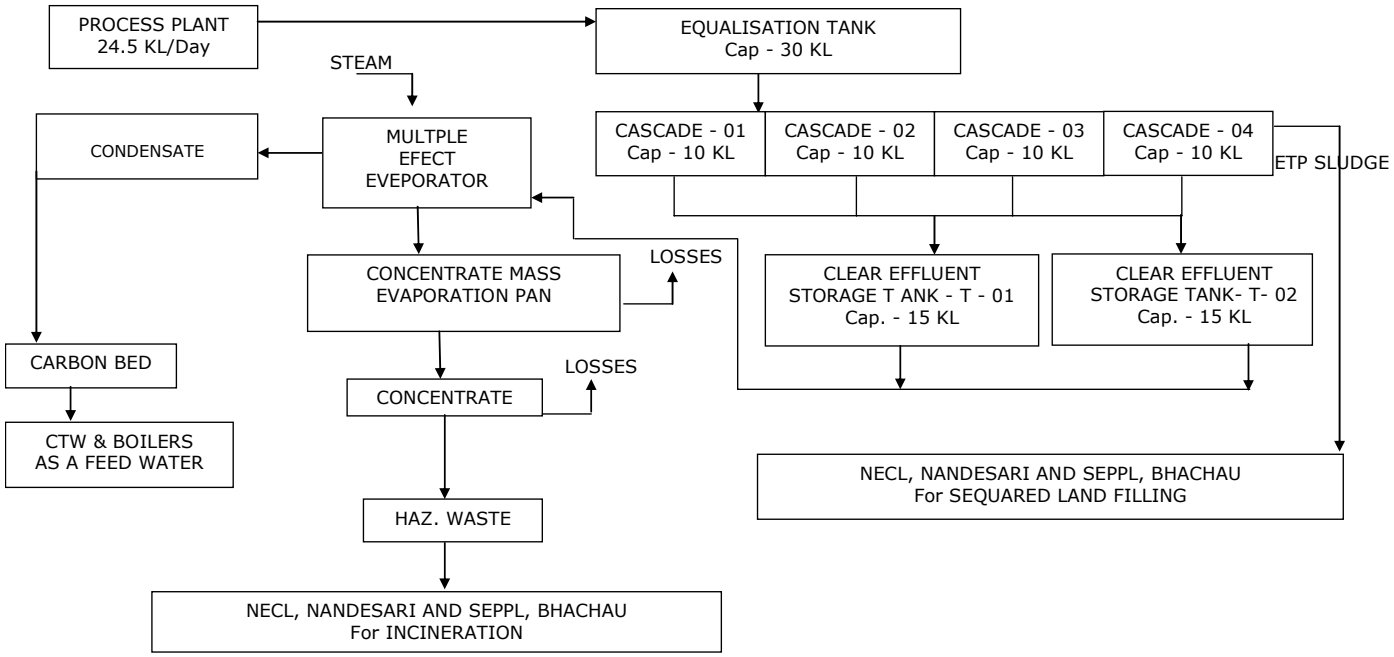
ANNEXURE – IV

WASTEWATER TREATMENT (EXISTING)

Brief Process:

1) Receive effluent from process plant, and it is collected in to the equalization pit.
2) Check & adjust pH of the pit by help of caustic lye in case of acidic effluent or with hydrochloric acid in case of basic effluent.
3) Transfer neutralized effluent in to cascade chamber.(CD-01 to CD-04, 10Kl per each.)
4) Keep effluent for settling, which results in settling down of heavy particles in to the cascade.
5) Transfer above super-natent clear effluent, in to the clear effluent storage tank, through transferring pump.
6) From clear effluent storage tank, feed the effluent to the multiple effect evaporation units.
7) In multiple effect evaporation units, effluent would be vaporized with help of steam and vacuum.
8) Condensate out water vapor generated from effluent, into the surface condenser of the multiple effect evaporation unit.
9) Collect separately the condensate water & transfer through carbon bed it for reusing as a boiler feed water as well as cooling tower.
10) Collect separately concentrate generated from the multiple effect evaporation unit, & transfer it for the further evaporation of water from concentrate into the multiple effect evaporation unit.
11) Once the concentrated liquids get some what viscous, and then collect it separately into the concentrated liquid storage tank, followed by transferring it into the Concentrate Mass Evaporation Pan (CME-Pan).
12) After evaporation of maximum water from concentrate with the help of CME Pan, collect the dry residual salt and store it separately in the solid waste store room and then send to NECL, Nandesari or SEPPL, Bhachau for incineration.

PROCESS FLOW CHART OF EFFLUENT TREATMENT PLANT



WASTEWATER TREATMENT (AFTER PROPOSED EXPANSION)

Brief Process:

All the Raw effluent coming from different plants and Utility-low COD are collected in 4 separate storage tank. These effluents are transferred into Oil & Grease separation tank where all Oily and floating material is removed. Then, it passes to 2 equalization tanks which are operated alternatively i.e. normally while one is under receiving; the other is put for further treatment of effluent. The treated effluent from this tank is pumped to an elevated Polyelectrolyte dosing tank. In the polyelectrolyte dosing tank polyelectrolyte, PAC or Alum dosing is carried out in tank. This effluent goes to the primary clarifier through the flash mixer, where the sludge formation is effected by flocculation & settling is formed, this sludge is transferred to sludge drying beds / Filter press and Clear Liquid goes the Aeration tank-1.

In Aeration tank-1 diffused aeration system is installed, which contains stabilized biomass. The diffused aeration system gives effective biological degradation and overflow from here goes to secondary clarifier-1 by gravity. The activated bio-sludge is re-circulated back to aeration tank-1 and excess dead / waste biomass is drained to sludge drying beds or decanter. Overflow of Secondary clarifier-1 goes to Aeration tank-2, here diffused aeration system is also installed in Aeration tank-2. Treated effluent from Aeration Tank-2 goes to secondary clarifier-2. The activated bio-sludge is re-circulation back to aeration tank-2 and excess dead / waste biomass is drained to sludge drying beds. Overflow of the clear effluent from secondary clarifiers goes to filter feed tank. Treated effluent from filter feed tank is pumped to the PSF & ACF for the tertiary treatment polishing unit and treated effluent collected in to final collection tank.

Final treated effluent is pumped to R.O. feed tank for further treatment in Reverse Osmosis System (RO System). The reject water of R.O. system goes to the Multi Effect Evaporator Plant. While permeate water is collected in storage tank and pumped to polishing RO system. The rejected is recycled back to first RO system and permeate is store for reuse.

The high COD effluent as per the effluent segregation scheme is collected in storage tank and transferred to neutralization tank. After neutralization high COD effluent treated through Solvent stripper in Multi Effect Evaporator plant and recovered solvent collected in solvent collection tank. Stripper residue is transferred to MEE plant. Concentrated mass of MEE is passed through centrifuge. Filtrate of centrifuge is re-circulated back in MEE and solid salt is kept in solid waste storage area, which is incinerated in common incinerator and Ash is send to approved GPCB disposal site. Condensate of MEE is reused in cooling tower.

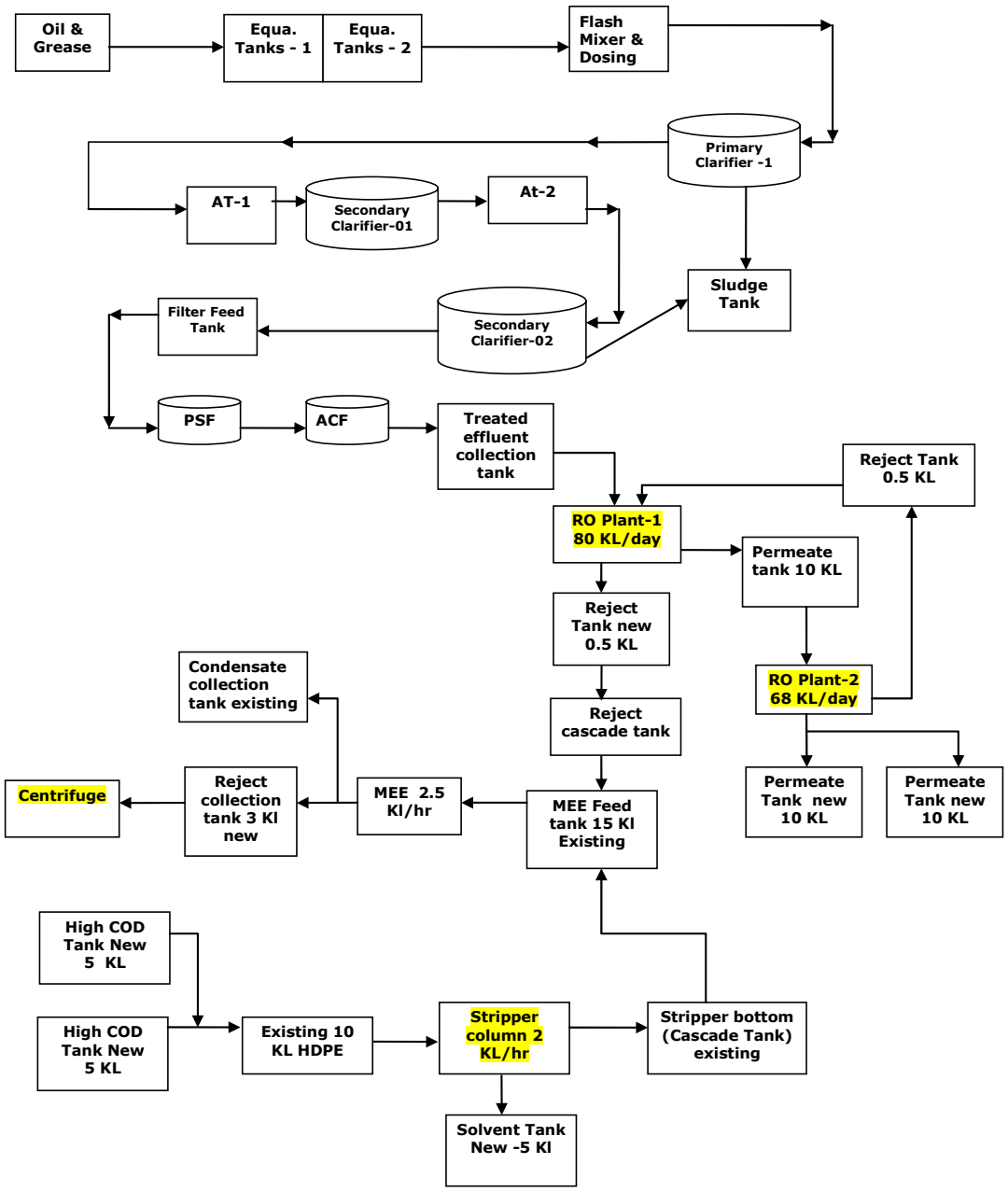
Standard Operating Procedure for Stripper operation as follows:

- The cooling tower Supply to the Main Condenser shall be on and required pressure shall be available.
- The Steam supply pressure shall be around kg/cm2g.

- Condensate shall completely drain the external forced circulation re-boiler.
- All drain and sample valves shall be closed.
- Fill the bottom portion column with the effluent to around 45% of the total range of the level in the level gauge. Ensure that the level in the column is below the re-circulation line of the external re-boiler of the column.
- Start the Re-circulation pump of the external forced circulation re-boiler.
- Slowly start the steam supply to external re-boiler and start heating the content. Observed the bottom temperature of the of the column, it will gradually rise from ambient temperature to around 105 ^{0}C, and then it will be become almost constant.
- Observed the top vapor temperature this will reach to around 80-95^{0}C on reaching temperature the condensation will start in the main condenser.
- Keep the column under the total reflux. The top vapour temperature will gradually drop to 70-75^{0}C.
- Keep the column under the total reflux till column stabilizes. At the steady state the top vapour temperature shall be around 70-75^{0}C while bottom temperature shall be around 102-105^{0}C. Top of the column shall be mixture of solvents with water while bottom of the column shall be effluent with around 1000ppm solvents.
- Start the continuous feed to the column at the step of 200 kg/hr till the desired rate.
- The reflux ratio shall be 1:5:1
- Adjust the reflux to maintain the column Top temperature. The water content in the Top distillate can be reduced y only increasing the reflux to the column.
- Adjust steam supply to the column maintain bottom temperature of the column i.e. the bottom concentration of solvents in the effluent around 1000ppm.
- The distillate to be withdrawal in such way that reflux drum is filled 25% at any time, this is to ensure continuous reflux to the column and also for the safety of the pump.
- The feed needs to be preheated through the pre-heater to reduce the steam consumption.
- During the operation following needs to be maintained constant / to be monitored:

- Top Temperature
- Bottom Temperature
- Level in the bottom portion of the column
- Level in the reflux drum
- Observe the parameter of continuous running stripper plant and recorded in stripper
- Column Log Sheet

ETP Flow Diagram



Tank & Pump Requirement for NEW ETP Plant

Sr. No.	Description	Tank	MOC	Capacity	Qty.
1	High COD tank PH adjustment with Pump	New	MS/RCC	5 KL	2
2	Stripper solvent Tank with Pump	New	MS/SS	5 KL	1
3	Permeate storage tank with Pump	New	HDPE	10 KL	3
4	MEE Reject Tank with Pump	New	HDPE	3 KL	1
5	RO-2 Reject tank with Pump	New	HDPE	0.5 KL	1
6	RO-1Reject tank with Pump	New	HDPE	0.5 KL	1
7	RO Reject storage tank	Existing	RCC Cascade		2
8	Stripper bottom storage	Existing	RCC Cascade		2
9	High COD stripper feed tank	Existing	HDPE	10 KL	1
10	MEE condensate tank	Existing	HDPE	5 KL	2
11	MEE Feed tank	Existing	HDPE	15 KL	1

ANNEXURE – V

LIST OF HAZARDOUS WASTE

Sr. No.	Type of Hazardous Waste	Schedule	As per CCA Existing Quantity (MT/Year)	Total After Proposed Quantity (MT/ Year)	Mode of Disposal
01	Effluent Treatment Plant Sludge	Sh.-1, 34.3	36	297	Collection, Storage, Transportation, Disposal at TSDF
02	Sludge from Wet Scrubber	Sh.-1, 36.2	6	12	
03	Discarded Containers/ Barrel/ Liners/ Contaminated with Haz. Waste/ Chemicals	Sh.-1, 33.3	272	357	Collection, Storage, Decontamination, Transportation, Disposal by Selling out to Authorized Recycler/ Re-Processor.
04	Used/Spent Oil	Sh.-1, 5.1	0.3	3.6	Collection, Storage, Transportation, Disposal by Selling out to Recycler/ Re-Processor.
05	Distillation Residue from contaminated organic solvent	Sh.-1, 36.4	6	28	Collection, Storage, Transportation and Disposal by Incineration at CHWI of NECL/ SEPPL or co-processing in cement industries.
06	Waste/ Residue	Sh.-1,23.1	0.024	0.36	
07	Spent Catalyst/Spent Carbon	Sh.-1, 28.2	1.8	145	
08	Filter and Filter Material	Sh.-1, 35.1	1.2	3.6	
09	Distillation Residue (CME Plant Residue)	Sh.-1, 36.4	6	25	
10	Dilute Solvent	-	0	525	Collection, Storage, Decontamination, Transportation, Disposal by Selling out to Authorized Recycler/ Re-Processor.
11	Stripper Solvent	-	0	1360	

ANNEXURE – VI

DETAILS OF STACK & VENTS

EXISTING

Sr. No.	Description	Stack Identification	Concentration of Pollutants Particulate Matter (In ppm)	Rate of Emission in m/sec.	Height of Stack from Ground Level
01	**IBR BOILER** **2.0 Ton/Hrs. Cap, Shall max make** Thermax Ltd, Pune	01	PM SO_2 NOx	7 to 8	31.5
02	**NON IBR BOILER** **(For Process Plant)** 600kg/hr Cap, Make Thermax Ltd, Pune	02	PM SO_2 NOx	5 to 6	16.1

Sr. No.	Type of Boiler	Type of Fuel	Fuel Consumption Rate	Remarks
01	**IBR BOILER** (For Process & ETP) **2.0 Ton/Hrs. Cap, Shall max make** Thermax Ltd, Pune	LDO/FO	0.130KL./Hrs.	For regular use
02	**NON IBR BOILER** **(For Process Plant)** 600kg/hr Cap, Make Thermax Ltd, Pune	LDO/FO	0.038KL/Hrs.	Will be used as stand by only

Stack No.	Stack attached to	Stack height in meter	Air Pollution Control Measures	Parameters
01	Scrubber for MEM Chloride /TBTC Plant	11	Ventury type Alkali Scrubber	HCl Cl_2 SO_2
02	Scrubber for Sartan Product	31	Ventury type Alkali Scrubber	HCl Cl_2 SO_2
03	Scrubber for Sartan Product	15	Ventury type Alkali Scrubber	HCl Cl_2 SO_2

PROPOSED

Stack No.	Stack attached to	Stack height in meter	Air Pollution Control Measures	Parameters
01	D.G.Set (750 KVA) Proposed	15	-	SPM SO_2 NOx

ANNEXURE – VII

STORAGE DETAILS OF HAZARDOUS CHEMICALS

SR. NO.	NAME OF CHEMICAL	HAZARDOUS INVOLVED	STORAGE CAPACITY	AVERAGE CAPACITY	TYPE0 OF STORAGE	CONDITION OF STORAGE	SAFETY MEASURES ADOPTED WHILE STORAGE
1	Methanol	Flammable	10 KL	8 KL	SS Tank	Liquid	Storage in dedicated area, Install flame arrestor with breather valve, install flame proof electrical fixture.
2	Acetone	Flammable	8 KL	8 KL	SS Tank	Liquid	
3	Iso Propyl Alcohol	Flammable	12 KL	10 KL	SS Tank	Liquid	
4	O-Xylene	Flammable	10 KL	8 KL	SS/GI/ Polylined/HDPE	Liquid	Drum shed house with firefighting equipment
5	Cyclohexane	Flammable	5 KL	3 KL	SS/GI/ Polylined/HDPE	Liquid	Drum shed house with firefighting equipment
6	Toluene	Flammable	15 KL	10 KL	SS/GI/ Polylined/HDPE	Liquid	Drum shed house with firefighting equipment
7	Caustic lye	Corrosive	15 KL	10 KL	MS Tank	Liquid	Storage in dedicated area. With firefighting equipment.
8	Thionyl Chloride	Corrosive	4 KL	2.5 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
9	Tri-Butyl-tin-chloride	Corrosive	4 KL	1.5 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
10	Sulphuric Acid	Corrosive	3 KL	1.5 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
11	Hydrochloric acid	Corrosive	5 KL	3 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
12	Valeroyl chloride	Corrosive	3 KL	1.5 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
13	Ethanethiol	Flammable	3 KL	2 KL	HDPE Drum	Liquid	Drum shed house with firefighting equipment
14	Hexane	Flammable	5 KL	3 KL	SS/GI/ Polylined/HDPE	Liquid	Drum shed house with firefighting equipment
15	Cyclohexane	Flammable	5 KL	3 KL	SS/GI/ Polylined/HDPE	Liquid	Drum shed house with firefighting equipment

ANNEXURE-VIII

SOCIO - ECONOMIC IMPACTS

1) EMPLOYMENT OPPORTUNITIES

The manpower requirement for the proposed expansion project is being 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 expansion 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 expansion is not expected to make any significant change in the existing status of the socio - economic environment of this region.

ANNEXURE-IX

PROPOSED TERMS OF REFERENCE FOR EIA STUDIES

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
- Regulatory framework
- Project location and Plant layout.
- Existing infrastructure facilities
- Water source and utilization including proposed water balance.
- Product spectrum (proposed products along with production capacity) and process
- List of hazardous chemicals with their toxicity levels.
- Mass balance of each product along with the batch size
- Storage and Transportation of raw materials and products.
- Existing environmental scenario

2. Description of the Environment and Baseline Data Collection

- Micrometeorological data for wind speed, direction, temperature, humidity and rainfall in 5 km area.
- Study of Data from secondary sources.
- Other industries in the impact area
- Prevailing environment quality standards
- Existing environmental status Vis a Vis air, water, noise, soil in 5 km area from the project site. For SPM, RSPM, SO_2, 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.

- 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.
- Control of fugitive emissions

5. Environmental Management Plan

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

6. Risk Assessment

- Objectives, Philosophy and methodology of risk assessment
- Details on storage facilities
- Identification of hazards
- Consequence analysis through occurrence & evaluation of incidents
- Recommendations on the basis of risk assessment done
- Disaster Management Plan.
- Safety precautions for the storage of Chemicals and vapour condensation.

7. Information for Control of Fugitive Emissions

8. Post Project Monitoring Plan for Air, Water, Soil and Noise.

9. Occupational Health and Safety Program for the Project.

10. Information on Rain Water Harvesting

11. **Green Belt Development plan**