APPLICATION FOR APPROVAL OF

TERMS OF REFERENCE

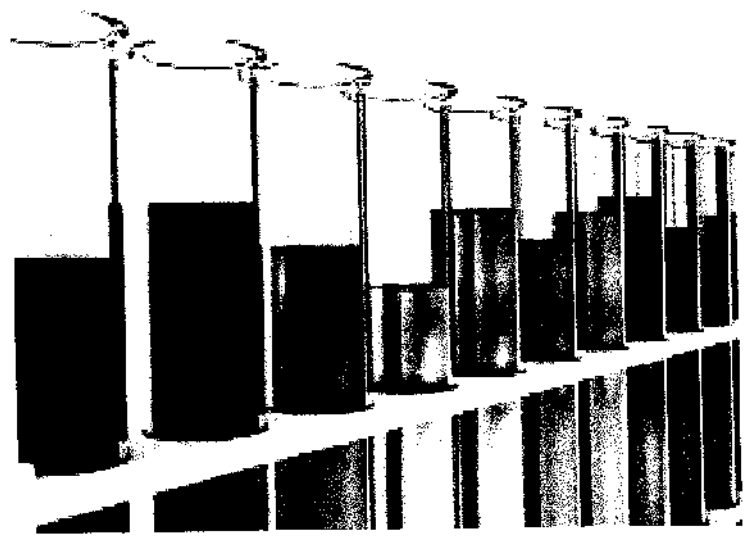
FOR

OBTAINING ENVIRONMENT CLEARANCE
(FOR EXPANSION)
OF

M/s. SYMED LABS LIMITED, UNIT-IV.
MANUFACTURING UNIT

AT

SY.NOS.163,163/A,163/B,164/A & 164/B, PITTAMPALLY(V),
CHITYAL (M), NALGONDA (DT)
ANDHRA PRADESH.



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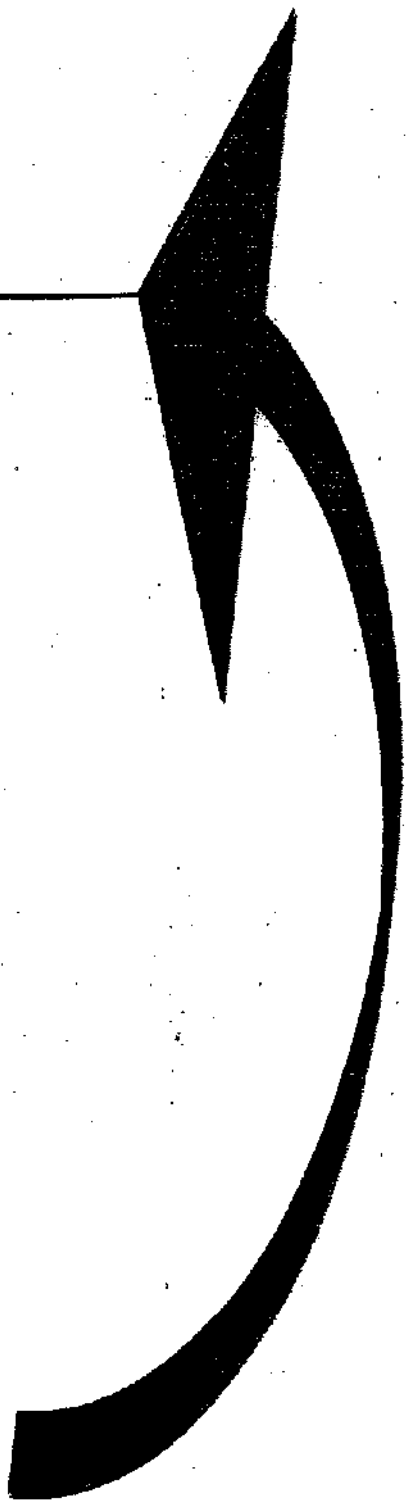

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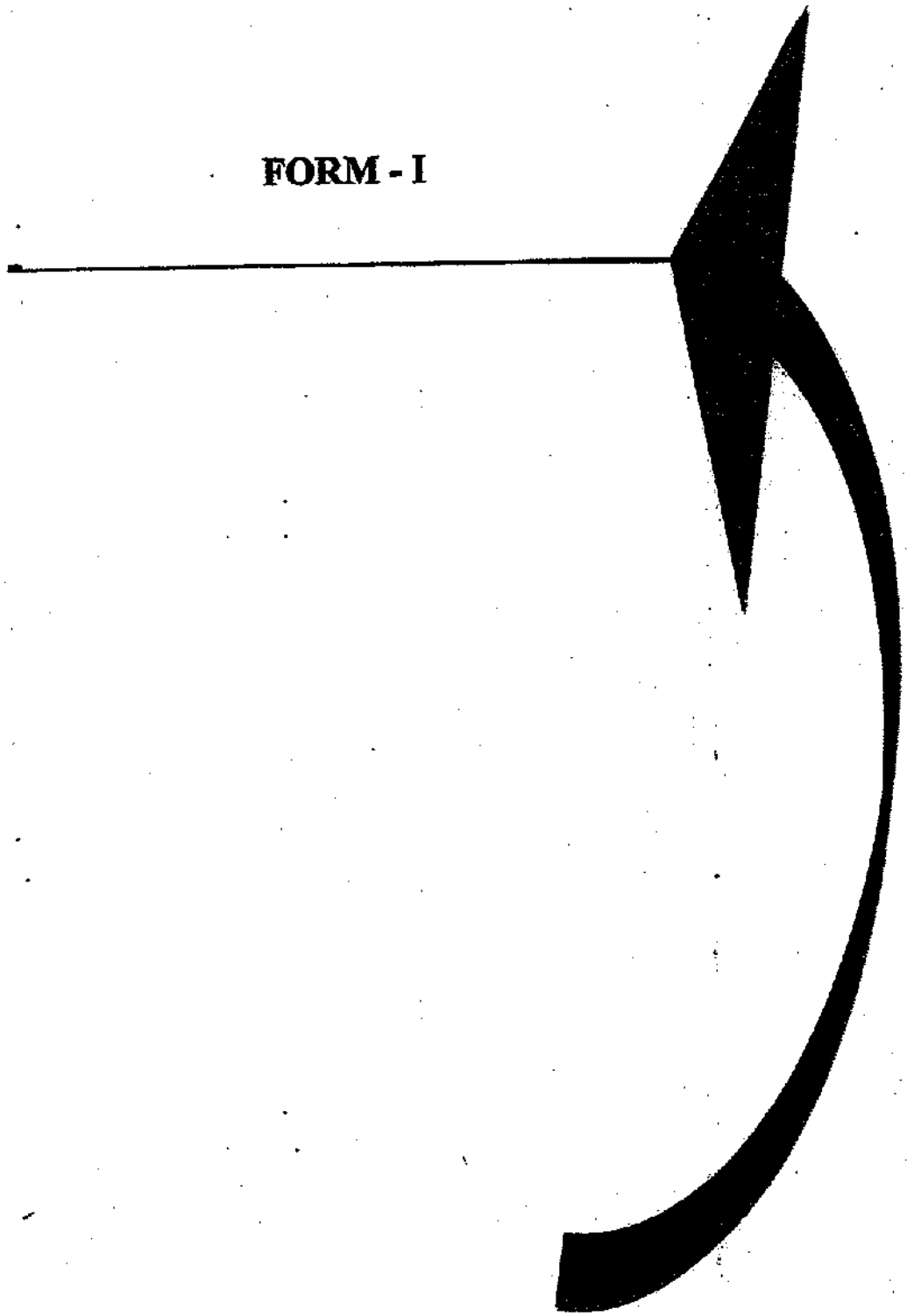
FORM - I



APPENDIX - I
FORM -1

I) Basic information

S.NO	ITEM	DETAILS
1.	Name of the project/s	**M/s. Symed Labs Ltd., Unit-IV**
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	Area Existing: [Expansion within existing land area] Proposed capacity after Expansion : 613.5TPA Proposed products with capacities are Enclosed as **Annexure - I**
4.	New/Expansion/Modernization	Expansion
5.	Existing Capacity/Area etc.	Existing capacity : 109.2 TPA Area existing : 21.3 Acres (86198.04SQM)
6.	Category of Project i.e. 'A' or 'B'	Category – 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	17^0 12'28.38" North Latitude 79^0 00' 56.28"East Longitude Survey No.163,163/A,163/B,164/A,164/B Pittampally (V) Chityal (M), Nalgonda (Dt), - 508114 Andhra Pradesh. Topo Map Enclosed as **Annexure-II**
10.	Nearest railway station Airport Along with distance in kms.	Chityal Railway station – 13 KMs Rajeev Gandhi International Air Port (shamshabad) - 62 KMs
11.	Nearest Town, City, Distric Headquarters Along with distance in Kms.	Nalgonda – 32 KMs Hyderabad – 60 KMs District Head Quarter Nalgonda - 32KMs.
12.	Village Panchayats, Zilla Parishad, Municipal Corporation, Local Body (Complete postal addresses with telephone nos. to be given)	Village Panchayat Pittampally (V) Chityal (M), Nalgonda (Dt)
13.	Name of the applicant	M.V. Nandachary
14.	Registered Address	**M/s. Symed Labs Ltd., Unit-IV** 8-3-166/6&7, 2nd Floor, Sree Arcade, Erragadda, Hyderabad - 500055
15.	Address for correspondence:	M/s. Right source Industrial Solutions Pvt. Ltd. Plot No.203,H.No.536/203,Prashantinagar, IDA, Kukatpally, Hyderabad-500072.

	Name	M.V. Nandachary
	Designation (Owner/Partner/CEO)	Director
	Address	8-3-166/6&7, 2nd Floor, Sree Arcade, Erragadda, Hyderabad - 500055
	Pin Code	500072
	E-mail	info@rightsource.co.in pharma.sharanaa@gmail.com nandachary@symedlabs.com
	Telephone No.	040-23812956,040-23075699, 40126589
	Fax No.	040-23070602
16.	Details of alternative sites examined, if any. Location of these sites should be shown on a Topo sheet	Not Applicable
17.	Interlinked Projects	Not Applicable
18.	Whether separate application of interlinked project has been submitted?	No
19.	If Yes, date of submission	--
20.	If no, reason	--
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?	Not Applicable
22.	Whether there is any Government Order/Policy relevant/relating to the site?	Nil
23.	Forest land involved (hectares)	NO
24.	Whether there is any litigation pending against the project and/or land in which the project is propose to be setup? (a) Name of the court (b) Case No. (c) Orders/directions of the Court, if any and its relevance with the proposed project.	NIL

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.)

S. 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	The proposal is expansion of the manufacturing capacity in the existing APIs Manufacturing unit.
1.2	Clearance of existing land, vegetation and buildings?	No	Proposed expansion in existing plant area
1.3	Creation of new land uses?	No	Existing land use - Private
1.4	Pre-construction investigations e.g. bore houses, soil testing?	No	Existing unit.
1.5	Construction works?	Yes	Construction of Production Blocks and utility blocks. Site Plan Enclosed - **Annexure-III**
1.6	Demolition works?	No	No demolition work
1.7	Temporary sites used for construction works or housing of construction workers?	No	Local Villagers will be employed for construction Activities
1.8	Above ground buildings, structures or earthworks including linear structures, cut and fill or excavations	No	Not Applicable.
1.9	Underground works including mining or tunneling?	No	Not Applicable.
1.10	Reclamation works?	No	Not Applicable.
1.11	Dredging?	No	Not Applicable.
1.12	Offshore structures?	No	Not Applicable.
1.13	Production and manufacturing processes?	Yes	Manufacturing processes Enclosed as **Annexure - IV**
1.14	Facilities for storage of goods or materials?	Yes	Common facility for storage of raw materials and solvents will be used
1.15	Facilities for treatment or disposal of solid waste or liquid effluents?	Yes	All the Liquid Waste generated from the plant will be treated in ZLD System. All the solid wastes will be segregated and stored at an elevated platform under roof with leachate collection system, and disposed to Cement Industries, TSDF based on their Calorific values.

			Some of the wastes like Containers, Liners etc., will be sold to SPCB authorized buyers. Used Oils and grease will be sold to authorize Reprocessors. Lead acid batteries send back to suppliers for buyback of New Batteries
1.16	Facilities for long term housing of operational workers?	No	Not Requires as there are nearby villages can accommodate the work force.
1.17	New road, rail or sea traffic during construction or operation?	No	Not Required.
1.18	New road, rail, air, waterborne or other transport infrastructure including new or altered routes and stations, ports, airports etc?	No	Not Required
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	-
1.21	Impoundment, damming, culverting, realignment or other changes to the hydrology of watercourses or aquifers?	No	-
1.22	Stream crossings?	No	-
1.23	Abstraction or transfers of water from ground or surface waters?	Yes	Water will be drawn from the Bore well (supply). Roof water harvesting will be suggested for recharge of Ground water to the maximum possible extent.
1.24	Changes in water bodies or the land surface affecting drainage or run-off?	No	Nil (There will not be any changes in water bodies or the land surface affecting drainage or run-off)
1.25	Transport of personnel or materials for construction, operation or decommissioning?	No	
1.26	Long-term dismantling or decommissioning or restoration works?	No	Not Applicable
1.27	Ongoing activity during decommissioning which could have an impact on the environment	No	Not Applicable
1.28	Influx of people to an area in either temporarily or permanently?	Yes	The proposed expansion shall increase the employment potential

1.29	Introduction of alien species?	No	No Introduction of alien species
1.30	Loss of native species or genetic diversity?	No	No Loss of native species or genetic diversity
1.31	Any other actions?	No	Every care shall be taken to protect the ecology of the surroundings

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)

S. No	Information/Checklist confirmation	Yes/No	Details thereof (with approximate quantities/rates, wherever possible) with source of information data
2.1	Land especially undeveloped or agricultural land (ha)	No	Existing unit
2.2	Water (expected source & competing users) unit: KLD	Yes	231.61KLD, Ground water supply Requirement of Water Enclosed as - **Annexure - V**
2.3	Minerals (MT)	No	No Minerals required
2.4	Construction material – stone, aggregates, sand/soil (expected source (MT)	No	
2.5	Forests and timber (source – MT)	No	No Timber will be used.
2.6	Energy including electricity and fuels (source, competing users) Unit: fuel (MT), energy (MW)	Yes	• Electricity– From – 1100 KVA - APCPDCL • Generator: Existing – 125 KVA (Dropped) • In addition to the above Dropped Generator the industry proposing Generators – 500 KVA – 1 No 320 KVA – 1 No 250 KVA – 1 No Fuel: HSD about 171.2 Liters per day (For Proposed) • Boiler: Existing Boiler – 1.0 TPH (Dropped) The Industry is proposing to install 5.0 TPH coal fired Boiler and another 2 TPH Coal Fired Boiler as Stand By, • Fuel: Coal for Proposed Boiler – 12.5 TPD
2.7	Any other natural resources (use appropriate standard units)	No	None

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.

S. 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, a nd water supplies)	Yes	Enclosed
3.2	Changes in occurrence of disease or affect disease vectors (e.g. insect or water borne diseases)	No	No such occurrence envisaged , since waste water generated will be treated properly and reused as per norms of PCB
3.3	Affect the welfare of people e.g. by changing living conditions?	Yes	Shall increase the employment potential for locals thereby effect the living conditions towards betterment
3.4	Vulnerable groups of people who could be affected by the project e.g. hospital patients, children, the elderly etc.,	No	None
3.5	Any other causes	No	Nil

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

S. 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	Not applicable
4.2	Municipal waste (domestic and or commercial wastes)	Yes	Commercial waste like empty cement bags, Iron scrap etc. will be sold to scrap buyers after the construction phase. Domestic waste like used paper, label, cartoons will be disposed to the scrap buyers. Organic waste from canteen will be disposed as per the local Panchayath / Municipal disposal mechanism.
4.3	Hazardous wastes (as per Hazardous Waste Management Rules)	Yes	As per the **Annexure - VI**

4.4	Other industrial process wastes	Yes	As per **annexure –VI**
4.5	Surplus product	No	Surplus production is not envisaged since production will be as per the market demand only.
4.6	Sewage sludge or other sludge from effluent treatment	Yes	As per **Annexure -VI**
4.7	Construction or demolition wastes	Yes	Construction activity involves creation of additional utilities.
4.8	Redundant machinery or equipment	No	None
4.9	Contaminated soils or other materials	No	Nil
4.10	Agricultural wastes	No	Nil
4.11	Other solid wastes	Yes	As per **Annexure – VI**

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

S. No	Information/Checklist confirmation	Yes/No	Details thereof (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	As per Enclosed - **Annexure –VII**
5.2	Emissions from production processes	Yes	All the reactors are connected with primary and secondary condensers with chilled brine Circulation to reduce the solvent losses and to control the emissions of volatile compounds. All the gaseous emissions generating during the production processes are mitigated by using suitable scrubbing system with suitable media. Quantities of gaseous emissions. As per the Enclosed **Annexure - VIII**
5.3	Emissions from materials handling including storage or transport	Yes	All the solvents are stored in storage tanks are connected with vent condensers .All the solvents will be pumped to the day tanks in production blocks in a closed pipe line system to avoid the fugitive losses of the volatiles.
5.4	Emissions from construction activities including plant and equipment	Yes	Negligible quantity of fugitive dust will generate.
5.5	Dust or odors from handling of materials including construction materials, sewage and waste	Yes	Negligible quantity of dust will arise in construction phase. During the operational phase possible sources are Coal storage areas and coal

			ash storage areas. Coal will be stored under the roof and on a Masonry platform under the roof. Coal ash will be stored on a platform and frequent sprinkling of water will arrest the flying dust.
5.6	Emissions from incineration of waste	No	No incineration of waste in the site
5.7	Emissions from burning of waste in open air (e.g. slash materials, construction debris)	No	No burning activity in the site. No emissions will generate
5.8	Emissions from any other sources	Yes	A little quantity of emissions will arise during the dispensing of Raw materials from the ware house, the dispensing area in the ware house is under the air handling system hence their will not be any health nuisance to the health of the workers as the air handling system will arrest these emissions and dispose into atmosphere as their quantity is very negligible

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

S. No	Information/Checklist confirmation	Yes/No	Details thereof (with approximate quantities/rates, wherever possible) with source of information data
6.1	From operation of equipment e.g. engines, ventilation plant, crushers	Yes	Material transport and construction equipment shall be source of noise, while transfer pumps ,vacuum systems, DG sets are the sources of noise during operation
6.2	From industrial or similar processes	Yes	• There is a chance of noise pollution from DG sets which are used as stand by .the DG sets are covered with an acoustic enclosure and with silencers will mitigate this noise. • Pumps, motors, gearboxes etc will generate little bit noise and will be mitigated with regular maintenance. • Apart from all these a thick plantation of green belt is proposed along with periphery of the compound wall will arrest the noise nuisance during the operation phase.

6.3	From construction or demolition	Yes	The noise generating from the construction/ commissioning equipment is very low as it is a small construction activity.
6.4	From blasting or pilling	No	None, since no blasting or pilling during construction
6.5	From construction or operational traffic	No	Negligible
6.6	From lighting or cooling systems	No	Negligible.
6.7	From any other sources	No	Nil

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

S. 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 the solvents are stored in storage tanks will be pumped to the day tanks in production blocks in a closed pipe line system to avoid spillages. The hazardous materials which are sending for production purpose from the Ware House to production Blocks will be sent in closed containers to avoid the spillage of such components.
7.2	From discharge of sewage or other effluents to water or the land (expected mode and place of discharge)	Yes	All the effluent generated will be collected on Above ground Storage tanks to avoid the contamination with soil. These tanks are lined with acid/alkali proof lining. Domestic effluent will\ be sent to septic Tank and the overflow is used for biological treatment to achieve ZLD. All the effluent will be treated in ZLD System and the recovered water will be reused. Hence, There s no impact due to water effluent generating from this unit.
7.3	By deposition of pollutants emitted to air into the land or into water	Yes	Stack emission is controlled by providing adequate height of the chimney and Bag filters will be provided to the boiler.
7.4	From any other sources	Yes	A little quantity of emissions will arise during the dispensing of Raw materials from the warehouse ,the dispensing area in the ware house is under the air handling system hence their will not be any health nuisance to

			the health of the workers as the air handling system will arrest these emissions and dispose into atmosphere as their quantity is very negligible
7.5	Is there a risk of long term build up of pollutants in the environment from these sources?	No	Not Applicable

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

S. 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	No explosions will occur during construction. During production-operations, all inbuilt safety precautions will be adopted and there will not be any damage to environment or human health.
8.2	From any other causes	Yes	Explosions and fire will be possible to occur, during the handling of hazardous chemicals through static electricity which is dissipated by provide earthing to the equipment.
8.3	Could the project be affected by natural disasters causing environmental damage (e.g. floods, earthquakes, landslides, cloudburst etc)?	No	No natural disasters are envisaged, since site is in an area where such occurrences do not arise

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.

S. 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	Yes	The project shall enhance the socioeconomic status of the area by increasing the demand for housing, and improving employment. there are no major support industries for this plant

	environment e.g. * Supporting infrastructure (roads, power supply, waste or waste water treatment, etc.) * Housing development * Extractive industries * Supply industries * Other		
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	The baseline environmental status of the surrounding areas is within the prescribed limits as observed from the secondary.

10. Environmental Sensitivity

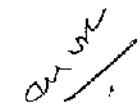
S. No	Areas	Name/ Identity	Aerial distance (within 25 km) Proposed project location boundary
10.1	Areas protected under international conventions, national or local legislation for their ecological, landscape, cultural or other related value	No	None
10.2	Areas which are important or sensitive for ecological reasons – Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	No	None
10.3	Areas used by protected, important or sensitive species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	No	None
10.4	Inland, coastal, marine or underground waters	No	None
10.5	State, National boundaries	No	None
10.6	Routes or facilities used by the public for access to recreation or	No	None

	other tourist, pilgrim areas		
10.7	Defense installations	No	None
10.8	Densely populated or built-up area	Yes	Chityal – 12.81 KMs Choutuppal - 13.5KMs
10.9	Areas occupied by sensitive man-made land uses (hospitals, places of worship, community facilities)	Yes	Chityal – 12.81 KMs Choutuppal - 13.5KMs Narketpalli – 18.65
10.10	Areas containing important, high quality or scarce resources (ground water resources, surface resources, forestry, agriculture, fisheries, tourism, minerals).	No	None
10.11	Areas already subjected to pollution or environmental damage. (Those where existing legal environmental standards are exceeded)	No	None
10.12	Areas susceptible to natural hazard which could cause the project to present environmental problems (earthquakes, subsidence, landslides, erosion, flooding or extreme or adverse climatic conditions)	No	None

"I hereby given undertaking that the data and information given in the application and enclosures are true to the best of my knowledge and behalf 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

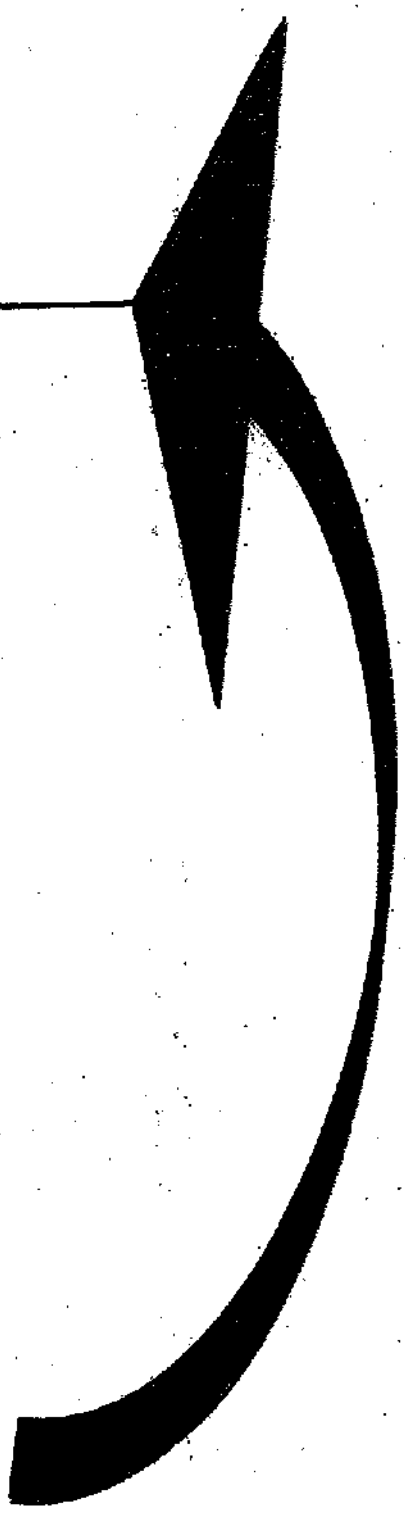
Date:
Place: Hyderabad

for **M/s. Symed Labs Limited**



M.V Nandachary
Director

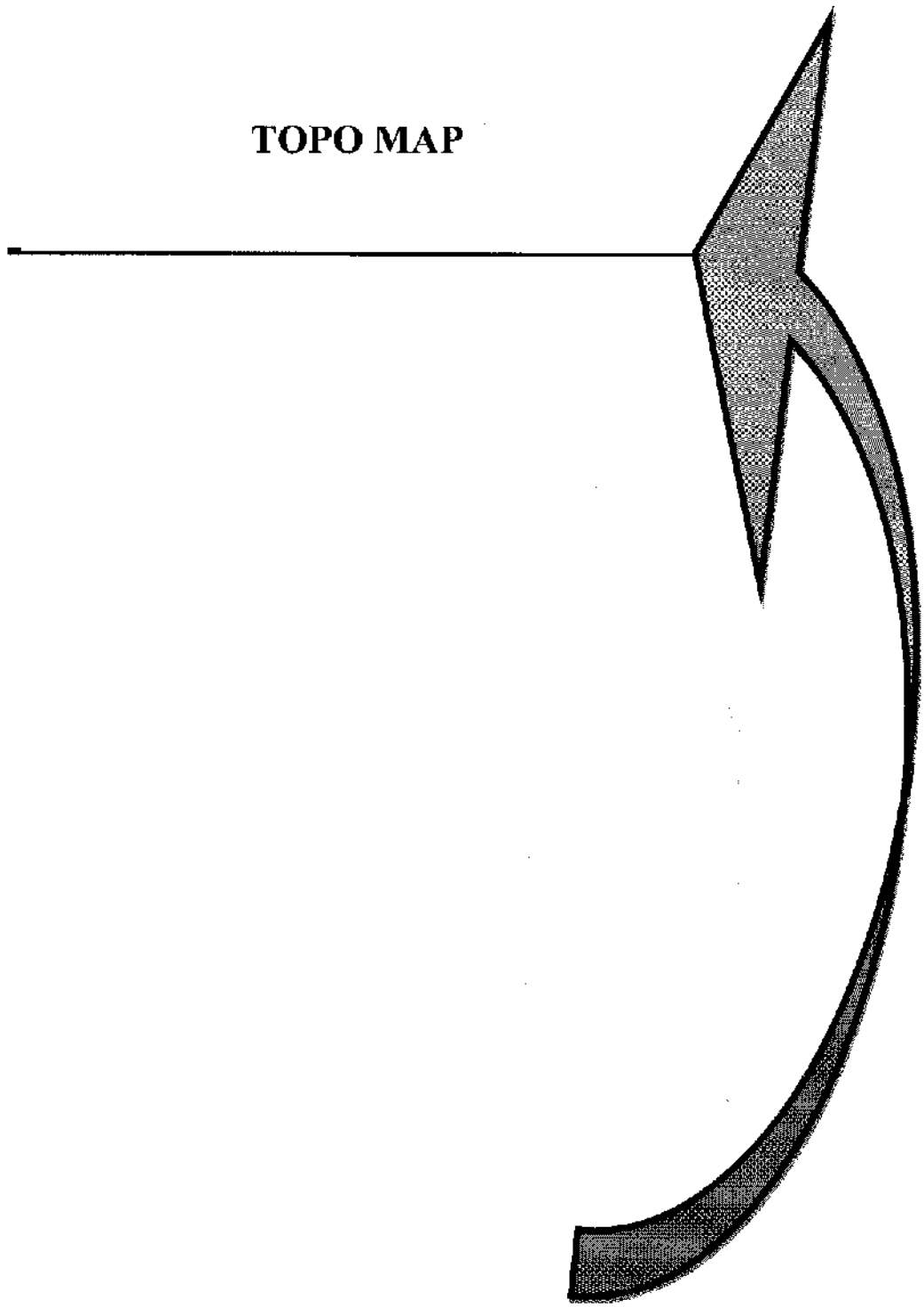
LIST OF PRODUCTS



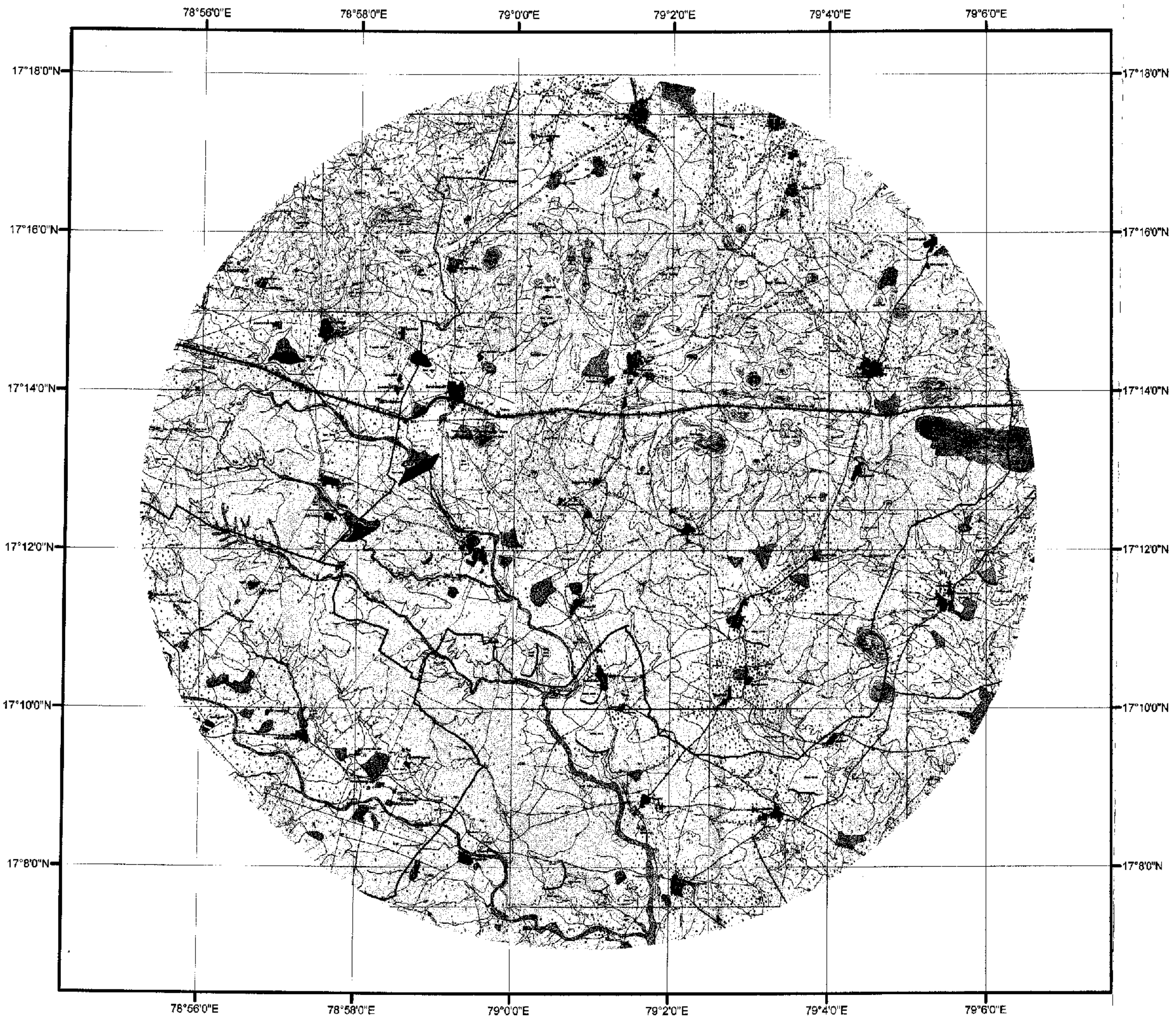
LIST OF PRODUCTS

S. No	Product Name	CAS No's	Quantity In Kg/Month	Quantity In Kg/Day
1	Amisulpride	71675-85-9	500.00	16.67
2	Carvedilol	72956-09-3	2000.00	66.67
3	Carvedilol Phosphate	610309-89-2	100.00	3.33
4	Carbidopa	93357-67-6	2000.00	66.67
5	Cinitapride Hydrogen tartrate	66564-14-5	50.00	1.67
6	Dapoxetine Hydrochloride	129938-20-1	500.00	16.67
7	Epalrestat	82159-09-9	1500.00	50.00
8	Eszopiclone	138729-47-2	25.00	0.83
9	Fluconazole	86386-73-4	3000.00	100.00
10	Iron sucrose	8047-67-4	10000.00	333.33
11	Itopride Hydrochloride	122892-31-3	2000.00	66.67
12	Ketorolac Tromethamine	74103-07-4	4000.00	133.33
13	Levocetirizine Dihydrochloride	130018-87-0	300.00	10.00
14	Levosulpride	23672-07-3	1500.00	50.00
15	Linezolid	165800-03-3	9000.00	300.00
16	Mosapride citrate dihydrate	63582-62-2	2000.00	66.67
17	Ondansetron Hydrochloride	103639-04-9	500.00	16.67
18	Pregabalin	148553-50-8	5000.00	166.67
19	Racecadotril	81110-73-8	3000.00	100.00
20	Tamsulosin Hydrochloride	106463-17-6	50.00	1.67
21	Tizanidine Hydrochloride	64461-82-1	50.00	1.67
22	Topiramate	97240-79-4	3000.00	100.00
23	Zotepine	26615-21-4	1000.00	33.33
24	Zopiclone	43200-80-2	50.00	1.67
	Total		***51125.00***	***1704.16***

TOPO MAP



Annexure-II



10 Km RADIUS
TOPO MAP
SHOWING SITE
SURROUNDINGS

N

1 0.5 0 1 2 3 4 Kilometers

1 centimeter = 1,213 meters

LEGEND

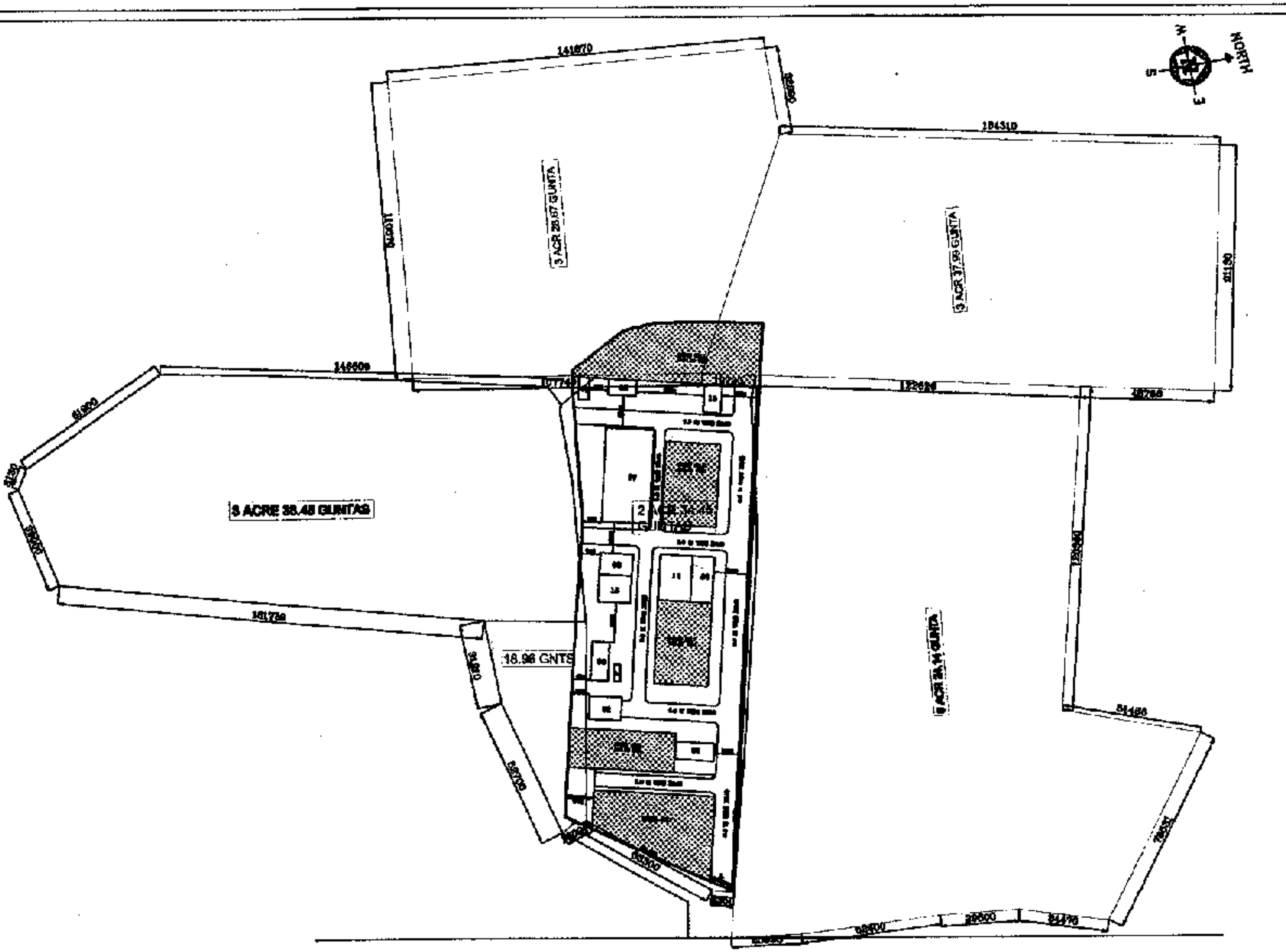
▲ PROJECT SITE

CO-ORDINATES
17°12'28.38"N 79°00'56.28"E

M/s. Symed Labs Ltd., Unit-IV

SITE PLAN

ANNEXURE-III



PLOT PLAN
SCALE:-1:600

SLL-GEN-1

M/s SYMED LABS LIMITED, UNIT-IV

Sy.NO:163/[illegible]/A,SITUATED AT PITTAMPALLY(V),CHITYAL(M), NALGONDA(DIST)

GENERAL NOTES

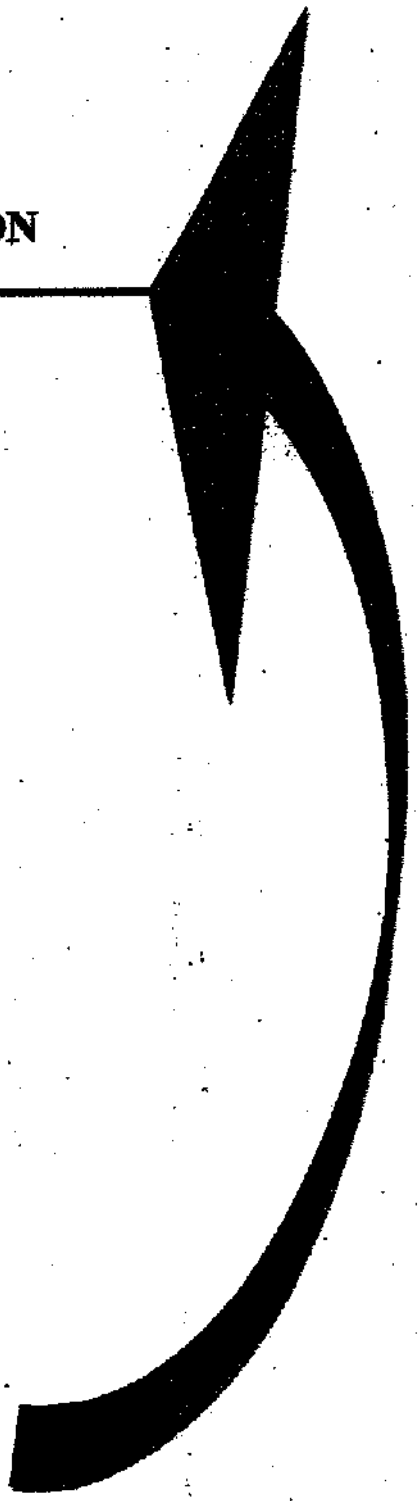
1)ALL DIMENSIONS ARE IN MM & MTS ONLY

PROPOSED ☐ EXISTING ☐ DELETION ☐

PLOT PLAN

SAI RAM DESIGNS&DRAFTING

PROCESS DESCRIPTION



1. AMISULPRIDE

Process Description:

Stage-1

4-Amino-5-(ethyl sulfonyl)-2-methoxybenzoic acid reacts with 1-(1-ethylpyrrolidin-2-yl) methane amine in the presence of ethyl chloro formate, Triethyl amine in acetone, Sodium hydroxide and water to yield Amisulpride (crude).

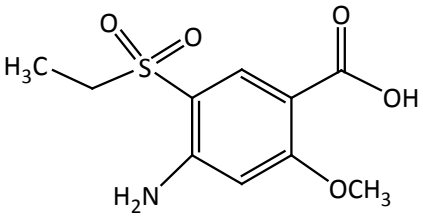
Stage-2

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

AMISULPRIDE

Route of Synthesis:

Stage-1:

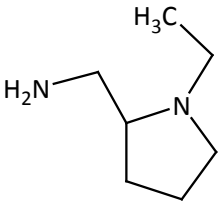


4-Amino-5-ethanesulfonyl-2-methoxy-benzoic acid

$C_{10}H_{13}NO_5S$

259.28

+



C-(1-Ethyl-pyrrolidin-2-yl)-methylamine

$C_7H_{16}N_2$

128.22

+ $(C_2H_5)_3N$ + $ClCOOC_2H_5$

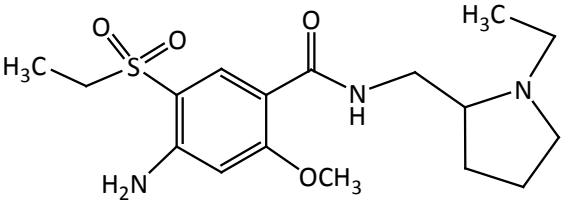
Triethyl amine

101.19

Ethyl chloro formate

108.52

MDC



Amisulpride (Crude)

$C_{17}H_{27}N_3O_4S$

369.48

+ $(C_2H_5)_3N.HCl$ + C_2H_5OH + CO_2 ↑

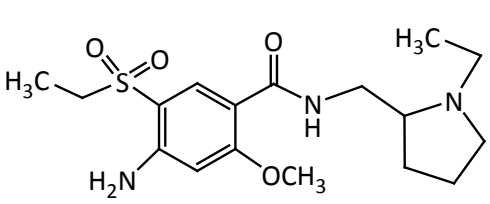
Triethyl amine hydrochloride

137.65

46.07

44.0

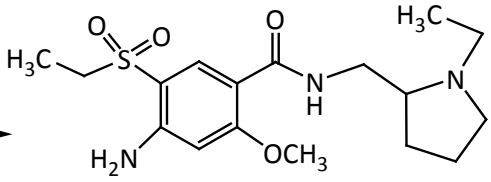
Stage-2:



Amisulpride(Crude)

$C_{17}H_{27}N_3O_4S$

369.48



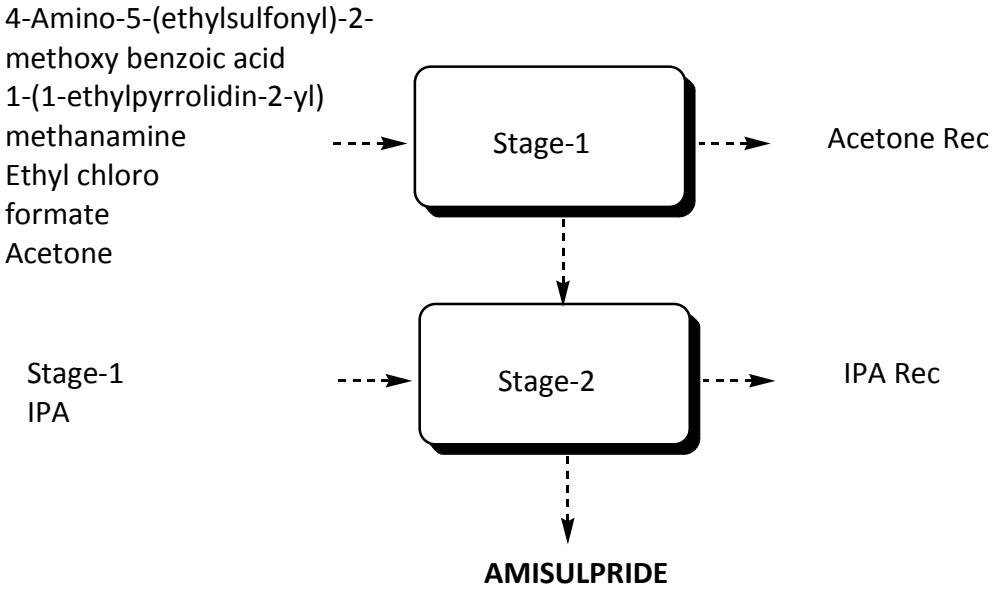
Amisulpride(pure)

$C_{17}H_{27}N_3O_4S$

369.48

AMISULPRIDE

Flow Chart:



AMISULPRIDE

Material Balance:

Material Balance of Amisulpride Stage-1 Batch Size: 200.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
2-Methoxy-4-amino-5-ethyl sulphonyl benzoic acid	141.00		Stage-1	200.00
1-Ethyl-2-amino methyl pyrrolidine	75.00		Acetone Recovery	597.00
Ethyl chloro formate	59.00		Acetone Loss	31.50
Triethylamine	80.00		Effluent water	1445.83
Sodium hydroxide	145.00		(Water-1200,Triethylamine HCl-74.83,Ethanol-25.0,Sodium hydroxide-145,Aetone-1)	
Acetone	630.00		Process Emissions	23.92
Water	1200.00		(Carbon dioxide-23.92)	
			Organic Residue	31.75
			(Organic impurities-31.25, Acetone-0.50)	
Total	2330.00		Total	2330.00

Material Balance of Amisulpride Stage-2 Batch Size: 200.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	200.00		Amisulpride(Pharma)	200.00
Isopropyl alcohol	150.00		Isopropyl alcohol Recovery	142.50
Activated carbon	9.00		Isopropyl alcohol Loss	7.50
			Spent carbon	9.00
Total	359.00		Total	359.00

2. CARBIDOPA

Process Description:

Stage-1

Methyldopa is reacted with Thionyl Chloride in presence of Methanol to obtain Methyldopa Methyl Ester

Stage-2

Toluene, Cyclohexanone, Purified water and Liq. Ammonia are charged into reactor and sodium hypochlorite solution is added. After competition of reaction, organic layer is separated and washed with Dil. Hydrochloric acid and purified water. The obtained organic layer and Boric acid is reacted with Carbidopa Stage-1. Obtained Organic layer is extracted into aqueous layer and further washings with chloroform then Stage-2 will be obtained

Stage-3

The Stage-2 Aqueous layer is refluxed for 8-10 hours. Cooled, then methanol was added to it and further PH adjusted to 3.0-3.5 with Ammonia and cool the mass to isolate stage-3 by centrifugation.

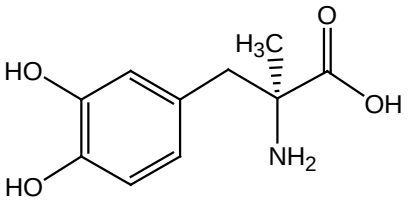
Stage-4

Crude carbidopa was dissolved in dilute hydrochloric acid and treated with activated carbon and sodium metabisulphite. To filtered solution methanol was added and PH was adjusted to 3.0-3.5 and filtered to get Carbidopa and further purified with Hydrochloric acid, water and sodium meta bisulphate.

CARBIDOPA

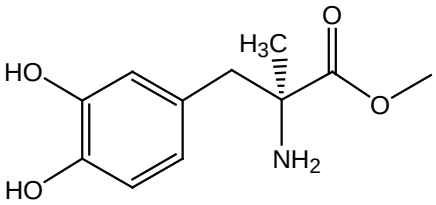
Route of Synthesis:

Stage-1:



+ $SOCl_2$ + CH_3OH + 2 NaOH ⟶

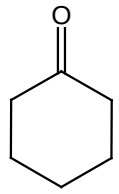
Methyl Dopa	Thionyl Chloride	Methanol	Sodium Hydroxide
$C_{10}H_{13}NO_4$	118.97	32.0	2X40.0=80.0
211.21			



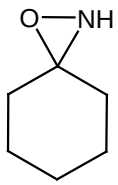
+ 2NaCl + $2H_2O$ + SO_2 ↑

Methyl Dopa Methyl Ester	Sodium Chloride	Water	Sulphur dioxide
$C_{11}H_{15}NO_4$	2X58.5=117	2X18.0=36.0	64.0
225.24			

Stage-2:



+ NaOCl + NH_3 ⟶

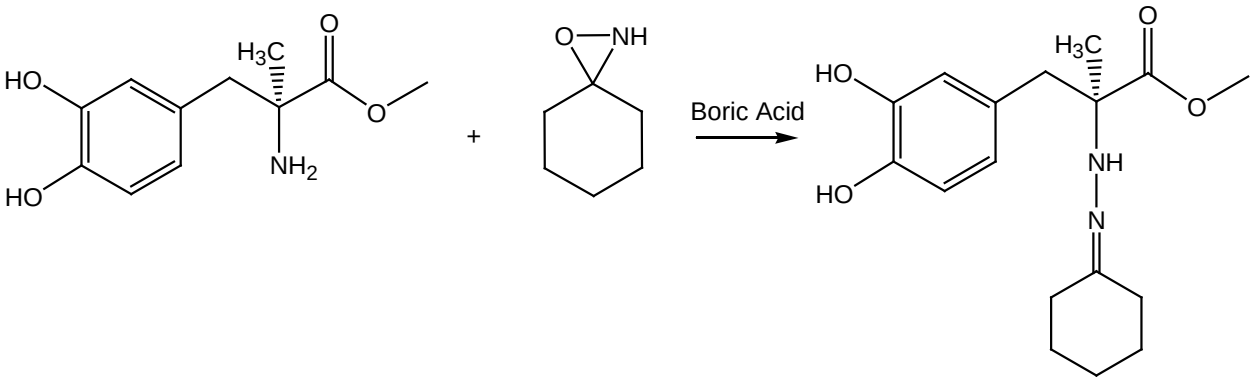


+ NaCl + H_2O

Cyclohexanone	74.44	17.0	3 3-pentamethylene oxaziridine	58.5	18.0
$C_6H_{10}O$			$C_6H_{11}NO$		
98.11			113.16		

Stage-3:

Step-A



Methyl Dopa Methyl Ester

$C_{11}H_{15}NO_4$

225.24

3 3-pentamethylene oxaziridine

$C_6H_{11}NO$

113.16

(s)-2-Cyclohexylidene-Hydrazino-2-(3,4-Dihydroxybenzyl)-Propionic acid methyl ester

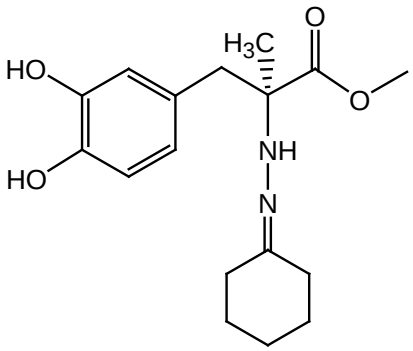
$C_{17}H_{24}N_2O_4$

320.38

\+ H_2O

18.0

Step-B



+ H_2O + NH_3 + HCl —Methanol→

(s)-2-Cyclohexylidene-Hydrazino-2-(3,4-Dihydroxybenzyl)-Propionic acid methyl ester

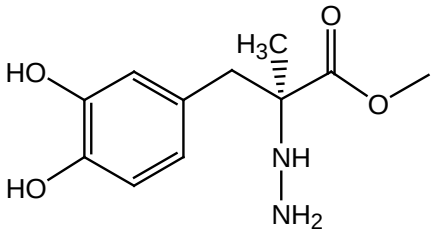
$C_{17}H_{24}N_2O_4$

320.38

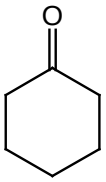
18.0

17.0

36.5



+



+ NH_4Cl

Carbidopa Methyl Ester

$C_{11}H_{16}N_2O_4$

240.26

Cyclohexane

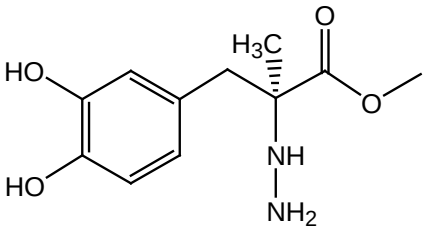
$C_6H_{10}O$

98.14

Ammonium Chloride

53.5

Stage-4:



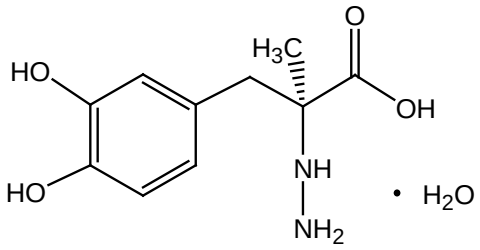
+ H_2O + HCl + NH_4OH —(Methanol)→

Carbidopa Methyl Ester

$C_{11}H_{16}N_2O_4$

240.26

18.0 36.5 35.0



+ CH_3OH + NH_4Cl

Carbidopa

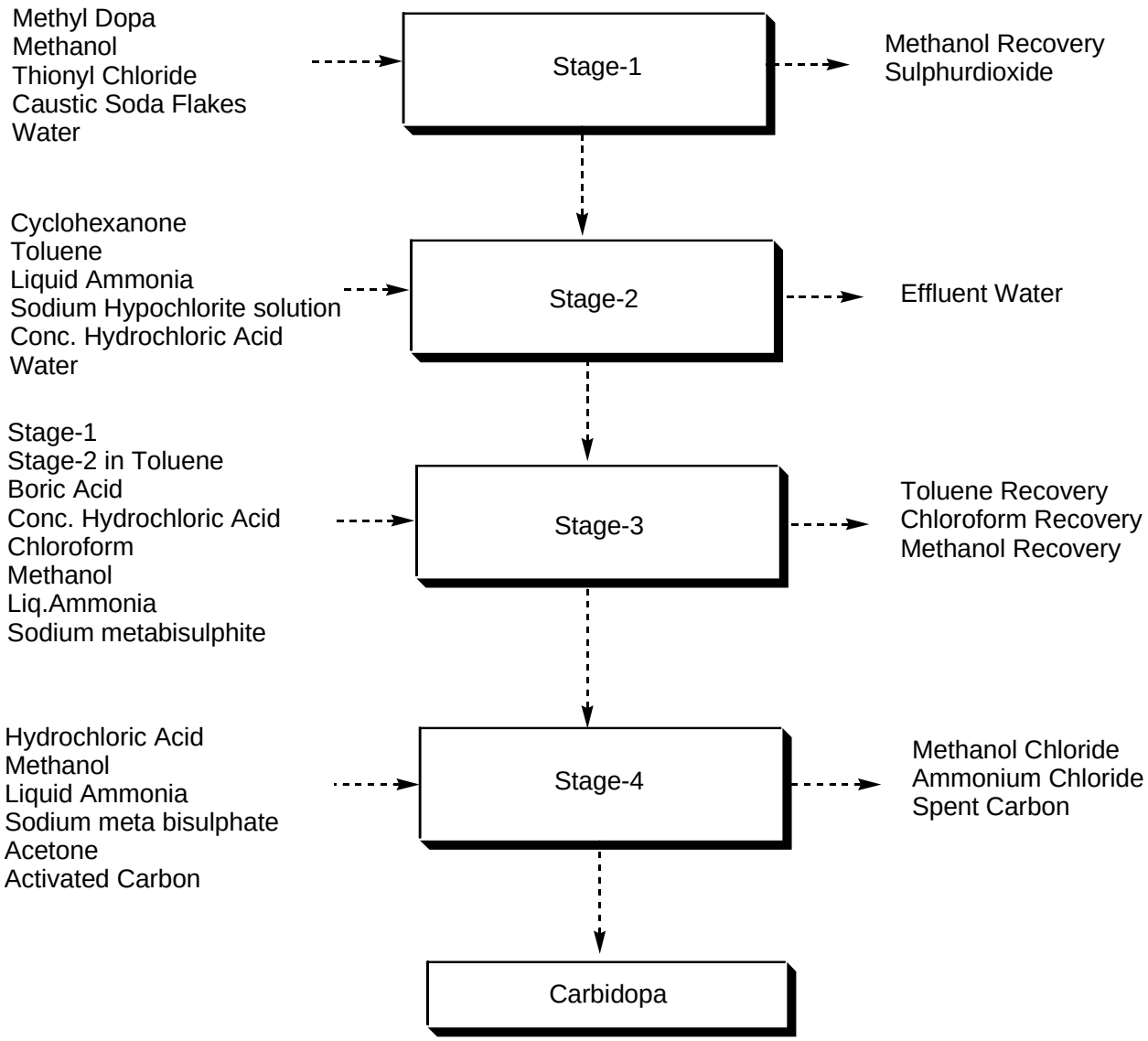
$C_{10}H_{14}N_2O_4$ H_2O

244.24

32.0 53.5

CARBIDOPA

Flow Chart:



CARBIDOPA

Material Balance:

Material balance of Carbidopa Stage-1 Batch Size: 25.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Methyl Dopa	40.00		Stage-1	40.00
Methanol	100.00		Methanol Recovery	85.00
Thionyl Chloride	22.53		Methanol Loss	5.00
Caustic Soda Flakes	15.50		Effluent Water	387.91
Water	355.00		(Water-355,generated water-6.82,Sodium Chloride-22.15, Methanol-3.94)	
			Process Emission	12.12
			(Sulfur dioxide)	
Total	533.03		Total	530.03

Material balance of Carbidopa Stage-2 Batch Size: 25.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Cyclohexanone	20.00		Stage-2 in Toluene	340.00
Toluene	320.00		Effluent Water	1786.97
Liquid Ammonia (10%)	35.00		(Water-1380,generated water-3.67,water from sodium hypochlorite-360,Sodium chloride-11.8,water from Ammonia-31.5)	
Sodium Hypochlorite	375.00		Spent Hydrochloric Acid (20%)	150.00
Conc. Hydrochloric Acid	30.00		Organic Residue	3.03
Water	1500.00			
Total	2280.00		Total	2280.00

Material balance of Carbidopa Stage-3 Batch Size: 25.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	40.00		Stage-3	35.00
Stage-2 in Toluene	340.00		Toluene Recovery	304.00
Boric Acid	7.25		Toluene Loss	16.00
Conc. Hydrochloric Acid	12.00		Chloroform Recovery	178.00
Chloroform	187.50		Chloroform Loss	9.50
Methanol	20.00		Cyclohexanone reuse	14.30
Liq.Ammonia	7.00		Effluent Water	547.28
Sodium metabisulphite	0.55		(Water-497.3,generated water-3.18,Methanol-20,Boric Acid-7.25,Ammonium chloride-19,Sodium metabisulphite-0.55)	
Water	500.00		Organic Residue	10.22
Total	1114.30		Total	1114.30

Material balance of Carbidopa Stage-4 Batch Size: 25.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-3	35.00		Carbidopa	25.00
Hydrochloric Acid	7.00		Methanol Recovery	175.00
Methanol	182.35		Methanol Loss	5.00
Ammonium hydroxide	5.00		Effluent Water	312.22
Sodium meta bisulphate	0.87		(Water-297.4, Methanol-4.67, Acetone-1.64, Ammonium Chloride-7.64,Sodium meta bisulphate-0.87)	
Acetone	1.64		Spent Carbon	5.00
Activated Carbon	5.00		Organic Residue	14.64
Water	300.00			
Total	536.86		Total	536.86

3. CARVEDILOL

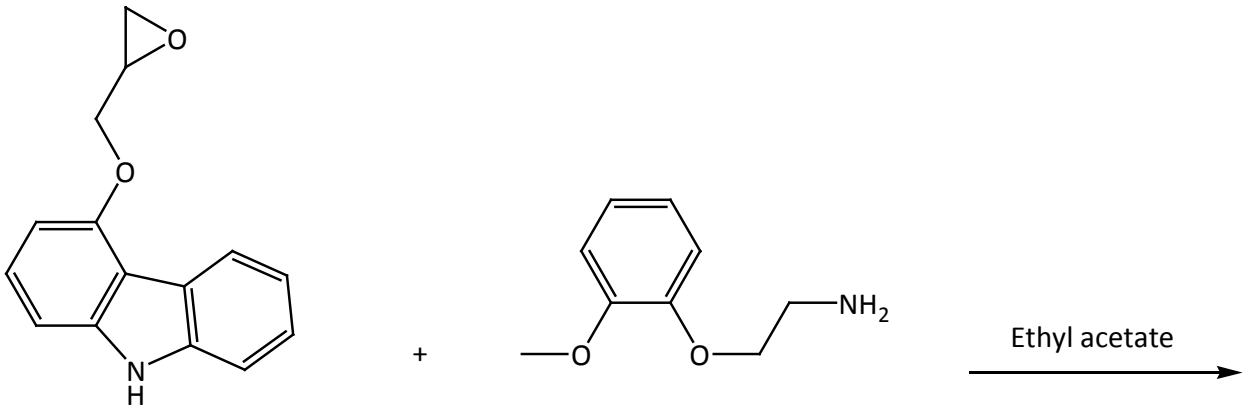
Process Description:

4-Oxiranylmethoxy-9H-Carbazole is condensed with 2-(2-methoxyphenoxy) ethylamine in the presence of Ethyl acetate to give Carvedilol as product.

CARVEDILOL

Route of synthesis:

Stage-1



4-(oxiranylmethoxy)-9H-Carbazole

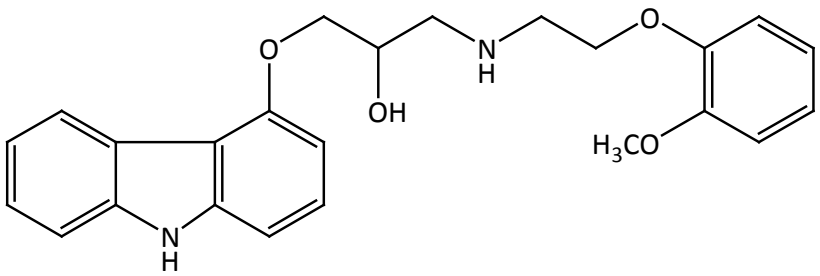
$C_{15}H_{13}NO_2$

239.27

2-(2-methoxyphenoxy) ethylamine

$C_9H_{13}NO_2$

167.21



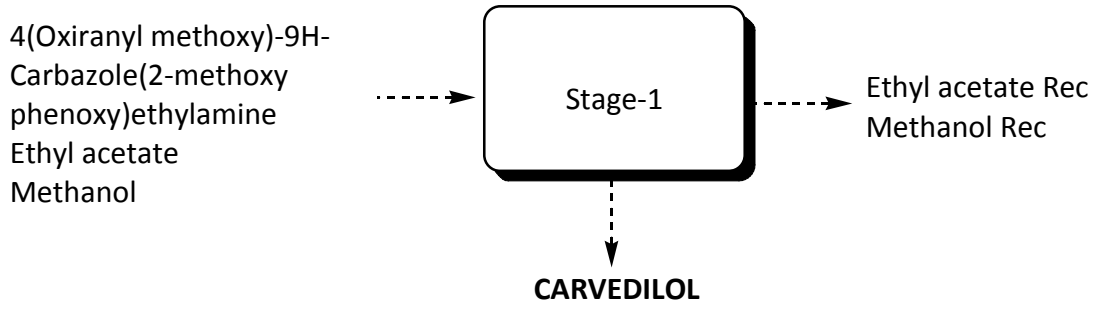
Carvedilol

$C_{24}H_{28}N_2O_4$

406.47

CARVEDILOL

Flow Chart:



CARVEDILOL

Material Balance:

Material balance of Carvedilol Stage-1 Batch Size:55.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
4(Oxiranyl methoxy)-9H-Carbazole	32.50		Carvedilol	55.00
(2-methoxyphenoxy)ethylamine	22.50		Ethyl acetate Recovery	393.00
Ethyl acetate	413.00		Ethyl acetate Loss	20.00
Methanol	395.00		Methanol Recovery	376.00
Activated carbon	7.00		Methanol Loss	19.00
			Spent Carbon	7.00
Total	870.00		Total	870.00

4. CARVEDILOL PHOSPHATE

Process Description:

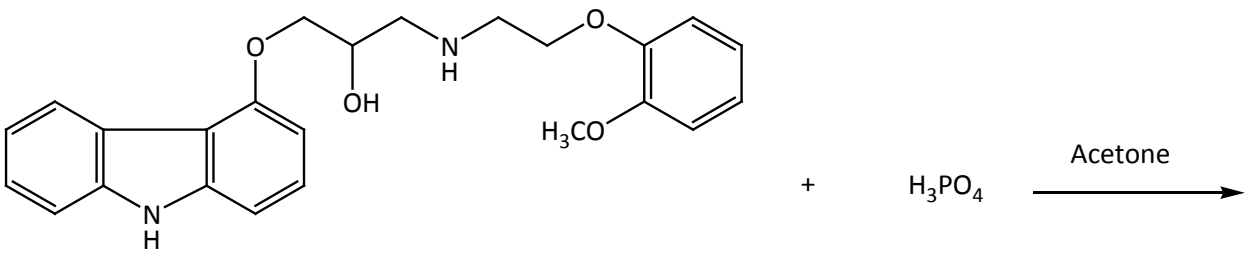
Stage-1

Carvedilol reacts with Phosphoric acid in the presence of Acetone and water media to give Carvedilol phosphate as product.

CARVEDILOL PHOSPHATE

Route of Synthesis:

Stage-1



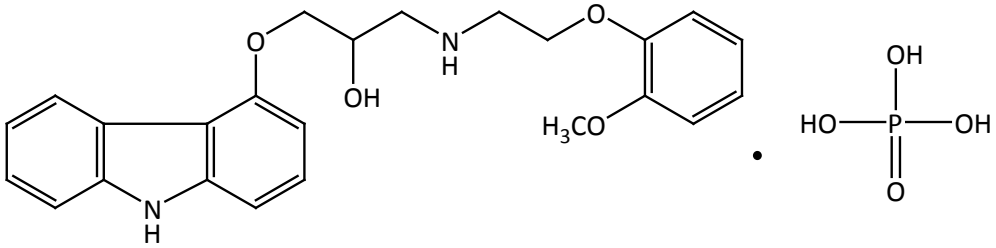
Carvedilol

$C_{24}H_{26}N_2O_4$

406.47

Phosphoric acid

98.0



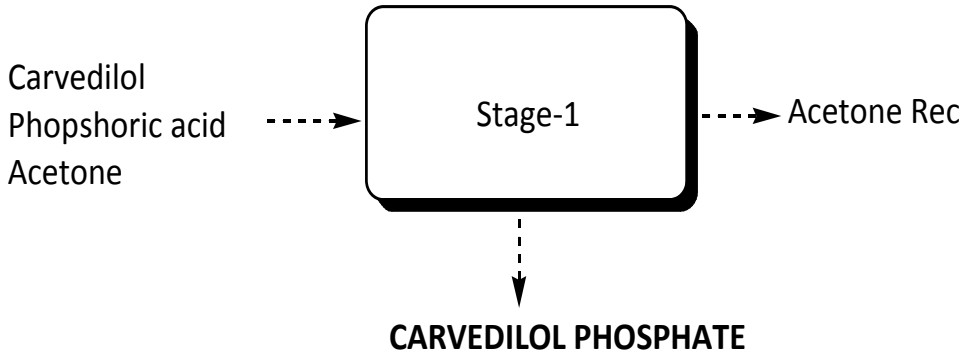
Carvedilol Phosphate

$C_{24}H_{29}N_2PO_8$

504.47

CARVEDILOL PHOSPHATE

Flow Chart:



CARVEDILOL PHOSPHATE

Material Balance:

Material balance of Carvedilol Phopshate Stage-1 Batch Size:58.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Carvedilol	47.00		Carvedilol Phosphate	58.00
Phosphoric acid	12.00		Acetone Recovery	376.00
Acetone	396.00		Acetone Loss	19.00
Water	50.00		Effluent water	51.50
			(Water-50,Acetone-1,phosphoric acid-0.5)	
			Organic Residue	0.50
Total	505.00		Total	505.00

5. CINITAPRIDE HYDROGEN TARTRATE

Process Description:

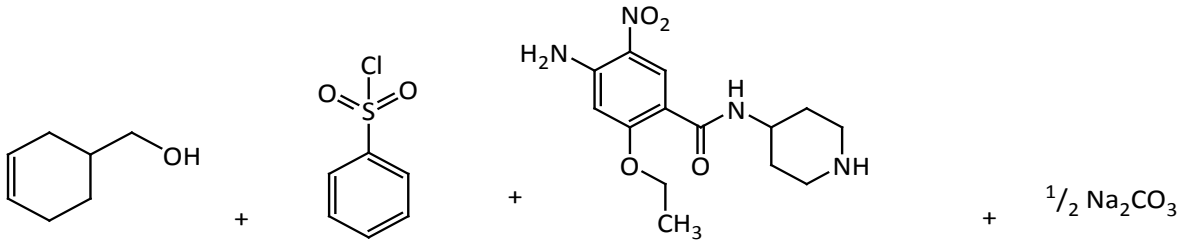
Stage-1

3-Cyclohexane-1-methanol reacts with Benzenesulfonyl chloride,4-Amino-2-ethoxy-5-nitro-N-(4-piperidyl)benzamide in presence of Cyclohexane and Methanol as a solvent media to give Cinitapride Hydrogen Tartrate

CINITAPRIDE HYDROGEN TARTRATE

Route of Synthesis

Stage-1



Cyclohex-3-enyl -methanol
$C_7H_{12}O$
112.17

+

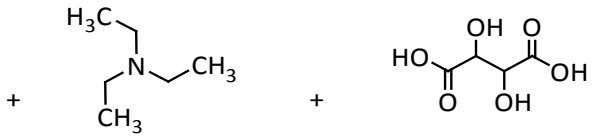
Benzene sulfonyl chloride
$C_6H_5ClO_2S$
176.62

+

4-Amino-2-ethoxy-5-nitro-*N* -piperidin-4-yl-benzamide
$C_{14}H_{20}N_4O_4$
308.33

+ $^1/_2\ Na_2CO_3$

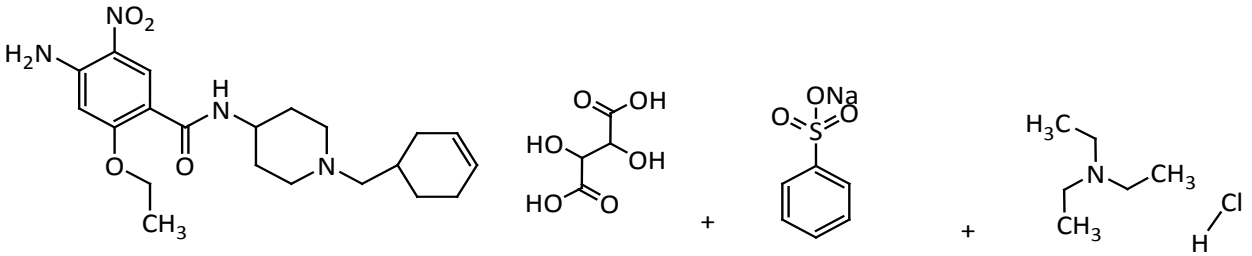
Sodium carbonate
53.00



+ Triethyl amine
101.19

+ Tartaric acid
$C_4H_6O_6$
150.09

Methanol



Cinitapride Hydrogen Tartrate
$C_{25}H_{36}N_4O_{10}$
552.57

+ Sodium benzene sulphonate
$C_6H_5NaO_3S$
180.16

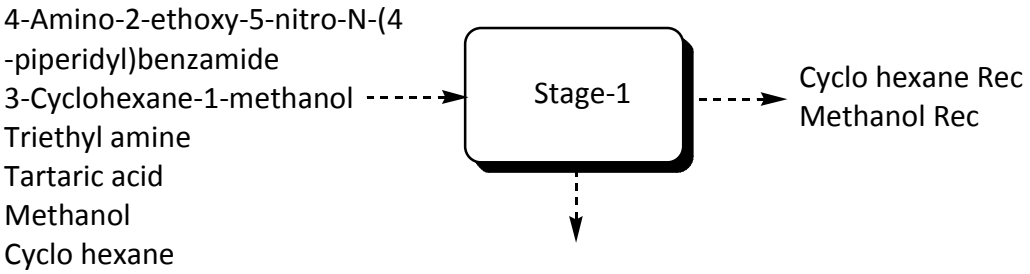
+ Triethyl amine Hydrochlorie
$C_6H_{16}ClN$
137.65

+ $^1/_2\ CO_2$ ↑ + $^1/2\ H_2O$

22.0 9.00

CINITAPRIDE HYDROGEN TARTRATE

Flow Chart



CINITAPRIDE HYDROGEN TARTRATE

Material Balance:

Material balance of Cinitapride Hydrogen Tartarate Stage-1 Batch Size:35.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
4-Amino-2-ethoxy-5nitro-N-(4-piperidyl)benzamide	19.51		Cinitapride Hydrogen Tartarate	35.00
3-Cyclohexene-1-methanol	7.10		Cyclohexane Recovery	84.20
Benzene sulfonyl chloride	11.17		Cyclohexane Loss	4.00
Sodium carbonate	3.35		DMF Recovery	189.00
TEA	24.60		DMF Loss	9.00
Tartaric acid	15.20		Methanol Recovery	222.00
Cyclohexane	88.20		Methanol Loss	11.00
DMF	198.00		Effluent water	819.54
Methanol	233.00		(Water-775,Generated water-0.56,Sodium benzene sulfonate-10.38,TEA HCl-8.7,Tartaric acid-5.7,Methanol-1,TEA-18.2)	
Activated carbon	4.00		Process Emission	1.39
Water	775.00		(Carbon dioxide)	
			Spent carbon	4.00
Total	1379.13		Total	1379.13

6. DAPOXETINE HYDROCHLORIDE

Process Description:

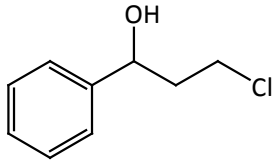
Stage-1

(S)-3-Chloro-1-phenyl propan-1-ol reacts with 1-Napthol in the presence of Di methyl amine and Isopropanol HCl in the presence of Methanol as a solvent media to give Dapoxetine Hydrochloride as product.

DAPOXETINE HYDROCHLORIDE

Route of Synthesis:

Stage -1:

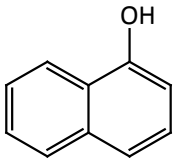


3-Chloro-1-phenyl-propan-1-ol

$C_9H_{11}ClO$

170.64

+

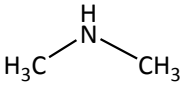


Naphthalen-1-ol

$C_{10}H_8O$

144.17

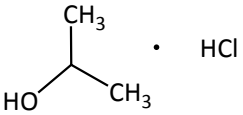
+



Dimethyl-amine

C_2H_7N

45.08

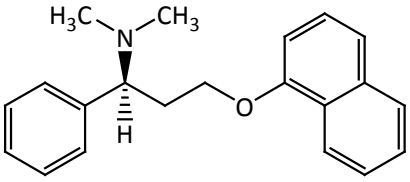


Isopropanol.HCl

C_3H_9ClO

95.56

Methanol

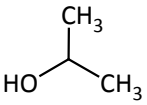


Dapoxetine Hydrochloride

$C_{21}H_{24}ClNO$

341.87

+



Isopropanol

C_3H_8O

60.10

+ HCl

Hydrochloric acid

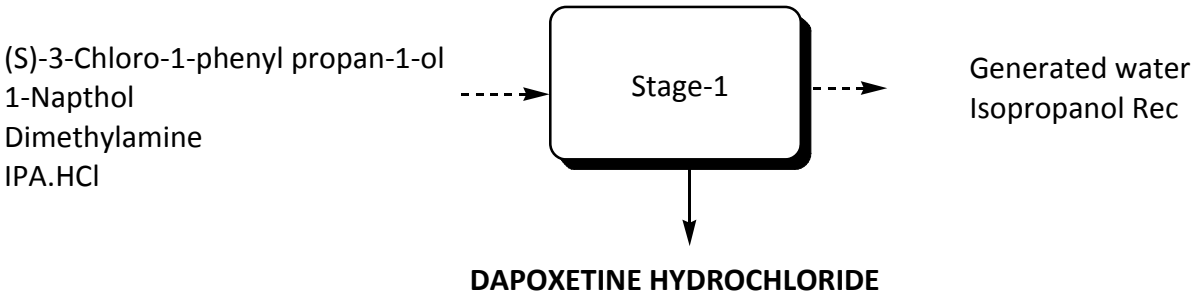
36.5

+ H_2O

18.00

DAPOXETINE HYDROCHLORIDE

Flow Chart:



DAPOXETINE HYDROCHLORIDE

Material Balance:

Material Balance of Dapoxetine Hydrochloride Stage-1 Batch Size:80.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
(S)-3-Chloro-1-phenyl propan-1-ol reacts	40.00		Dapoxetine Hydrochloride	80.00
1-Napthol	34.00		Methanol Recovery	952.20
Dimethylamine	33.00		Methanol Loss	39.80
IsopropanolHCl	55.00		Ethyl acetate Recovery	1334.75
Dimethyl sulfoxide	280.00		Ethyl acetate Loss	70.25
Potassium hydroxide	34.00		Effluent water	3350.24
Mesyl chloride	50.00		(Water-2925,Generated water-4.22,Isopropanol-34.2,Mesyl chloride-50, N,N-Dimethyl amino pyridine -0.02,HCl-20.8,DMSO-280,KOH-34,Methanol-2)	
Triethylamine	126.00		Triethylamine Recovery(For Reuse)	126.00
N,N-Dimethyl amino pyridine	0.02		Spent carbon	14.00
Methanol	995.00		Organic Residue	23.78
Ethyl acetate	1405.00		(Organic impurities-20.78, Methanol-1)	
Activated carbon	14.00			
Water	2925.00			
Total	5991.02			5991.02

7. EPALRESTAT

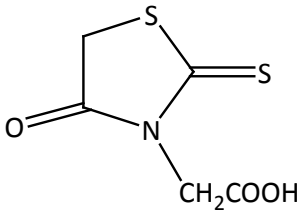
Process Description:

3-Carboxy methyl rhodanine reacts with 2-methyl cinnamaldehyde in sodium acetate, acetic acid by using DMF as solvent media to give pure Epalrestat as Product.

EPALRESTAT

Route of Synthesis:

Stage-1

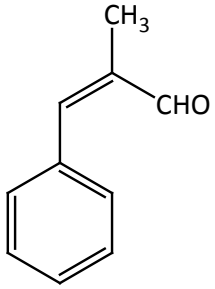


3-Carboxy methyl rhodanine

$C_5H_5NO_3S_2$

191.23

+

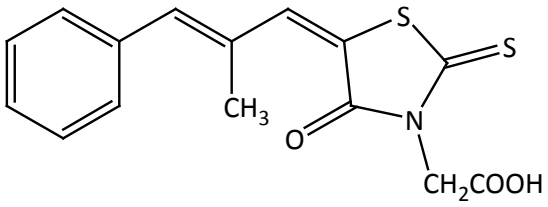


2-Methyl-3-phenyl-propenal

$C_{10}H_{10}O$

146.19

DMF →



Epalrestat

$C_{15}H_{13}NO_3S_2$

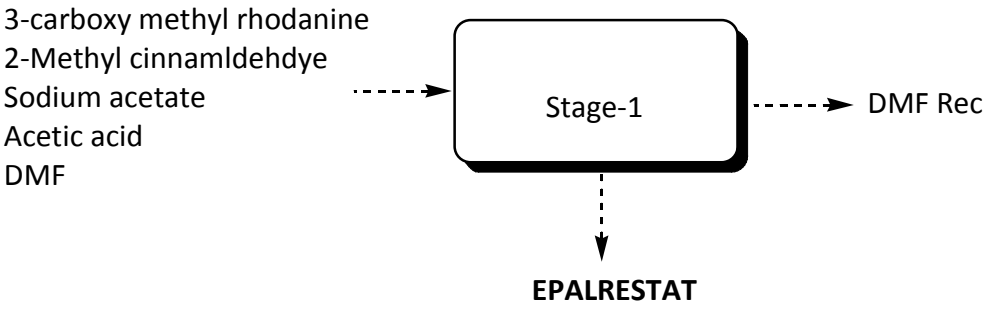
319.40

+ H_2O

18.0

EPALRESTAT

Flow Chart:



EPALRESTAT

Material Balance:

Material balance of Epalrestat Stage-1 Batch Size:120.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
3-carboxy methyl rhodanine	72.00		Epalrestat	120.00
2-Methyl cinnamldehdye	55.00		DMF Recovery	2831.00
Sodium acetate	78.00		DMF Loss	149.00
Acetic acid	797.00		Acetic acid Recovery	758.00
DMF	2981.00		Acetic acid Loss	39.00
Activated carbon	19.00		Effluent water	4376.77
Water	4291.00		(Water-4291,Generated water-6.77,DMF-1,Sodium acetate-78)	
			Spent carbon	19.00
			Organic Residue	0.23
Total	8293.00		Total	8293.00

8. ESZOPICLONE

Process Description:

Stage-1

O-Phenylenediamine reacts with glyoxal, potassium permanganate, Hydrochloric acid in presence of Toluene as a solvent media to give Stage-1 as a product.

Stage-2

Stage-1 product is condensed with 2-Amino-5-chloropyridine in Acetonitrile and cyclized in Toluene then reduced with Sodium borohydride to give Stage-2 as a product.

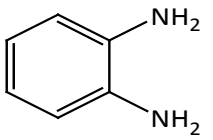
Stage-3

Stage-2 product reacts with N-Methyl piperazine and Triphosgene and Potassium chloride in presence of Isopropyl alcohol as a solvent media to give Eszopiclone as a product.

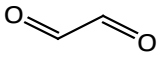
ESZOPICLONE

Route of Synthesis

Stage-1



Benzene-1,2-diamine
$C_6H_8N_2$
108.14

+ 

Glyoxal
$C_2H_2O_2$
58.04

+ 2 $KMnO_4$

Potassium permanganate
316.07

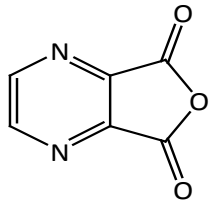
+ 2 HCl

Hydrochloric acid
73.00

+ H_2O

18.00

Toluene



Furo[3,4-*b*]pyrazine -5,7-dione
$C_6H_2N_2O_3$
150.09

+ 2 KCl

Potassium chloride
149.10

+ 2 MnO_2

Manganese dioxide
173.87

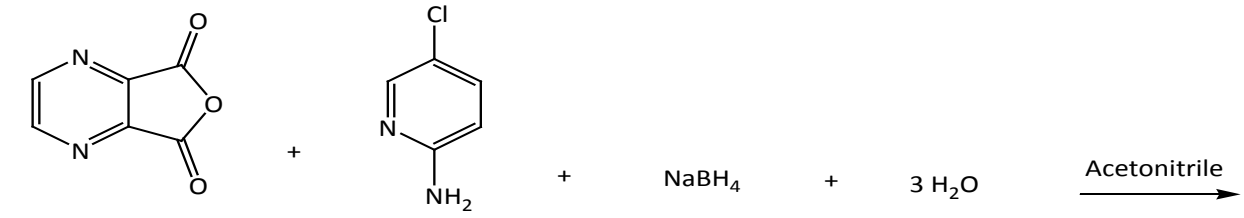
+ 2 CO_2 ↑

Carbon dioxide
88.00

+ 6 H_2 ↑

12.00

Stage-2



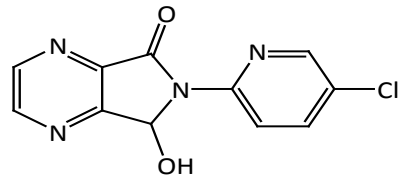
Furo[3,4-*b*]pyrazine -5,7-dione
$C_6H_2N_2O_3$
150.09

+

5-Chloro-pyridin -2-ylamine
$C_5H_5ClN_2$
128.56

+ $NaBH_4$ Sodium borohydride 37.83

+ $3\ H_2O$ 3X18=54.0



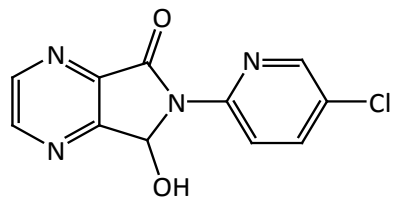
6-(5-Chloro-pyridin-2-yl)-7-hydroxy -6,7-dihydro-pyrrolo[3,4-*b*] pyrazin-5-one
$C_{11}H_7ClN_4O_2$
262.65

+ H_2O 18.00

+ $NaBO_3$ Sodium perborate 81.80

+ $4\ H_2$ ↑ 8.00

Stage-3

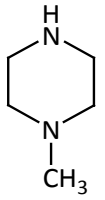


6-(5-Chloro-pyridin-2-yl)-7-hydroxy -6,7-dihydro-pyrrolo[3,4-*b*] pyrazin-5-one

$C_{11}H_7ClN_4O_2$

262.65

+

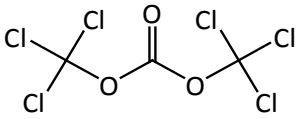


N-Methyl piperazine

$C_5H_{12}N_2$

100.16

+



Triphosgene

$C_3Cl_6O_3$

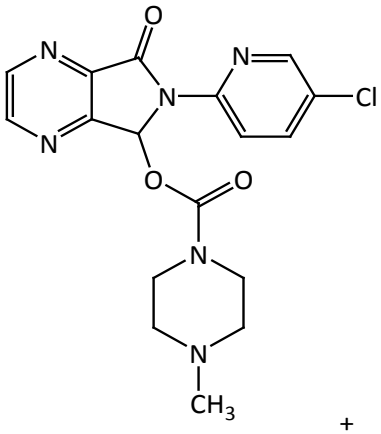
1/3X296.75=98.91

+ K_2CO_3

Potassium carbonate

138.21

Isopropyl alcohol



Eszopiclone

$C_{17}H_{17}ClN_6O_3$

388.81

+ CO_2 ↑

Carbon dioxide

44.00

+ H_2O

18.00

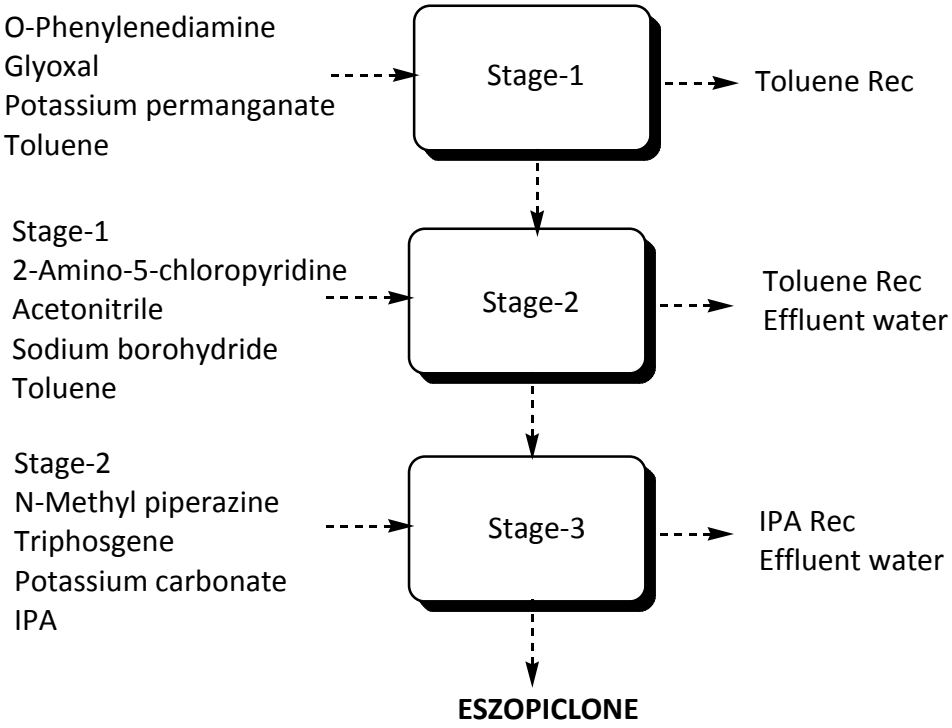
+ 2 KCl

Potassium chloride

2X74.5=149.0

ESZOPICLONE

Flow Chart



ESZOPICLONE

Material Balance:

Material balance of Eszopiclone Stage-1 Batch Size:10.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
O-Phenylene diamine	24.20		Stage-1	19.70
Glyoxal	7.60		Toluene Recovery	220.80
Potassium permanganate	158.00		Toluene Loss	9.20
Toluene	230.00		EDC Recovery	41.80
Hydrochloric acid	33.00		EDC Loss	2.20
Sodium bisulfate	35.00		Acetic anhydride Recovery	159.60
Ethylene chloride	44.00		Acetic anhydride Loss	8.40
Acetic anhydride	168.00		Effluent water	358.49
Sodium hydroxide	10.00		(Water-127.64,Potassium chloride-74.53,Manganese dioxide-86.90,HCl-23.42,Sodium bisulfate-35,,Sodium hydroxide-10,Toluene-1)	
Hyflow	2.50		Spent hyflow	2.50
Water	130.00		Process Emissions	17.52
			(Carbon dioxide-11.52,Hydrogen-6)	
			Organic Residue	2.09
Total	842.30		Total	842.30

Material balance of Eszopiclone Stage-2 Batch Size:10.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	19.70		Stage-2	10.90
2-Amino-5-Chloropyridine	16.90		Toluene Recovery	153.60
Sodium boro hydride	6.00		Toluene Loss	6.40
Hydrochloric acid	27.00		Acetonitrile Recovery	213.75
Acetic acid	1.60		Acetonitrile Loss	11.25
Acetonitrile	225.00		Chloroform Recovery	1453.50
Toluene	160.00		Chloroform Loss	76.50
Chloroform	1530.00		1,4-Dioxane Recovery	28.80
1,4-Dioxane	30.00		1,4-Dioxane Loss	1.30
Activated carbon	6.00		Effluent water	1117.86
Water	1080.00		(Water-1072.92,Generated water-2.37,Sodium per borate-12.97, HCl-27,Acetic acid-1.60,Toluene-1)	
			Spent carbon	6.00
			Process Emissions	1.26
			(Hydrogen-1.26)	
			Organic Residue	21.08
Total	3102.20		Total	3102.20

Material balance of Eszopiclone Stage-3 Batch Size:10.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2	10.90		Eszopiclone	10.00
N-Methyl piperazine	26.00		MDC Recovery	3334.50
Triphosgene	26.00		MDC Loss	175.50
Potassium carbonate	83.00		Methyl tertiary butyl ketone Recovery	183.35
Tetrabutyl ammonium bromide	1.00		Methyl tertiary butyl ketone Loss	9.65
1,4-Toluyl tartaric acid monohydrate	45.00		Methanol Recovery	410.88
Sodium hydroxide	45.00		Methanol Loss	17.12
Methylene chloride	3510.00		Acetone Recovery	779.00
Methyl tertiary butyl ketone	193.00		Acetone Loss	41.00
Methanol	428.00		Isopropyl alcohol Recovery	153.60
Acetone	820.00		Isopropyl alcohol Loss	6.40
Isopropyl alcohol	160.00		Effluent water	1085.83
Activated carbon	1.50		(Water-900,Generated water-2.36,Potassium chloride-89.47, Tetra butyl ammonium bromide-1,1,4-Toluyl tartaric acid mono hydrate-45, sodium hydroxide-45, Methanol-1,Acetone-2)	
Water	900.00		Spent carbon	1.50
			Process Emissions	26.42
			(carbon dioxide-26.42)	
			Organic Residue	14.65
Total	6249.40		Total	6249.40

9. FLUCONAZOLE

Process Description:

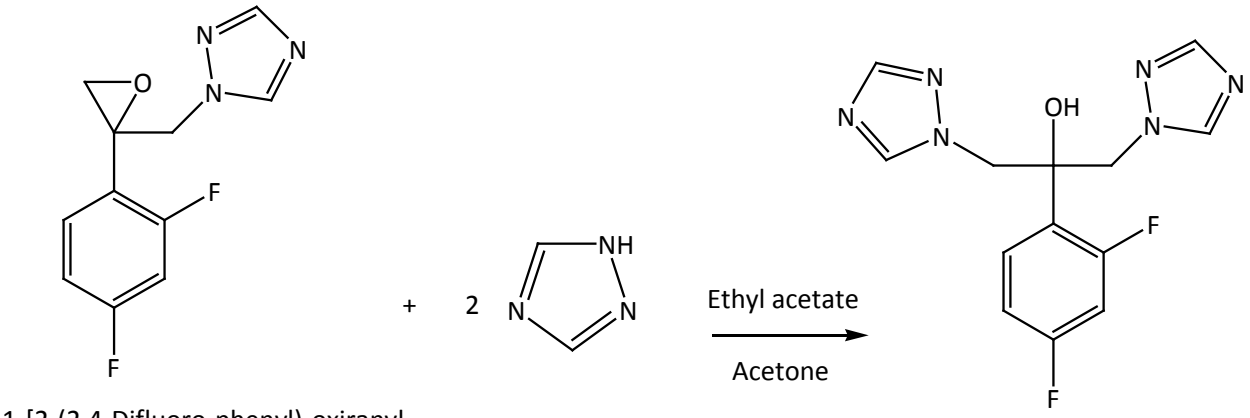
Stage-1

1-[2-(2, 4-Difluorophenyl-2, 3-epoxypropyl]-1H-[1, 2, 4] triazole is reacted with 1,2,4-triazole in the presence of Potassium carbonate, Acetone and Ethyl acetate to give Fluconazole as product.

FLUCONAZOLE

Route of Synthesis:

Stage-1



1-[2-(2,4-Difluoro-phenyl)-oxiranyl methyl]-1*H*-[1,2,4]triazole

$C_{11}H_9F_2N_3O$

237.21

1,2,4-Triazole

$C_2H_3N_3$

2X69.07=138.14

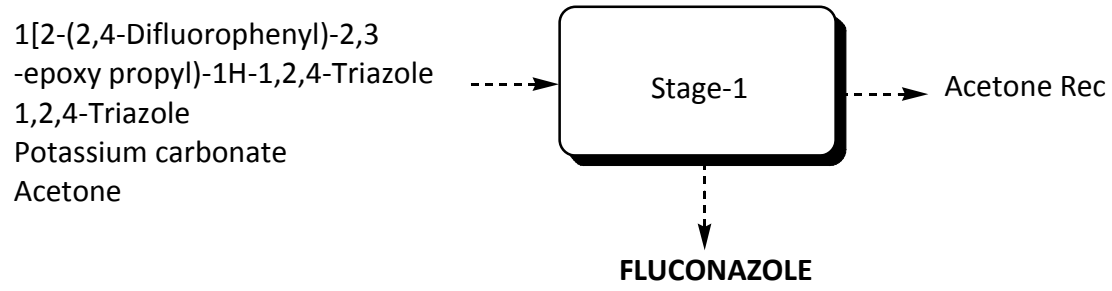
Fluconazole

$C_{13}H_{12}F_2N_6O$

306.27

FLUCONAZOLE

Flow Chart:



FLUCONAZOLE

Material Balance:

Material balance of Fluconazole Stage-1 Batch Size:100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
1[2-(2,4-Difluorophenyl)-2,3-epoxy propyl)-1H-1,2,4-Triazole	77.45		Fluconazole	100.00
1,2,4-Triazole	45.10		Acetone Recovery	600.00
Potassium carbonate	130.00		Acetone Loss	30.00
Acetone	630.00		Ethyl acetate Recovery	1023.00
Ethyl acetate	1076.00		Ethyl acetate Loss	53.00
Activated carbon	10.00		Spent carbon	10.00
			Inorganic solid waste	130.00
			(Potassium carbonate)	
			Organic Residue	22.55
Total	1968.55		Total	1968.55

10. IRON SUCROSE

Process Description:

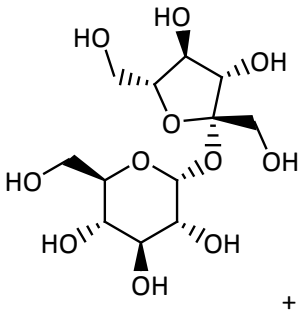
Stage-1

Ferric chloride reacts with Sucrose in presence of Sodium carbonate, Sodium hydroxide to give Iron Sucrose as a product.

IRON SUCROSE

Route of Synthesis:

Stage-1



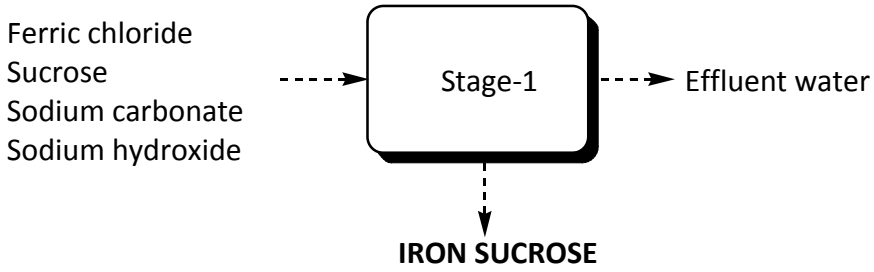
$5\ FeCl_3$	+	$2\ Na_2CO_3$	+	$10\ H_2O$	+		+	NaOH		
Ferric chloride		Sodium carbonate		10X18=180.0		Sucrose		Sodium Hydroxide		
5X162.3=811.5		2X106=212.0				$C_{12}H_{22}O_{11}$		40.0		
						342.00				

↓

$Na_2Fe_5O_8(OH)\ 3H_2OC_{12}H_{22}O_{11}$	+	3 NaCl	+	12 HCl	+	H_2O	+	$2\ CO_2$ ↑	
Iron sucrose		175.33		437.53		18.0		2X44=88.0	
866.00									

IRON SUCROSE

Flow Chart



IRON SUCROSE

Material Balance:

Material balance of Iron Sucrose Stage-1 Batch Size:100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Ferric Chloride	93.71		Iron Sucrose	100.00
Sodium carbonate	24.45		Effluent water	1722.54
Sucrose	55.00		(Water-1629.22,Sodium chloride-20.22,HCl-50.52,Generated water-2.07,Sucrose-15.51, Sodium hydroxide-5)	
Sodium hydroxide	5.00		Process Emissions	5.62
Water	1650.00		(Carbon dioxide-10.14)	
Total	1828.16		Total	1828.16

11. ITOPRIDE HYDROCHLORIDE

Process Description:

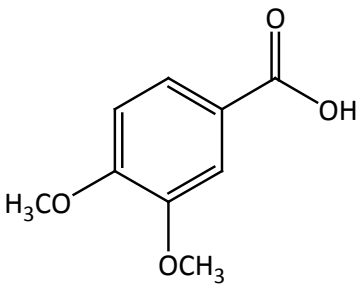
Stage-1

3, 4-Dimethoxybenzoic acid reacts with Thionyl chloride, 4-(N, N-Di methyl amino ethoxy) benzyl amine in presence of Toluene, Methanol as a solvent media to give Itopride Hydrochloride as a product**.**

ITOPRIDE HYDROCHLORIDE

Route of Synthesis

Stage-1

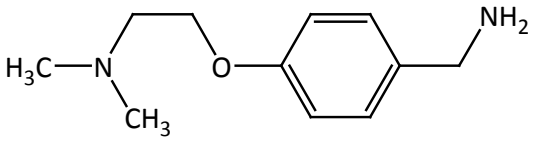


3,4-Dimethoxy
-benzoic acid
$C_9H_{10}O_4$
182.17

+ $SOCl_2$

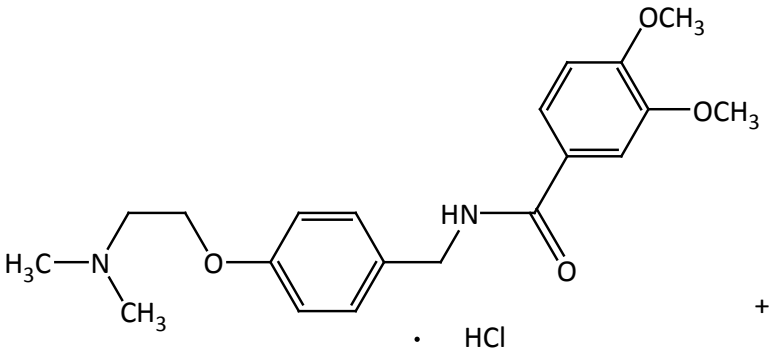
Thionyl chloride
118.97

+



[2-(4-Aminomethyl-phenoxy)
-ethyl]-dimethyl-amine
$C_{11}H_{18}N_2O$
194.27

Toluene



· HCl

N-[4-(2-Dimethylamino-ethoxy)
-benzyl]-3,4-dimethoxy-benzamide
Hydrochloride
$C_{20}H_{27}ClN_2O_4$
394.89

+ SO_2 ↑

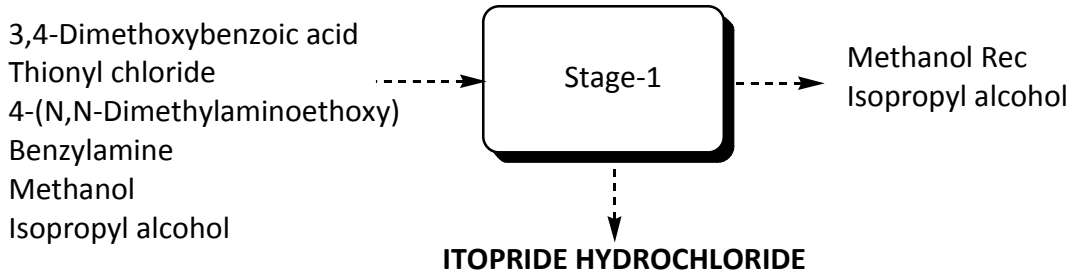
Sulphurdioxide
64.06

+ HCl

Hydrochloric
acid
36.5

ITOPRIDE HYDROCHLORIDE

Flow Chart



ITOPRIDE HYDROCHLORIDE

Material Balance:

Material balance of Itopride Hydrochloride Stage-1 Batch Size:93.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
3,4-Dimethoxybenzoic acid	42.90		Itopride Hydrochloride	93.00
Thionyl chloride	28.01		Toluene Recovery	1404.00
4-(N,N-di methyl amino ethoxy)benzyl amine	45.74		Toluene Loss	73.00
Hydrochloric acid	10.50		Chloroform Recovery	427.00
Aq.ammonia	159.00		Chloroform Loss	22.00
IPA.HCl	94.00		IPA Recovery	978.80
Toluene	1478.00		IPA Loss	47.00
Chloroform	449.00		Methanol Recovery	481.00
IPA	943.00		Methanol Loss	25.00
Methanol	506.00		Effluent water	631.29
Activated carbon	16.00		(Water-600,Hydrochloric acid-30.29,Toluene-1)	
Water	600.00		Aq. ammonia Reuse	159.00
			Spent carbon	16.00
			Process Emission	15.06
			(Sulfur dioxide)	
Total	4372.15		Total	4372.15

12. KETOROLAC TROMETHAMINE

Process Description:

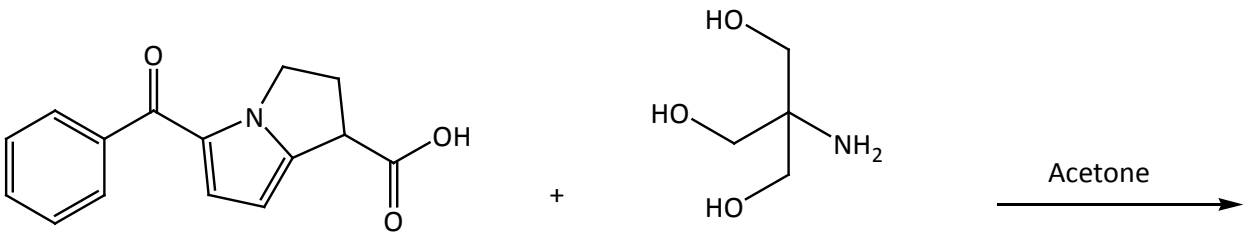
Stage-1

Ketrolac reacts with Tromethamine in presence of Acetone, Methanol to give Ketrolac tromethamine as product.

KETOROLAC TROMETHAMINE

Route of Synthesis:

Stage-1



Ketrolac

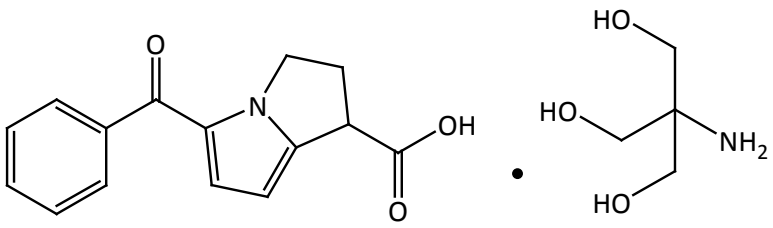
$C_{15}H_{13}NO_3$

255.27

Tromethamine

$C_4H_{11}NO_3$

121.14



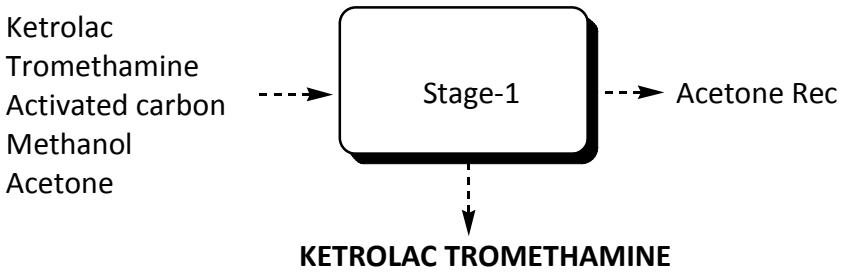
Ketrolac tromethamine

$C_{19}H_{24}N_2O_6$

376.41

KETOROLAC TROMETHAMINE

Flow Chart:



KETOROLAC TROMETHAMINE

Material Balance:

Material balance of Ketorolac tromethamine Stage-1 Batch Size:103.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Ketrolac	69.86		Ketrolac tromethamine	103.00
Tromethamine	33.14		Methanol Recovery	251.00
Activated carbon	13.00		Methanol Loss	13.00
Methanol	265.00		Acetone Recovery	2165.00
Acetone	2278.00		Acetone Loss	112.00
Water	63.00		Effluent water	65.00
			(Water-63,Methanol-1,Acetone-1)	
			Spent carbon	13.00
Total	2722.00		Total	2722.00

13. LEVOCETIRIZINE DIHYDROCHLORIDE

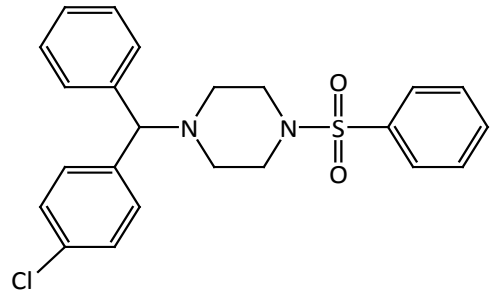
Process Description:

1-[(4-Chlorophenyl) phenyl methyl]-4-[(phenyl sulphonyl] piperazine is deprotected with 4-Hydroxy benzoic acid in Hydro bromic acid then is condensed with 2(2-Chloroethoxy acetamide) in presence of Sodium carbonate in toluene and is reacted with sodium hydroxide and Hydrochloric Acid in acetone to give Levocetrizine Di hydrochloride as product**.**

LEVOCETIRIZINE DIHYDROCHLORIDE

Route of Synthesis:

Stage-1

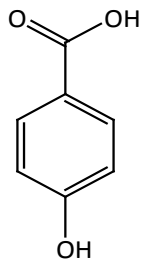


1-Benzenesulfonyl-4-[(4-chloro-phenyl)-phenyl-methyl]-piperazine

$C_{23}H_{23}ClN_2O_2S$

426.96

+

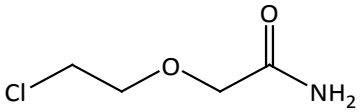


4-Hydroxy benzoic acid

$C_7H_6O_3$

138.12

+

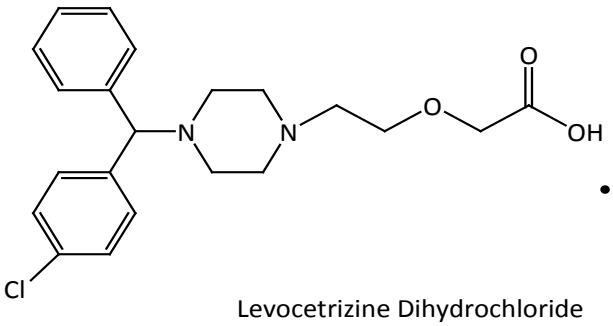


2-(2-Chloro-ethoxy)-acetamide

$C_4H_8ClNO_2$

137.56

+ Na_2CO_3 Sodium carbonate 106.0 + HBr Hydrobromic acid 80.91 + 2NaOH Sodium hydroxide 2X40=80.0 + 4HCl Hydrochloric acid 4X36.5=146.0 —Acetone→



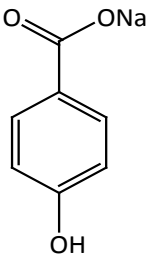
Levocetrizine Dihydrochloride

$C_{21}H_{27}Cl_3N_2O_3$

461.89

• 2 HCl

+

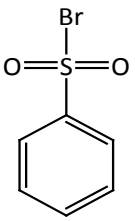


Sodium salt of 4-Hydroxy benzoic acid

$C_7H_5NaO_3$

160.10

+



Benzene sulfonyl bromide

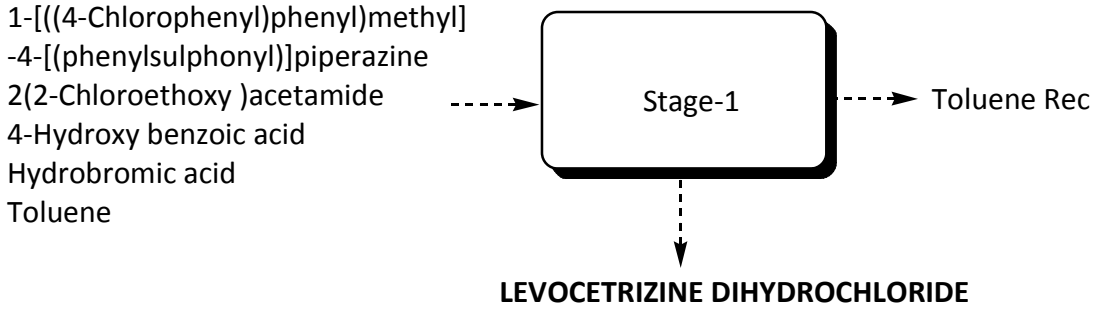
$C_6H_5BrO_2S$

221.07

+ 2NaCl 2X58.5=117.0 + $NaHCO_3$ 84.01 + NH_4Cl 53.49 + H_2O 18.0

LEVOCETIRIZINE DIHYDROCHLORIDE

Flow Chart:



LEVOCETIRIZINE DIHYDROCHLORIDE

Material Balance:

Material balance of Levocetirizine Dihydrochloride Stage-1 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
1-[((4-Chlorophenyl)phenyl)methyl]-4-[(phenylsulphonyl)]piperazine	46.20		Levocetirizine Dihydrochloride	50.00
2(2-Chloroethoxy)acetamide	14.90		Toluene Recovery	1440.00
4-Hydroxy benzoic acid	16.00		Toluene Loss	75.00
Hydrobromic acid	8.80		MDC Recovery	1767.00
Sodium hydroxide	8.70		MDC Loss	93.00
Hydrochloric acid	15.80		Acetone Recovery	442.00
Sodium carbonate	11.50		Acetone Loss	23.00
Potassium iodide	1.70		Effluent water	2302.24
Toluene	1515.00		(Water-2270,Generated water-1.94,Sodium chloride-12.7, Sodium bicarbonate-9.11, Ammonium chloride-5.79, Potassium Iodide-1.7,Toluene-1)	
MDC	1860.00		Spent carbon	4.00
Acetone	465.00		By-Product	41.36
Activated carbon	4.00		(Sodium salt of 4-Hydroxy benzoic acid-18.54,Benzene sulfonyl bromide-22.82)	
Water	2270.00			
Total	6237.60		Total	6237.60

14. LEVOSULPRIDE

Process Description:

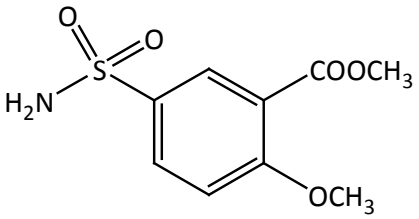
Stage-1

Methyl-2-methoxy-5-sulfamoyl benzoate is reacted with 1-ethyl-2-amino methyl pyrrolidine in ethylene glycol, Methanol and Activated carbon to give Levosulpride as product.

LEVOSULPRIDE

Route of Synthesis:

Stage-1

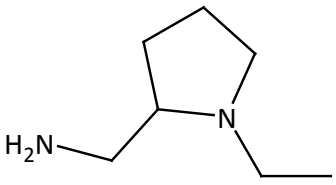


2-Methoxy-5-sulfamoyl
-benzoic acid methyl ester

$C_9H_{11}NO_5S$

245.25

+

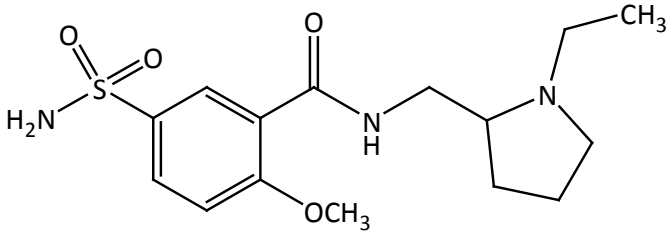


1-Ethyl-2-aminomethyl
pyrrolidine

$C_7H_{16}N_2$

128.22

Methanol



Levosulpride

$C_{15}H_{23}N_3O_4S$

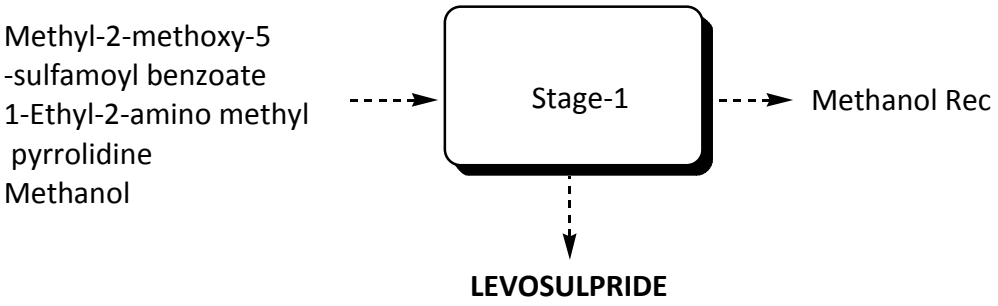
341.43

+ CH_3OH

32.0

LEVOSULPRIDE

Flow Chart:



LEVOSULPRIDE

Material Balance:

Material balance of Levosulpride Stage-1 Batch Size:136.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Methyl-2-methoxy-5-sulfamoyl benzoate	97.68		Levosulpride	136.00
1-Ethyl-2-amino methyl pyrrolidine	51.06		Ethylene glycol Recovery	276.00
Ethylene glycol	290.00		Ethylene glycol Loss	14.00
Methanol	1900.00		Methanol Recovery	1817.74
Activated carbon	5.00		Methanol Loss	95.00
			Spent carbon	5.00
Total	2343.74		Total	2343.74

15. LINEZOLID

Process Description:

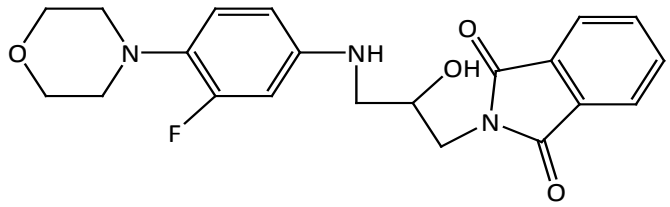
Stage-1:

N-[3-pthalimido-2R-Hydroxy propyl]-3-(fluoro-4-morpholinyl) aniline is treated with carbonyl diimidazole, Hydrazine hydrate and acetic anhydride in the presence of MDC and Methanol to give Linezolid as product.

LINEZOLID

Route of Synthesis:

Stage-1

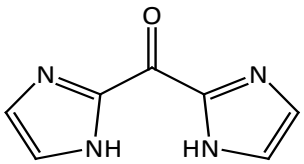


2-[3-(3-Fluoro-4-morpholin-4-yl-phenylamino) -2-hydroxy-propyl]-isoindole-1,3-dione

$C_{21}H_{22}FN_3O_4$

399.42

+

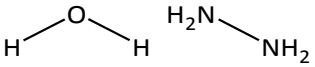


Carbonyl diimidazole

$C_7H_6N_4O$

162.15

+

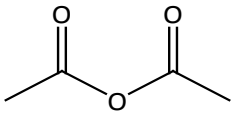


Hydrazine hydrate

H_6N_2O

50.06

+

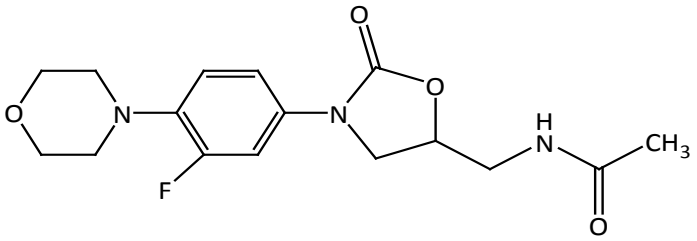


Acetic anhydride

$C_4H_6O_3$

102.09

MDC

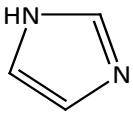


Linezolid

$C_{16}H_{20}FN_3O_4$

337.35

+ 2



Imidazole

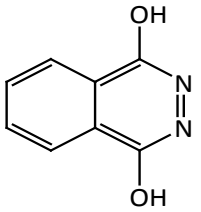
$C_3H_4N_2$

2X68.08=136.16

+ CH_3COOH

60.0

+



Phthalazine -1,4-diol

$C_8H_6N_2O_2$

162.15

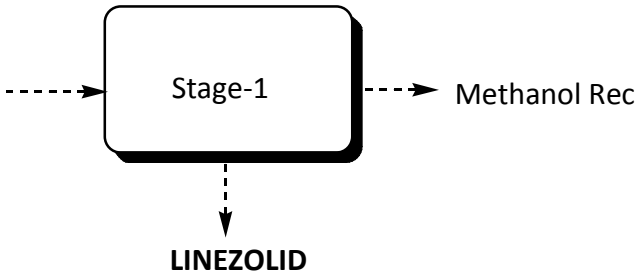
+ H_2O

18.0

LINEZOLID

Flow Chart:

N-[3-Phthalimido-2R-hydroxy propyl-3-fluoro-4-morpholinyl aniline
Carbonyl diimidazole
Hydrazine Hydrate
Methanol



LINEZOLID

LINEZOLID

Material Balance:

Material balance of Linezolid Stage-1 Batch Size:90.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
N-[3-Phthalimido-2R-hydroxypropyl-3-fluoro-4-morpholinyl aniline	106.55		Linezolid	90.00
Carbonyl di imidazole	43.25		Methanol Recovery	715.00
Hydrazine Hydrate	13.35		Methanol Loss	37.00
Acetic anhydride	27.23		MDC Recovery	2548.00
Methanol	753.00		MDC Loss	134.00
MDC	2682.00		Ethyl acetate Recovery	765.00
Activated carbon	10.80		Ethyl acetate Loss	40.00
Ethyl acetate	805.00		Acetone Recovery	1471.00
Acetone	1548.00		Acetone Loss	77.00
Water	1422.00		Effluent water	1523.38
			(Water-1422,Generated water-4.8,Acetic acid-16,Phthalazine-1,4-diol-43.25,Methanol-1,Imidazole-36.33)	
			Spent carbon	10.80
Total	7411.18		Total	7411.18

16. MOSAPRIDE CITRATE DIHYDRATE

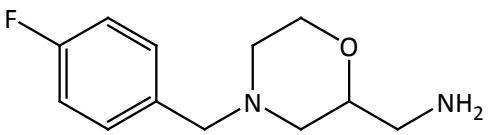
Process Description:

2-Amino methyl-4-(4-fluorobenzyl0morpholine is condensed with 4-amino-5-chloro-2-ethoxy benzoic acid in presence of Triethyl amine in Ethyl chloro formate and MDC then is purified with Methanol and is reacted with citric acid to give Mosapride Citrate Dihydrate as product.

MOSAPRIDE CITRATE DIHYDRATE

Route of Synthesis:

Stage-1

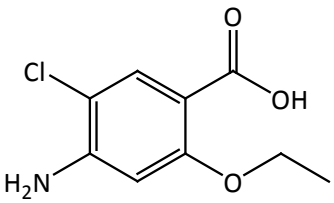


C-[4-(4-Fluoro-benzyl)-morpholin-2-yl]-methylamine

$C_{12}H_{17}FN_2O$

224.27

+

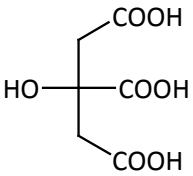


4-Amino-5-chloro-2-ethoxy -benzoic acid

$C_9H_{10}ClNO_3$

215.63

+



Citric acid

$C_6H_8O_7$

192.12

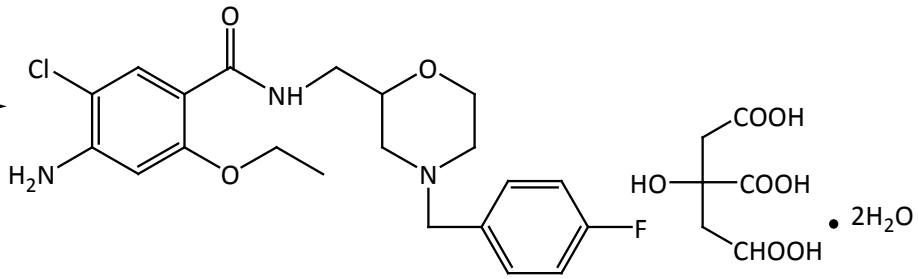
+ H_2O

Water

18.0

MDC

Acetone



Mosapride Citrate Dihydrate

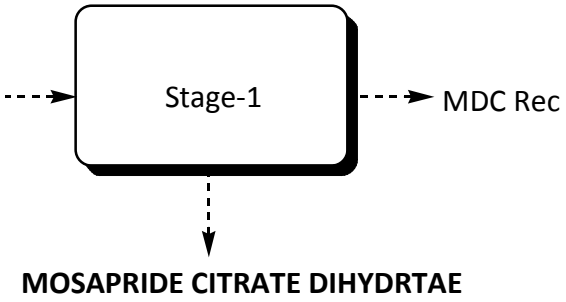
$C_{27}H_{37}ClFN_{312}$

650.01

MOSAPRIDE CITRATE DIHYDRATE

Flow Chart:

2-Amino methyl-4-(4-fluoro benzyl)morpholine
4-Amino-5-chloro-2-ethoxy benzoic acid
Citric acid
MDC



MOSAPRIDE CITRATE DIHYDRTAE

MOSAPRIDE CITRATE DIHYDRATE

Material Balance:

Material balance of Mosapride citrate dihydrate Stage-1 Batch Size:75.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
2-Amino methyl-4-(4-fluorobenzyl)morpholine	25.87		Mosapride citrate dihydrate	75.00
4-Amino-5-chloro-2-ethoxy benzoic acid	24.87		MDC Recovery	1772.00
Citric acid	22.16		MDC Loss	93.00
Ethyl chloro formate	19.00		Acetone Recovery	224.00
TEA	33.00		Acetone Loss	11.00
MDC	1865.00		Methanol Recovery	199.00
Acetone	235.00		Methanol Loss	10.00
Methanol	210.00		Effluent water	2285.90
Activated Carbon	16.00		(Water-2232.9,TEA-33,Ethyl chloroformate-19,Methanol-1)	
Water	2235.00		Spent carbon	16.00
Total	4685.90		Total	4685.90

17. ONDANSETRON HYDROCHLORIDE DIHYDRATE

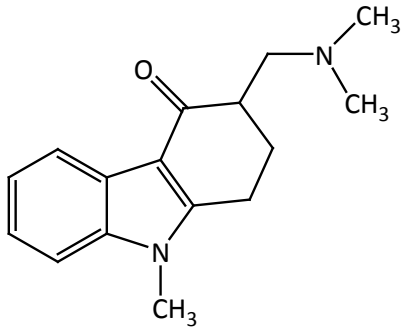
Process Description:

3-Dimethylaminomethyl-9-methyl-1, 2, 3, 9-tertahydro-carbazol-4-one reacts with 2-methyl imidazole, Hydrochloric acid in the presence of Methanol as solvent media to give Ondansetron Hydrochloride Di hydrate as product**.**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Route of Synthesis:

Stage-1

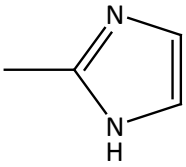


3-Dimethylaminomethyl-9-methyl-1,2,3,9-tetrahydro-carbazol-4-one

$C_{16}H_{20}N_2O$

256.34

+



2-Methyl imidazole

$C_4H_6N_2$

82.10

+ HCl

Hydrochloric acid

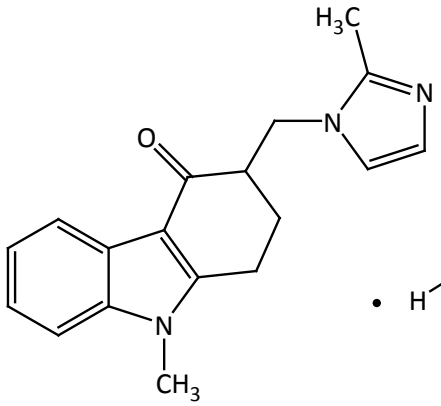
36.5

+ $2H_2O$

Water

2X18=36.0

Methanol



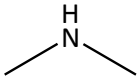
Ondansetron Hydrochloride Dihydrate

$C_{18}H_{24}ClN_3O_3$

365.86

•  • $2H_2O$

+



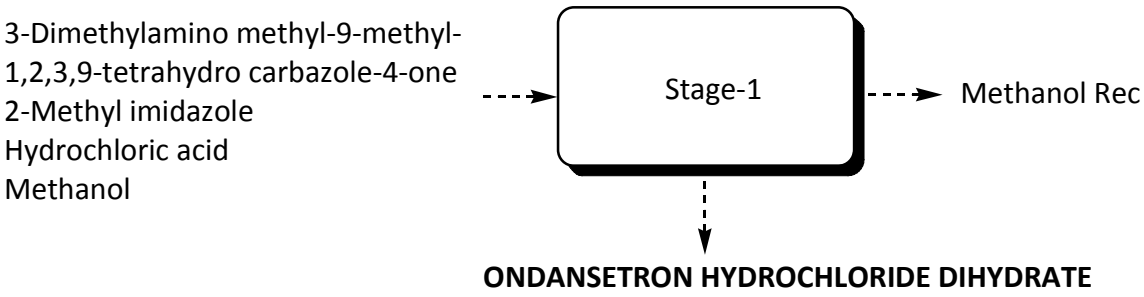
Dimethyl amine

C_2H_7N

45.08

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Flow Chart:



ONDANSETRON HYDROCHLORIDE DIHYDRATE

Material Balance:

Material balance of Ondansetron Hydrochloride Dihydrate Stage-1 Batch Size:15.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
3-Dimethylamino methyl-9-methyl-1,2,3,9-tetrahydro carbazole-4-one	10.50		Ondansetron Hydrochloride Dihydrate	15.00
2-Methyl imidazole	4.00		Methanol Recovery	68.00
Hydrochloric acid	6.40		Methanol Loss	3.00
Methanol	72.00		Effluent water	628.27
Activated carbon	22.50		(Water-620.53,Dimethyl amine-1.84,Hydrochloric acid-4.9, Methanol-1)	
Water	622.00		Spent carbon	22.50
			Organic Residue	0.63
Total	737.40		Total	737.40

18. PREGABALIN

Process Description:

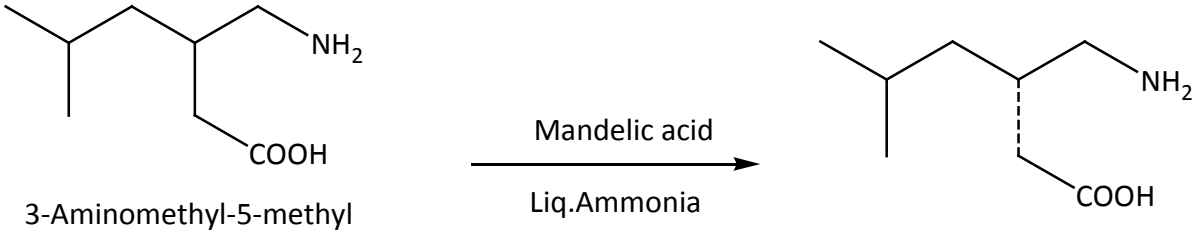
Stage-1

3-(Amino methyl)-5-methyl hexanoic acid reacts with Mandelic acid and with Liq. Ammonia to give Pregabalin as product.

PREGABALIN

Route of Synthesis:

Stage-1



3-Aminomethyl-5-methyl -hexanoic acid

$C_8H_{17}NO_2$

159.23

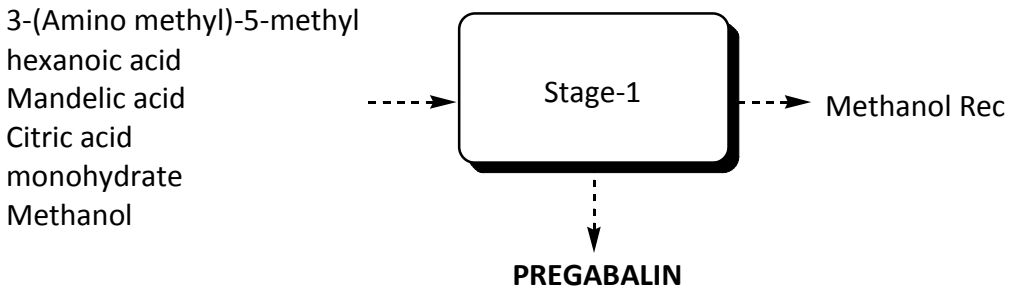
Pregabalin

$C_8H_{17}NO_2$

159.23

PREGABALIN

Flow Chart:



PREGABALIN

Material Balance:

Material balance of Pregabalin Stage-1 Batch Size:95.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
3-(Amino methyl)-5-methyl hexanoic acid	99.10		Pregabalin	95.00
Mandelic acid	129.10		Methanol Recovery	1390.00
Liq. Ammonia	14.60		Methanol Loss	73.00
Citric acid monohydrate	74.60		Mandelic acid Recovery & Reuse	129.10
Methanol	1464.00		Effluent water	1511.80
Activated carbon	8.00		(Water-1421.6,Citric acid monohydrate-74.6,Liq-Ammonia-14.6,Methanol-1)	
Water	1421.60		Spent carbon	8.00
			Organic Residue	4.10
Total	3211.00		Total	3211.00

19. RACECADOTRIL

Process Description:

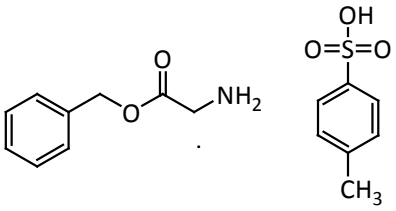
Stage-1

2-Benzylacryloyl chloride is reacted with Glycine benzyl ester-p-tosylate,Triethylamine and Thioacetic acid to give Racecadotril (Pharma) as product.

RACECADOTRIL

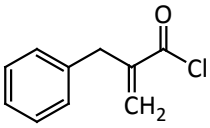
Route of Synthesis:

Stage-1:



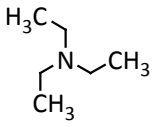
Glycine benzyl ester
p-tosylate
$C_{16}H_{19}NO_5S$
337.39

+



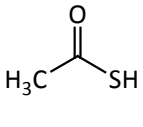
2-Benzyl-acryloyl chloride
$C_{10}H_9ClO$
180.63

+



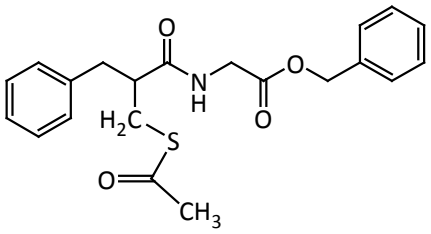
Triethyl amine
$C_6H_{15}N$
101.19

+



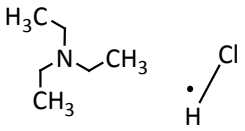
Thioacetic acid
C_2H_4OS
76.12

Toluene



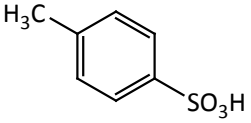
Racecadotril(Pharma)
$C_{21}H_{23}NO_4S$
385.48

+



Triethyl amine
Hydrochloride
$C_6H_{16}ClN$
137.65

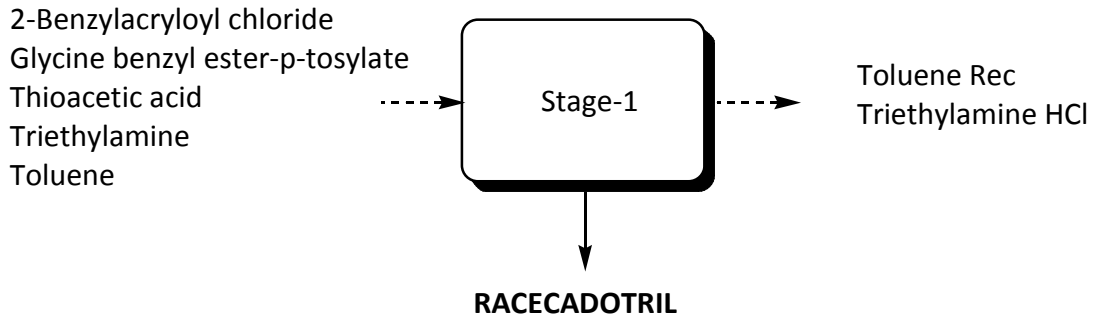
+



P-Toluene sulfonic acid
$C_7H_8O_3S$
172.20

RACECADOTRIL

Flow Chart:



RACECADOTRIL

Material Balance:

Material Balance of Racecadotril Stage-1 Batch Size: 80.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
2-Benzylacryloyl chloride	58.00		Racecadotril	80.00
Glycine benzyl ester-p-tosylate	70.00		Isopropyl alcohol Recovery	1073.50
Thioacetic acid	30.00		Isopropyl alcohol Loss	56.50
Triethylamine	100.00		Toluene Recovery	364.80
Sodium bicarbonate	16.00		Toluene Loss	15.20
Hydrochloric acid	6.50		n-Hexane Recovery	460.80
Isopropyl alcohol	1130.00		n-Hexane Loss	19.20
n-Hexane	480.00		Methanol Recovery	978.50
Toluene	380.00		Methanol Loss	51.50
Methanol	1030.00		Effluent water	1497.32
Activated carbon	10.00		(Water-1300,Triethylamine HCl-136.10,p-Toluene sulfonic acid-35.72,Sodium bicarbonate-16, HCl-6.5,Toluene-1,Methanol-2)	
Water	1300.00		Spent carbon	10.00
			Organic Residue	3.18
Total	4610.50		Total	4610.50

20. TAMSULOSIN HYDROCHLORIDE

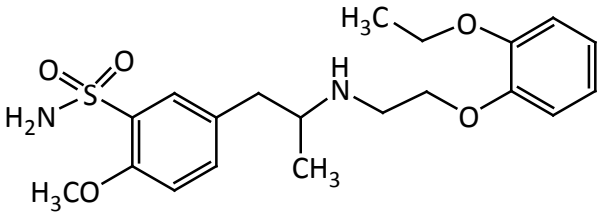
Process Description:

(R)-5-[[2-(2-Ethoxy phenoxy) ethyl) amino] propyl]-2-methoxy benzene reacts with hydrochloric acid in the presence of methanol as solvent media to give Tamsulosin Hydrochloirde as product.

TAMSULOSIN HYDROCHLORIDE

Route of Synthesis:

Stage-1:



+ HCl —Methanol→

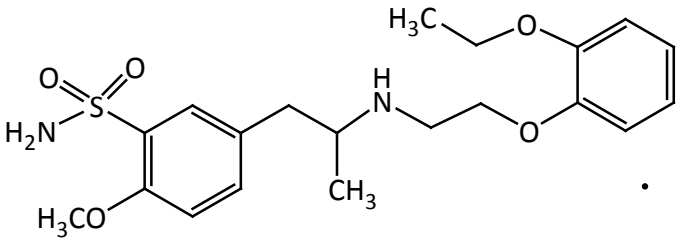
5-{2-[2-(2-Ethoxy-phenoxy)-ethylamino]-propyl}-2-methoxy-benzenesulfonamide

$C_{20}H_{28}N_2O_5S$

408.51

Hydrochloric acid

36.5



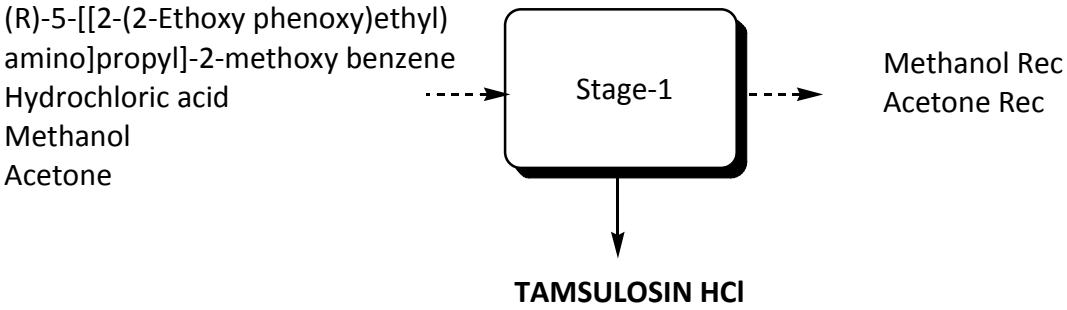
Tamsulosin hydrochloride

$C_{20}H_{28}N_2O_5S \bullet HCl.$

444.98

TAMSULOSIN HYDROCHLORIDE

Flow Chart:



TAMSULOSIN HYDROCHLORIDE

Material Balance:

Material Balance of Tamsulosin Hydrochloride Stage-1 Batch Size: 20.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
(R)-5-[[2-(2-Ethoxy phenoxy) ethyl)amino]propyl]-2-methoxy benzene	19.30		Tamsulosin Hydrochloride	20.00
Hydrochloric acid	13.30		Methanol Recovery	182.40
Methanol	190.00		Methanol Loss	7.60
Acetone	310.00		Acetone Recovery	294.50
Water	22.00		Acetone Loss	15.50
			Effluent water	34.37
			(Water-22,Hydrochloric acid-10.37, Methanol-1,Acetone-1)	
			Organic Residue	0.23
Total	554.60		Total	554.60

21. TIZANIDINE HYDROCHLORIDE

Process Description:

Stage-1

4-Amino-5-chloro-2, 1, 3-benzothiadiazole is condensed with 1-acetyl imidazolin-2-one reacts with phosphorous oxychloride and sodium hydroxide in water to give stage-1 as product.

Stage-2

Stage-1 product reacts with Hydrochloric acid in methanol to give Stage-2 as product.

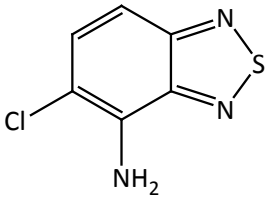
Stage-3

Stage-2 product is purified by methanol,caron to give Pure Tizianidine Hydrochloride as product.

TIZANIDINE HYDROCHLORIDE

Route of Synthesis:

Stage-1

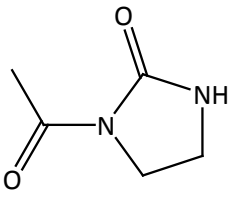


5-Chloro-benzo[1,2,5]thiadiazol-4-ylamine

$C_6H_4ClN_3S$

185.63

+



1-Acetyl-imidazolidin-2-one

$C_5H_8N_2O_2$

128.13

+ $POCl_3$

Phosphorous oxychloride

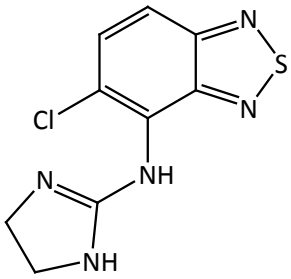
153.33

+ 4NaOH

Sodium hydroxide

4X40=160.0

Water



Tizianidine

$C_9H_8ClN_5S$

253.71

+ CH_3COOH

60.0

+ 3NaCl

3X58.5=175.5

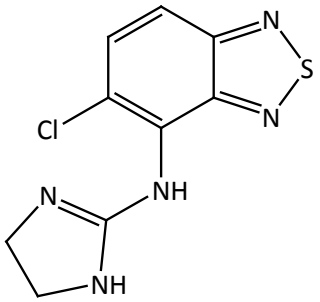
+ NaH_2PO_4

119.98

+ H_2O

18.0

Stage-2



Tizianidine

$C_9H_8ClN_5S$

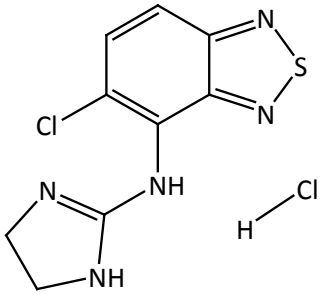
253.71

\+ HCl

Hydrochloric acid

36.50

Methanol

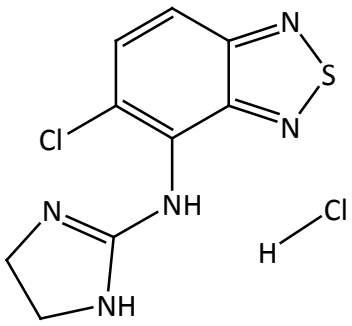


Tizianidine Hydrochloride (Crude)

$C_9H_9Cl_2N_5S$

290.21

Stage-3



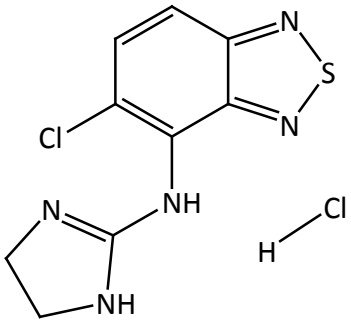
Tizianidine Hydrochloride (Crude)

$C_9H_9Cl_2N_5S$

290.21

Methanol

Water



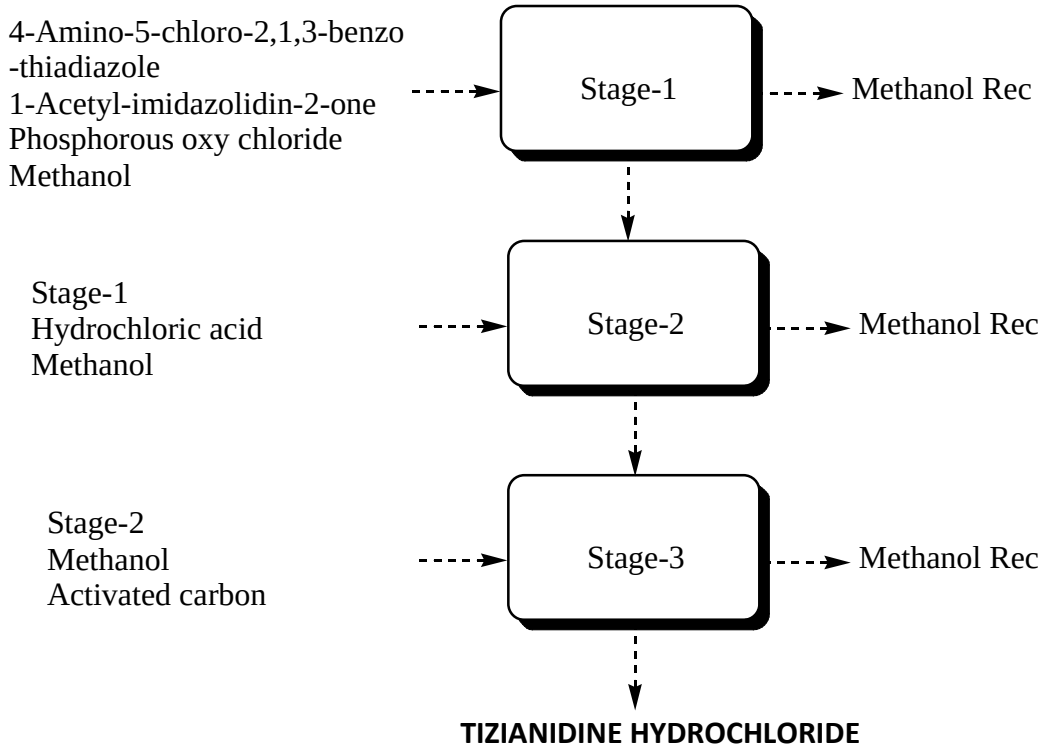
Tizianidine Hydrochloride (Pure)

$C_9H_9Cl_2N_5S$

290.21

TIZANIDINE HYDROCHLORIDE

Flow Chart:



TIZANIDINE HYDROCHLORIDE

Material Balance:

Material balance of Tizianidine Hydrochloride Stage-1 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
4-Amino-5-chloro-2,1,3-benzo-thiadiazole	75.00		Stage-1	102.50
1-Acetyl-imidazolidin-2-one	52.00		Methanol Recovery	4360.00
Phosphorous oxy chloride	62.00		Methanol Loss	229.00
Sodium hydroxide	65.00		Effluent water	5232.50
Methanol	4590.00		(Water-5080,Generated water-7.3,Acetic acid-24.3,Sodium chloride-71.5,Sodium di hydrogen phosphate-48.4,Methanol-1)	
Activated carbon	115.00		Spent carbon	115.00
Water	5080.00			
Total	10039.00		Total	10039.00

Material balance of Tizianidine Hydrochloride Stage-2 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	102.50		Stage-2	117.30
Hydrochloric acid	14.80		Methanol Recovery	332.00
Methanol	350.00		Methanol Loss	17.00
Water	50.00		Effluent water	51.00
			(Water-50,Methanol-1)	
Total	517.30		Total	517.30

Material balance of Tizianidine Hydrochloride Stage-3 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2	177.30		Tizianidine Hydrochloride	153.00
Methanol	590.00		Methanol Recovery	549.00
Activated carbon	40.00		Methanol Loss	29.00
Water	320.00		Effluent water	321.00
			(Water-320,Methanol-1)	
			Spent carbon	40.00
			Organic Residue	35.30
Total	1127.30		Total	1127.30

22. TOPIRAMATE

Process Description

Stage-1

(D)-Fructose reacts with Acetone in presence of in presence of Sulfuric acid Isopropyl alcohol and n-Hexane as a solvent media to give Stage-1 as a product.

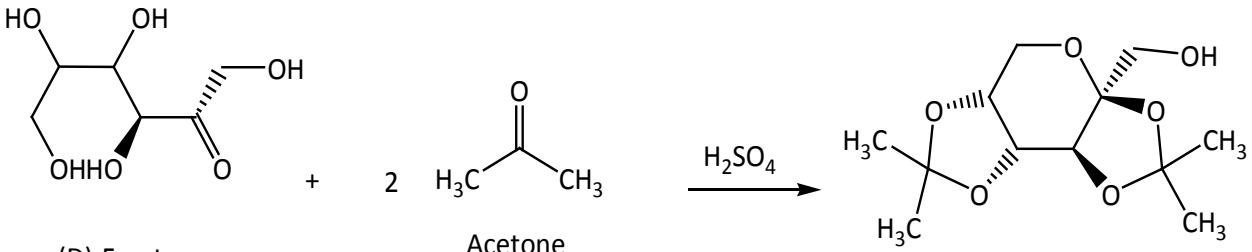
Stage-2

Stage-1 product reacts with Sulfuryl chloride and further reacts with Ammonia in presence of Ethyl acetate as a solvent media to give Topiramate as a product.

TOPIRAMATE

Route of Synthesis

Stage-1



(D)-Fructose

$C_6H_{12}O_6$

180.16

Acetone

C_3H_6O

2X58.08=116.16

2,2,7,7-Tetramethyl-tetrahydro -bis[1,3]dioxolo[4,5-b;4',5'-d] pyran-3a-yl)-methanol

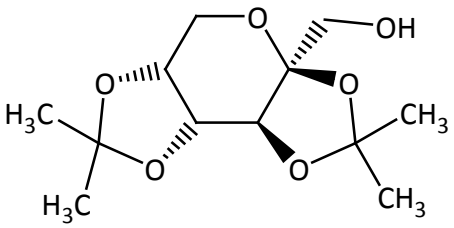
$C_{12}H_{20}O_6$

260.28

+ 2 H_2O

2X18=36.00

Stage-2

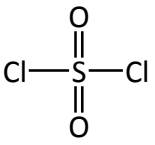


2,2,7,7-Tetramethyl-tetrahydro -bis[1,3]dioxolo[4,5-b;4',5'-d] pyran-3a-yl)-methanol

$C_{12}H_{20}O_6$

260.28

+



Sulfuryl chloride

134.97

+ NH_3 ↑ +

Ammonia

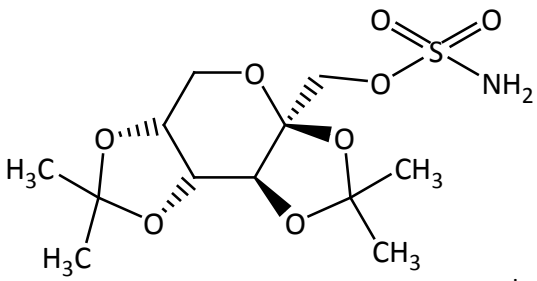
17.03

NaOH

Sodium hydroxide

40.00

Ethyl acetate



Topiramate

$C_{12}H_{21}NO_8S$

339.36

+

NaCl

Sodium chloride

58.44

+ HCl

Hydrochloric acid

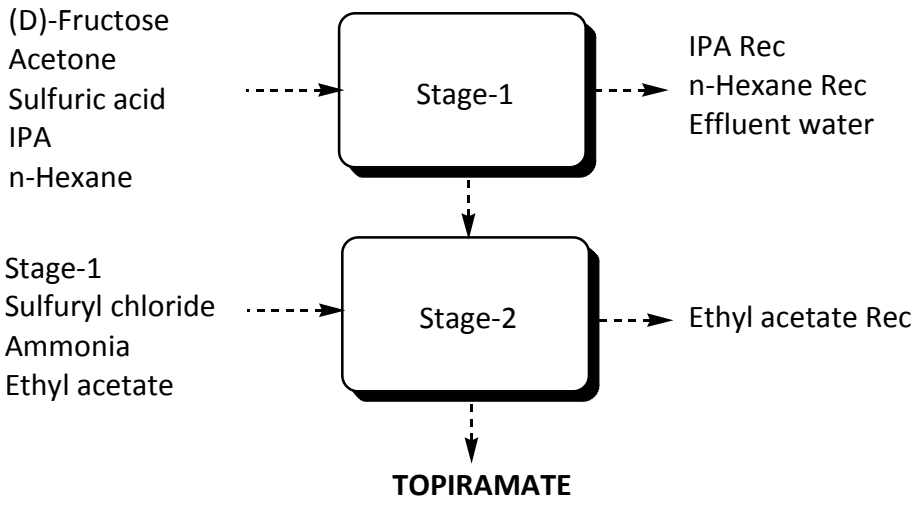
36.5

+ H_2O

18.00

TOPIRAMATE

Flow Chart



TOPIRAMATE

Material Balance:

Material Balance of Topiramate Stage-1 Batch Size: 25.0Kgs				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
D-Fructose	50.00		Stage-1	50.00
Acetone	317.00		Isopropyl alcohol Recovery	11.00
Sulfuric acid	55.00		Isopropyl alcohol Loss	1.00
Sodium hydroxide	38.00		n-Hexane Recovery	79.00
Isopropyl alcohol	12.00		n-Hexane Loss	4.00
n-Hexane	83.00		Sulfuric acid Re use	55.00
Water	38.00		Effluent water	85.99
			(Water-38,Generated water-9.99, Sodium hydroxide-38)	
			Organic Residue	22.54
			Acetone Recovery	284.47
Total	593.00		Total	593.00

Material Balance of Topiramate Stage-2 Batch Size: 25.0Kgs				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	50.00		Topiramate	25.00
Sulfuryl chloride	53.00		Ethyl acetate Recovery	256.00
Ammonia	3.26		Ethyl acetate Loss	14.00
Sodium hydroxide	20.00		Toluene Recovery	1652.00
Pyridine	34.00		Toluene Loss	87.00
Citric acid	25.00		MDC Recovery	632.00
Sodium carbonate	25.00		MDC Loss	33.00
Hydrochloric acid	19.00		IPA Recovery	108.00
MDC	665.00		IPA Loss	6.00
Toluene	1740.00		Pyridine Recovery	34.00
Ethyl acetate	270.00		Effluent water	2078.75
IPA	115.00		(Water-1950,Generated water-0.21,Citric acid-25,Sodium carbonate-25,Hydrochloric acid-26,Sulfuryl chloride-27,Sodium hydroxide-12.3,Sodium chloride-11.24,Toluene-1,IPA-1)	
Activated carbon	4.00		Spent carbon	4.00
Water	1950.00		Organic Residue	43.51
Total	4973.26		Total	4973.26

23. ZOPICLONE

Process Description:

Stage-1

O-Phenylene diamine reacts with glyoxal, potassium permanganate, Hydrochloric acid and water in the presence of Toluene as solvent media to give Stage-1 as product.

Stage-2

Stage-1 product condensed with 2-Amino-5-chloropyridine in acetonitrile and cyclized in Toluene then reduced with sodium borohydride and water to give Stage-2 as product.

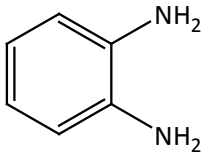
Stage-3

Stage-2 product recats with N-Methyl piperazine and Triphogene in MDC in the presence of Potassium carbonate in MDC to give Zopiclone as product.

ZOPICLONE

Route of Synthesis:

Stage-1

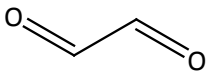


O-Phenylene Diamine

$C_6H_8N_2$

108.14

+



Glyoxal

$C_2H_2O_2$

58.04

+ $2KMNO_4$

Potassium permangnate

2X158=316.0

+ 2HCl

Hydrochloric acid

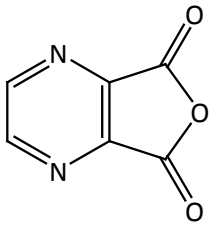
2X36.5=73.0

+ H_2O

Water

18.0

Toluene



Furo[3,4-*b*]pyrazine-5,7-dione

$C_6H_2N_2O_3$

150.09

+ 2 KCl

2X74.55=149.10

+ $2MnO_2$

2X86.94=173.88

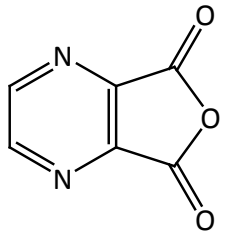
+ $2CO_2$ ↑

2X44=88.0

+ $6H_2$ ↑

12.0

Stage-2

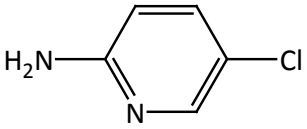


Furo[3,4-*b*]pyrazine-5,7-dione

$C_6H_2N_2O_3$

150.09

+



2-Amino-5-chloro pyridine

$C_5H_5ClN_2$

128.56

+ $NaBH_4$

Sodium borohydride

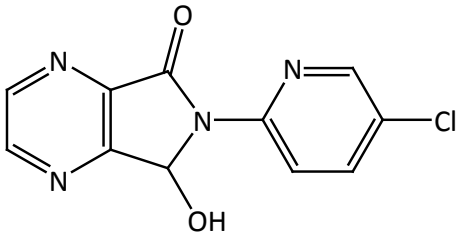
37.83

+ $2H_2O$

Water

2X18=36.0

Acetonitrile



6-(5-Chloro-pyridin-2-yl)-7-hydroxy-6,7-dihydro-pyrrolo[3,4-*b*]pyrazin-5-one

$C_{11}H_7ClN_4O_2$

262.65

+ $NaBO_3$

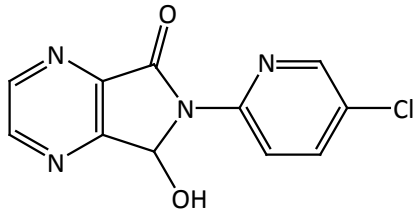
Sodium perborate

81.80

+ $4H_2\uparrow$

4X2=8.0

Stage-3

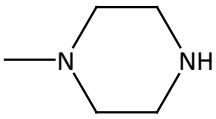


6-(5-Chloro-pyridin-2-yl)-7-hydroxy-6,7-dihydro-pyrrolo[3,4-*b*]pyrazin-5-one

$C_{11}H_7ClN_4O_2$

262.65

+

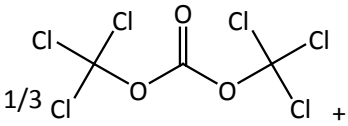


N-Methyl piperazine

$C_5H_{12}N_2$

100.16

+



Triphosgene

$C_3Cl_6O_3$

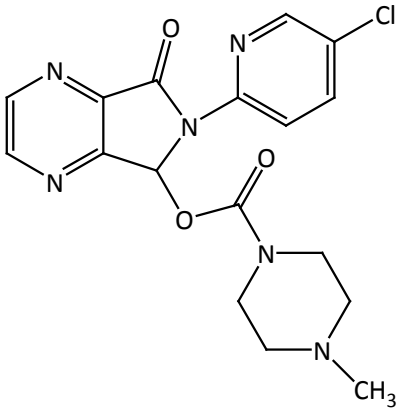
296.75/3=98.91

+ K_2CO_3

Potassium carbonate

138.20

MDC



Zopiclone (Pure)

$C_{17}H_{17}ClN_6O_3$

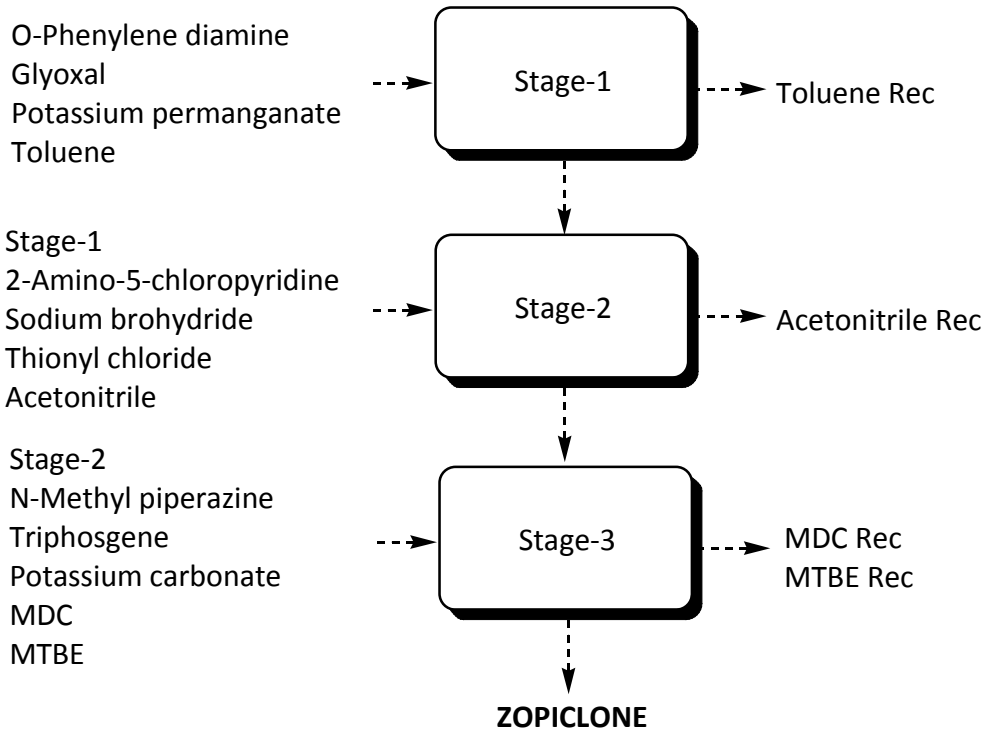
388.81

+ CO_2 ↑ + 2 KCl + H_2O

44.0 2X74.55=149.10 18.0

ZOPICLONE

Flow Chart:



ZOPICLONE

Material Balance:

Material balance of Zopiclone Stage-1 Batch Size: 45.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
O-Phenylene diamine	12.76		Stage-1	17.71
Glyoxal	6.90		Toluene Recovery	569.00
Potassium permanganate	37.30		Toluene Loss	30.00
Toluene	600.00		EDC Recovery	107.00
Hydrochloric acid	8.62		EDC Loss	5.00
Sodium bisulfate	90.00		Acetic anhydride Recovery	414.00
EDC	112.00		Acetic anhydride Loss	21.00
Acetic anhydride	435.00		Effluent water	481.99
Sodium hydroxide	25.00		(Water-327.9,Potassium chloride-17.59,Manganese dioxide-20.5,Sodium bisulfate-90,Sodium hydroxide-25,Toluene-1)	
Hyflow	6.00		Spent hyflow	6.00
Water	330.00		Process Emission	11.79
			(Carbon dioxide-10.38,Hydrogen-1.41)	
			Organic Residue	0.09
Total	1663.58		Total	1663.58

Material balance of Zopiclone Stage-2 Batch Size: 45.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	17.71		Stage-2	31.00
2-Amino-5-chloropyridine	15.16		Toluene Recovery	151.00
Sodium borohydride	4.46		Toluene Loss	8.00
Hydrochloric acid	27.00		Acetonitrile Recovery	212.00
Acetic acid	1.70		Acetonitrile Loss	11.00
Acetonitrile	223.00		Chloroform Recovery	4627.00
Toluene	160.00		Chloroform Loss	243.00
Chloroform	4870.00		1,4-Dioxane Recovery	47.00
1,4-Dioxane	49.00		1,4-Dioxane Loss	2.00
Activated carbon	6.50		Effluent water	3450.04
Water	3415.00		(Water-3410.7,Sodiumperborate-9.64,Acetic acid-1.7,Hydrochloric acid-27,Toluene-1)	
			Process Emission	0.94
			(Hydrogen)	
			Organic Residue	0.05
			Spent carbon	6.50
Total	8789.53		Total	8789.53

Material balance of Zopiclone Stage-3 Batch Size:45.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2	31.00		Zopiclone	45.00
N-Methyl piperazine	11.82		MDC Recovery	3335.00
Triphosgene	11.70		MDC Loss	175.00
Potassium carbonate	16.50		MTBE Recovery	184.00
Tetra butyl ammonium bromide	1.00		MTBE Loss	9.00
MDC	3510.00		Effluent water	920.72
MTBE	193.00		(Water-900,Generated water-2.12,Potassium chloride-17.6, Tetra butyl ammonium bromide-1)	
Activated carbon	1.50		Spent carbon	1.50
Water	900.00		Process Emission	5.19
			(Carbon dioxide)	
			Organic Residue	1.11
Total	4676.52		Total	4676.52

24. ZOTEPINE

Process Description:

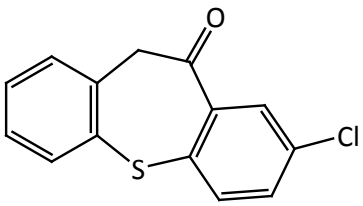
Stage-1

8-Chloro-11H-dibenzo [b,f]thipine-10-one is condensed with (2-Chloroethyl)-dimethyl amine hydrochloride in the presence of Potassium carbonate in MTBE to give Zotepine as product.

ZOTEPINE

Route of Synthesis:

Stage-1

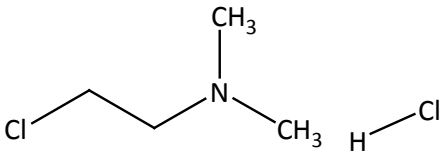


8-Chloro-11*H*-dibenzo[*b,f*] thiepin-10-one

$C_{14}H_9ClOS$

260.74

+



(2-Chloro-ethyl)-dimethyl -amine; hydrochloride

$C_4H_{11}Cl_2N$

144.04

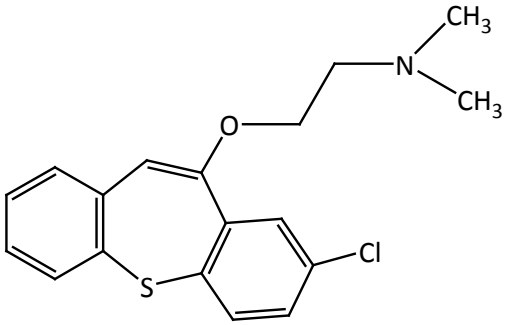
+

K_2CO_3

Potassium carbonate

138.21

MIBK



Zotepine

$C_{18}H_{18}ClNOS$

331.86

+ 2KCl

2X74.55=149.10

+ CO_2 ↑

44.0

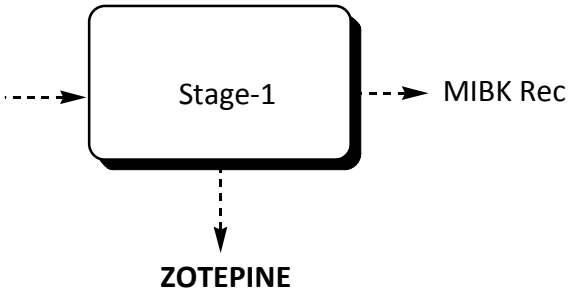
+ H_2O

18.0

ZOTEPINE

Flow Chart:

8-Chloro-11H-dienzo[b,f]
thiepine-10-one
2-(Chloro ethyl) dimethyl
amine hydrochloride
Potassium carbonate
MIBK



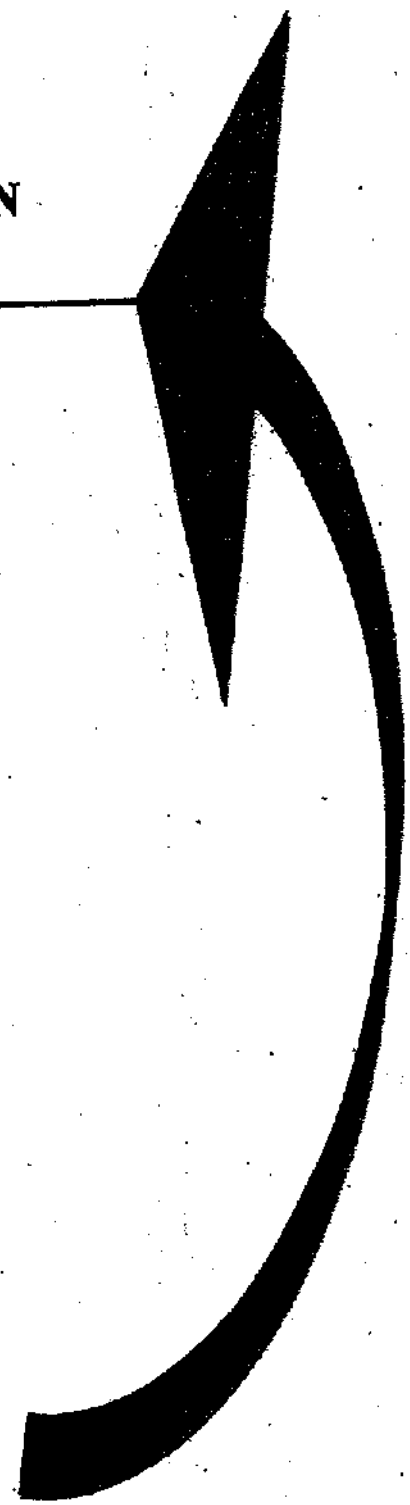
ZOTEPINE

ZOTEPINE

Material Balance:

Material balance of Zotepine Stage-1 Batch Size:10.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
8-Chloro-11H-dienzo[b,f]thiepine-10-one	8.00		Zotepine	10.00
2-(Chloro ethyl) di methyl amine hydrochloride	4.50		Toluene Recovery	326.00
Potassium carbonate	4.50		Toluene Loss	17.00
Hydrochloric acid	50.00		Cyclo hexane Recovery	665.00
Aq.Ammonia	240.00		Cyclo hexane Loss	35.00
MIBK	700.00		Ethanol Recovery	228.00
Toluene	345.00		Ethanol Loss	12.00
Cylco hexane	700.00		MIBK Recovery	665.00
Ethanol	240.00		MIBK Loss	35.00
Activated carbon	10.00		Effluent water	1157.38
Water	1100.00		(Water-1100,Generated water-0.55,Potassium chloride-4.58, Hydrochloric acid-50,Toluene-2,Potassium carbonate-0.25)	
			Spent carbon	10.00
			Aq. Ammonia Reuse	240.00
			Process Emission	1.35
			(Carbon dioxide)	
			Organic Residue	0.27
Total	3402.00		Total	3402.00

WATER CONSUMPTION DETAILS



WATER CONSUMPTION DETAILS

S. No	Purpose	Water Consumption In KLD
1	Process	39.61
2	Washings	5.00
3	Boiler Make up	41.00
4	Cooling towers Make up	131.00
5	DM Plant	4.00
6	Scrubbing system	2.00
7	Domestic	3.00
8	Gardening	6.00
	Total	***231.61***

SOLID WASTE DETAILS

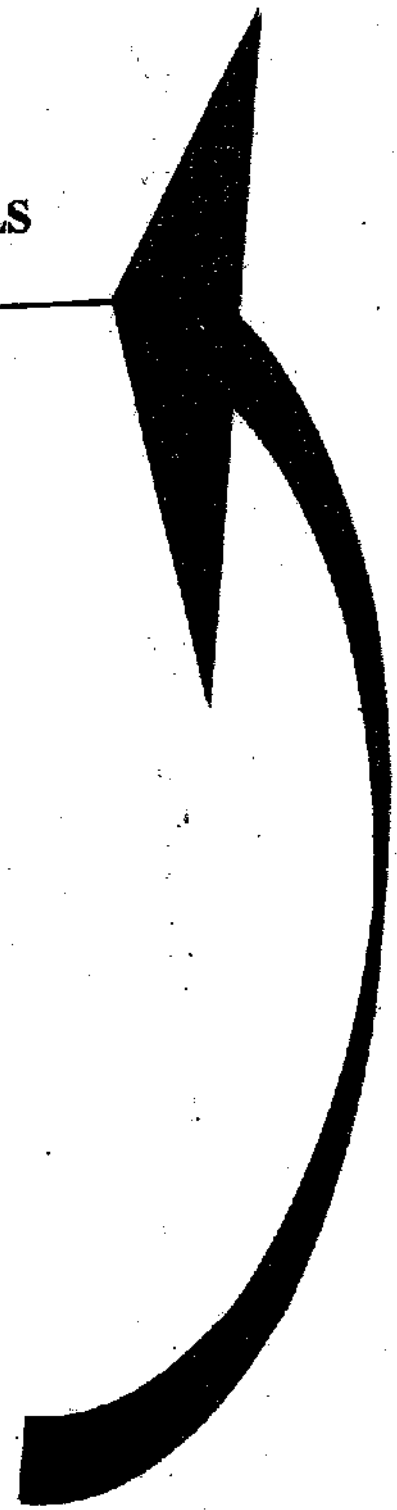
SOLID WASTE DETAILS

S. No	Description	Quantity In Kg/Day	Method Of Disposal
1	Organic Solid Waste	386.00	Sent to TSDF/Cement Industries
2	Spent Carbon	232.00	Sent to TSDF/Cement Industries
3	ETP Sludge	75.00	Sent to TSDF
4	Coal ash from Boiler	5875.00	Sent to Brick Manufacturers
5	Evaporation salts	2688.00	Sent to TSDF
6	Spent solvents	57995.07	Recovery & Reuse
7	Inorganic solid waste	130.00	Sent to TSDF
8	Distillation bottom Residue	50.00	Sent to TSDF/Cement Industries

HAZARDOUS WASTE DETAILS

S. No	Description	Quantity	Mode of Disposal
1	Waste Oils & Grease	50 Ltrs/Annum	APPCB Authorized Agencies for Reprocessing/Recycling
2	Detoxified Containers	200 No's/Month	After Detoxification sent back to suppliers/APPCB Authorized Parties
3	Used Lead Acid Batteries	5 No's/Year	Send back to suppliers for buyback of New Batteries

STACK EMISSION DETAILS



STACK EMISSION DETAILS FOR PROPOSED BOILER

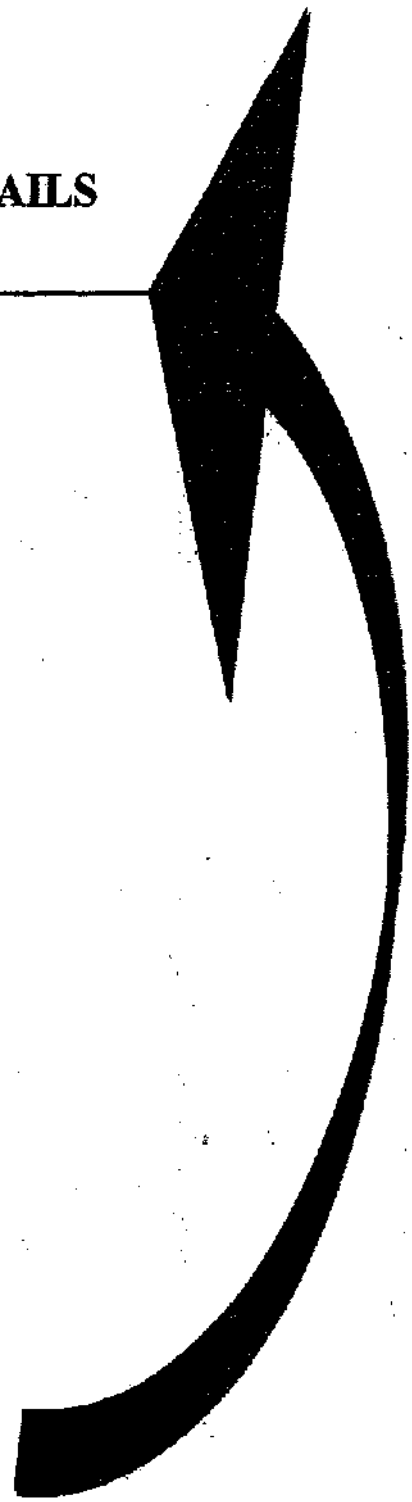
Particulars	Units	5.0 TPH Coal fired Boiler
Type of Fuel	--	Indian Coal
Coal Consumption	TPD	12.5
Ash Content	%	47
Sulphur Content	%	0.8
Nitrogen Content	%	1.07
No. of Stacks	No	1
Height of the Stack	m	32
Diameter of Stack	M	0.60
Temperature of Flue Gas	^{o}C	110
Velocity of Flue Gas	m/s	8.5
Particulate Matter at outlet of Bag filter (Based on 115 mg/Nm3 at outlet)	gm/sec	0.27
Sulphur dioxide emission	gm/sec	1.15
Oxides of Nitrogen emission	gm/sec	1.54

- ***The Industry has 2.0TPH Coal fired boiler as Standby.***

STACK EMISSION DETAILS FOR PROPOSED DG SETS

Capacity In KVA	Emission of SPM in Mg/Nm^3	Emission Of SO_2 in Mg/Nm^3	Emission of NO_x in Mg/Nm^3	Stack dia. In m	Flue Gas Temp. in ^OC	Stack Height in (m)	Flue gas Velocity In m/sec.
500 KVA	80.0	190.0	235.0	0.30	220	10	23.20
250KVA	65.0	110.0	135.0	0.30	220	10	18.50
320KVA	70.0	135.0	160.0	0.30	220	10	20.50

PROCESS EMISSION DETAILS



PROCESS EMISSION DETAILS

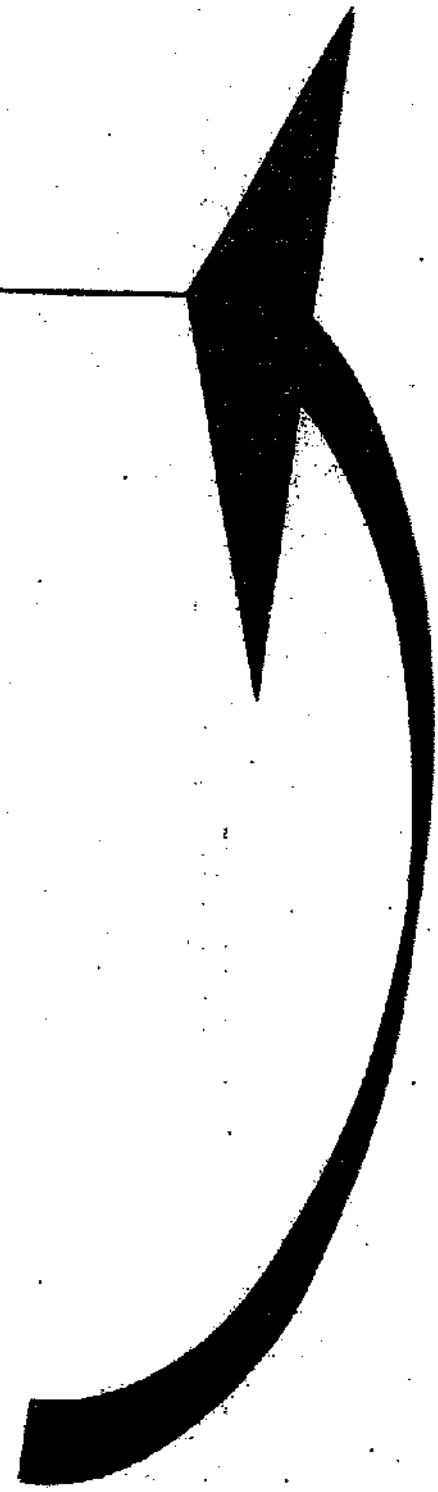
POLLUTING PROCESS EMISSION DETAILS:

S. No	Name of the Gas	Quantity In Kg/Day	Treatment Method
1	Sulfur dioxide	44.00	Scrubbed by using C. S. Lye solution

NON- POLLUTING PROCESS EMISSION DETAILS:

S. No	Name of the Gas	Quantity In Kg/Day	Treatment Method
1	Carbon dioxide	29.00	Dispersed in to Atmosphere
2	Hydrogen	0.66	Diffused with Flame Arrestor

DRAFT TOR



Proposed Draft Terms of Reference for Preparation of EIA & EMP For M/s. Symed Labs Ltd., Unit-IV.

01. Executive summary of the project
02. Justification of the project
03. Promoters and their back ground
04. Regulatory framework
05. A map indicating location of the project and distance from severely polluted areas
06. Project site location along with site map of 10 km area and site details providing various industries, surface water bodies, forests etc.
07. A copy of Gazette Notification issued by the Govt. of Andhra Pradesh indicating location of the project in Notified Industrial Area
08. Plant Layout
09. Infrastructure facilities including power sources
10. Total cost of the project along with total capital cost and recurring costs environmental pollution control measures
11. Present land use based on satellite imagery for the study area of 10 km radius.
12. Details of the total land and break-up of the land use for green belt and other uses
13. Location of National Park/Wild life sanctuary/Reserve Forest within 10 km radius of the project
14. List of products along with the production capacities
15. Maximum number of products and its production capacity to be manufactured at a time (worst-case scenario)
16. Detailed list of raw material required and source, mode of storage and transportation.
17. Explore the use of solvent other than benzene
18. Manufacturing process details along with the chemical reactions and process flow chart.
19. Site-specific micro-meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall is necessary
20. Ambient air quality monitoring at 6 locations within the study area of 10 km., aerial coverage from project site
21. One season site-specific micro-meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall and AAQ data (excluding monsoon season) for $PM_{2.5}$, PM_{10}, SO_2, NOx and VOCs including
22. The monitoring stations should take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests. Data for water and noise monitoring should also be included
23. Air pollution control measures proposed for the effective control of gaseous emissions within permissible limits. Multicyclone followed by bag filter to be provided to boiler to control particulate emissions
24. Name of all solvents to be used in the process and details of solvent recovery system.
25. Design details of ETP, incinerator, boiler, and scrubbers/bag filters etc.
26. Details of water and air pollution and its mitigation plan
27. An action plan to control and monitor secondary fugitive emissions from all the Sources

28. Determination of atmospheric inversion level at the project site and assessment of ground level concentration of pollutants from the stack emission based on Site-specific meteorological features
29. Air quality modelling for proposed plant
30. Action plan for Zero Liquid Discharge of effluent should be included. Segregation of the Wastewater should be based on the pollution load and high TDS effluent should be treated in MEE
31. Ground water quality monitoring minimum at 6 locations should be carried out.
32. Geological features and Geo-hydrological status of the study area and ecological status (Terrestrial and Aquatic)
33. The details of solid and hazardous wastes generation, storage, utilization and disposal particularly related to the hazardous waste calorific value of hazardous waste and detailed characteristic of the hazardous waste. Action plan for the disposal of fly ash generated from boiler should be included
34. Precautions to be taken during storage and transportation of hazardous chemicals should be clearly mentioned and incorporated
35. Membership for the disposal of liquid effluent in CETP or Zero Liquid discharge action plan and solid/hazardous waste in TSDF
36. An action plan to develop green belt in 33 % area
37. Occupational health of the workers needs elaboration including evaluation of Noise, heat, illumination, dust, any other chemicals, metals being suspected in Environment and going into body of workers either through inhalation, ingestion or through skin absorption and steps taken to avoid musculo-skeletal disorders (MSD), backache pain in minor and major joints, fatigue etc. Occupational Hazards specific pre-placement and periodical monitoring should be carried out
38. Socio-economic development activities should be in place
39. Note on compliance to the recommendations mentioned in the CREP guidelines
40. Detailed Environment management Plan (EMP) with specific reference to details of air pollution control system, wastewater management, monitoring frequency, responsibility and time bound implementation plan for mitigation measure should be provided
41. Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof
42. A tabular chart with index for point wise compliance of above TORs

ENCLOSURES

LIST OF BY- PRODUCTS

LIST OF BY- PRODUCTS

S. No	Name of the By-Product	Quantity In Kg/Day
1	Sodium salt of 4-Hydroxy benzoic acid	3.71
2	Benzene sulfonyl bromide	4.56

LIST OF SPENT CATALYST

S. No	Name of the Spent Catalyst	Quantity In Kg/Day
1	Palladium carbon	25.22
2	Raney Nickel	14.00
3	Catalyst D	10.80

LIST OF RAW MATERIALS

1. AMISULPRIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	2-Methoxy-4-amino-5-ethyl sulphonyl benzoic acid	141.00	11.75
2	1-Ethyl-2-amino methyl pyrrolidine	75.00	6.25
3	Ethyl chloro formate	59.00	4.92
4	Triethylamine	80.00	6.67
5	Sodium hydroxide	145.00	12.08
6	Acetone	630.00	52.50
7	Isopropyl alcohol	150.00	12.50
8	Activated carbon	9.00	0.75

2. CARBIDOPA

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Methyl Dopa	40.00	106.67
2	Thionyl Chloride	22.53	60.08
3	Caustic Soda Flakes	15.50	41.33
4	Cyclohexanone	20.00	53.33
5	Toluene	320.00	853.33
6	Liquid Ammonia (10%)	35.00	93.33
7	Sodium Hypochlorite	375.00	1000.00
8	Conc. Hydrochloric Acid	49.00	130.67
9	Boric Acid	7.25	19.33
10	Chloroform	187.50	500.00
11	Methanol	302.35	806.27
12	Liq.Ammonia	7.00	18.67
13	Sodium metabisulphite	0.55	1.47
14	Ammonium hydroxide	5.00	13.33
15	Sodium meta bisulphate	0.87	2.32
16	Acetone	1.64	4.37
17	Activated Carbon	5.00	13.33

3. CARVEDILOL

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	4(Oxiranyl methoxy)-9H-Carbazole	32.50	39.39
2	(2-methoxyphenoxy)ethylamine	22.50	27.27
3	Ethyl acetate	413.00	500.56
4	Methanol	395.00	478.74
5	Activated carbon	7.00	8.48

4. CARVEDILOL PHOSPHATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Carvedilol	47.00	2.69
2	Phosphoric acid	12.00	0.69
3	Acetone	396.00	22.70

5. CINITAPRIDE HYDROGEN TARTRATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	4-Amino-2-ethoxy-5nitro-N-(4-piperidyl)benzamide	19.51	0.93
2	3-Cyclohexene-1-methanol	7.10	0.34
3	Benzene sulfonyl chloride	11.17	0.53
4	Sodium carbonate	3.35	0.16
5	TEA	24.60	1.17
6	Tartaric acid	15.20	0.72
7	Cyclohexane	88.20	4.20
8	DMF	198.00	9.44
9	Methanol	233.00	11.11
10	Activated carbon	4.00	0.19

6. DAPOXETINE HYDROCHLORIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(S)-3-Chloro-1-phenyl propan-1-ol reacts	40.00	8.33
2	1-Napthol	34.00	7.08
3	Dimethylamine	33.00	6.88
4	IsopropanolHCl	55.00	11.46
5	Dimethyl sulfoxide	280.00	58.33
6	Potassium hydroxide	34.00	7.08
7	Mesyl chloride	50.00	10.42
8	Triethylamine	126.00	26.25
9	N,N-Dimethyl amino pyridine	0.02	0.00
10	Methanol	995.00	207.29
11	Ethyl acetate	1405.00	292.71
12	Activated carbon	14.00	2.92

7. EPALRESTAT

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	3-carboxy methyl rhodanine	72.00	30.00
2	2-Methyl cinnamldehdye	55.00	22.92
3	Sodium acetate	78.00	32.50
4	Acetic acid	797.00	332.08
5	DMF	2981.00	1242.08
6	Activated carbon	19.00	7.92

8. ESZOPICLONE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	O-Phenylene diamine	24.20	2.02
2	Glyoxal	7.60	0.63
3	Potassium permanganate	158.00	13.17
4	Toluene	390.00	32.50
5	Hydrochloric acid	33.00	2.75
6	Sodium bisulfate	35.00	2.92
7	Ethylene chloride	44.00	3.67
8	Acetic anhydride	168.00	14.00
9	Sodium hydroxide	10.00	0.83
10	Hyflow	2.50	0.21
11	2-Amino-5-Chloropyridine	16.90	1.41
12	Sodium boro hydride	6.00	0.50
13	Hydrochloric acid	27.00	2.25
14	Acetic acid	1.60	0.13
15	Acetonitrile	225.00	18.75
16	Chloroform	1530.00	127.50
17	1,4-Dioxane	30.00	2.50
18	Activated carbon	7.50	0.63
19	N-Methyl piperazine	26.00	2.17
20	Triphosgene	26.00	2.17
21	Potassium carbonate	83.00	6.92
22	Tetrabutyl ammonium bromide	1.00	0.08
23	1,4-Toluyl tartaric acid monohydrate	45.00	3.75
24	Sodium hydroxide	45.00	3.75
25	Methylene chloride	3510.00	292.50
26	Methyl tertiary butyl ketone	193.00	16.08
27	Methanol	428.00	35.67
28	Acetone	820.00	68.33
29	Isopropyl alcohol	160.00	13.33

9. FLUCONAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1[2-(2,4-Difluorophenyl)-2,3-epoxy propyl)-1H-1,2,4-Triazole	77.45	77.45
2	1,2,4-Triazole	45.10	45.10
3	Potassium carbonate	130.00	130.00
4	Acetone	630.00	630.00
5	Ethyl acetate	1076.00	1076.00
6	Activated carbon	10.00	10.00

10. IRON SUCROSE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Ferric Chloride	93.71	312.37
2	Sodium carbonate	24.45	81.50
3	Sucrose	55.00	183.33
4	Sodium hydroxide	5.00	16.67

11. ITOPRIDE HYDROCHLORIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	3,4-Dimethoxybenzoic acid	42.90	30.76
2	Thionyl chloride	28.01	20.08
3	4-(N,N-di methyl amino ethoxy)benzyl amine	45.74	32.80
4	Hydrochloric acid	10.50	7.53
5	Aq.ammonia	159.00	114.00
6	IPA.HCl	94.00	67.40
7	Toluene	1478.00	1059.73
8	Chloroform	449.00	321.93
9	IPA	943.00	676.13
10	Methanol	506.00	362.80
11	Activated carbon	16.00	11.47

12. KETOROLAC TROMETHAMINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Ketrolac	69.86	90.42
2	Tromethamine	33.14	42.89
3	Activated carbon	13.00	16.83
4	Methanol	265.00	343.00
5	Acetone	2278.00	2948.49

13. LEVOCETRIZINE DIHYDROCHLORIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1-[((4-Chlorophenyl)phenyl)methyl]-4-[(phenylsulphonyl)]piperazine	46.20	9.24
2	2(2-Chloroethoxy)acetamide	14.90	2.98
3	4-Hydroxy benzoic acid	16.00	3.20
4	Hydrobromic acid	8.80	1.76
5	Sodium hydroxide	8.70	1.74
6	Hydrochloric acid	15.80	3.16
7	Sodium carbonate	11.50	2.30
8	Potassium iodide	1.70	0.34
9	Toluene	1515.00	303.00
10	MDC	1860.00	372.00
11	Acetone	465.00	93.00
12	Activated carbon	4.00	0.80

14. LEVOSULPRIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Methyl-2-methoxy-5-sulfamoyl benzoate	97.68	35.91
2	1-Ethyl-2-amino methyl pyrrolidine	51.06	18.77
3	Ethylene glycol	290.00	106.62
4	Methanol	1900.00	698.57
5	Activated carbon	5.00	1.84

15. LINEZOLID

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	N-[3-Phthalimido-2R-hydroxypropyl-3-fluoro-4-morpholinyl aniline	106.55	355.17
2	Carbonyl di imidazole	43.25	144.17
3	Hydrazine Hydrate	13.35	44.50
4	Acetic anhydride	27.23	90.77
5	Methanol	753.00	2510.00
6	MDC	2682.00	8940.00
7	Activated carbon	10.80	36.00
8	Ethyl acetate	805.00	2683.33
9	Acetone	1548.00	5160.00

16. MOSAPRIDE CITRATE DIHYDRATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	2-Amino methyl-4-(4-fluorobenzyl)morpholine	25.87	23.00
2	4-Amino-5-chloro-2-ethoxy benzoic acid	24.87	22.11
3	Citric acid	22.16	19.70
4	Ethyl chloro formate	19.00	16.89
5	TEA	33.00	29.34
6	MDC	1865.00	1657.99
7	Acetone	235.00	208.92
8	Methanol	210.00	186.69
9	Activated Carbon	16.00	14.22

17. ONDANSETRON HYDROCHLORIDE DIHYDRATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	3-Dimethylamino methyl-9-methyl-1,2,3,9-tetrahydro carbazole-4-one	10.50	11.67
2	2-Methyl imidazole	4.00	4.44
3	Hydrochloric acid	6.40	7.11
4	Methanol	72.00	79.99
5	Activated carbon	22.50	25.00

18. PREGABALIN

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	3-(Amino methyl)-5-methyl hexanoic acid	99.10	173.85
2	Mandelic acid	129.10	226.48
3	Liq. Ammonia	14.60	25.61
4	Citric acid monohydrate	74.60	130.87
5	Methanol	1464.00	2568.34
6	Activated carbon	8.00	14.03

19. RACECADOTRIL

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	2-Benzylacryloyl chloride	58.00	72.50
2	Glycine benzyl ester-p-tosylate	70.00	87.50
3	Thioacetic acid	30.00	37.50
4	Triethylamine	100.00	125.00
5	Sodium bicarbonate	16.00	20.00
6	Hydrochloric acid	6.50	8.13
7	Isopropyl alcohol	1130.00	1412.50
8	n-Hexane	480.00	600.00
9	Toluene	380.00	475.00
10	Methanol	1030.00	1287.50
11	Activated carbon	10.00	12.50

20. TAMSULOSIN HYDROCHLORIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(R)-5-[[2-(2-Ethoxy phenoxy) ethyl)amino]propyl]-2-methoxy benzene	19.30	1.61
2	Hydrochloric acid	13.30	1.11
3	Methanol	190.00	15.83
4	Acetone	310.00	25.83

21. TIZANIDINE HYDROCHLORIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	4-Amino-5-chloro-2,1,3-benzo-thiadiazole	75.00	2.50
2	1-Acetyl-imidazolidin-2-one	52.00	1.73
3	Phosphorous oxy chloride	62.00	2.07
4	Sodium hydroxide	65.00	2.17
5	Methanol	5530.00	184.33
6	Activated carbon	115.00	3.83
7	Hydrochloric acid	14.80	0.49
8	Activated carbon	40.00	1.33

22. TOPIRAMATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	D-Fructose	50.00	200.00
2	Acetone	317.00	1268.00
3	Sulfuric acid	55.00	220.00
4	Sodium hydroxide	38.00	152.00
5	Isopropyl alcohol	127.00	508.00
6	n-Hexane	83.00	332.00
7	Sulfuryl chloride	53.00	212.00
8	Ammonia	3.26	13.04
9	Sodium hydroxide	20.00	80.00
10	Pyridine	34.00	136.00
11	Citric acid	25.00	100.00
12	Sodium carbonate	25.00	100.00
13	Hydrochloric acid	19.00	76.00
14	MDC	665.00	2660.00
15	Toluene	1740.00	6960.00
16	Ethyl acetate	270.00	1080.00
17	Activated carbon	4.00	16.00

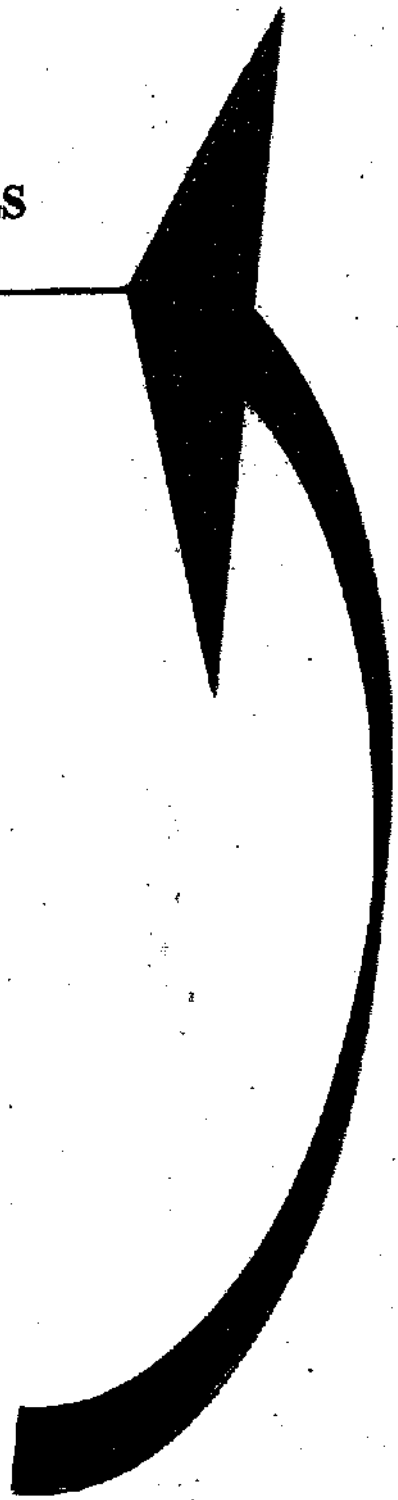
23. ZOPICLONE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	O-Phenylene diamine	12.76	0.47
2	Glyoxal	6.90	0.26
3	Potassium permanganate	37.30	1.38
4	Toluene	760.00	28.12
5	Hydrochloric acid	35.62	1.32
6	Sodium bisulfate	90.00	3.33
7	EDC	112.00	4.14
8	Acetic anhydride	435.00	16.10
9	Sodium hydroxide	25.00	0.93
10	Hyflow	6.00	0.22
11	2-Amino-5-chloropyridine	15.16	0.56
12	Sodium borohydride	4.46	0.17
13	Acetic acid	1.70	0.06
14	Acetonitrile	223.00	8.25
15	Chloroform	4870.00	180.19
16	1,4-Dioxane	49.00	1.81
17	Activated carbon	8.00	0.30
18	N-Methyl piperazine	11.82	0.44
19	Triphosgene	11.70	0.43
20	Potassium carbonate	16.50	0.61
21	Tetra butyl ammonium bromide	1.00	0.04
22	MDC	3510.00	129.87
23	MTBE	193.00	7.14

24. ZOTEPINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	8-Chloro-11H-dienzo[b,f]thiepine-10-one	8.00	26.67
2	2-(Chloro ethyl) di methyl amine hydrochloride	4.50	15.00
3	Potassium carbonate	4.50	15.00
4	Hydrochloric acid	50.00	166.67
5	Aq.Ammonia	240.00	800.00
6	MIBK	700.00	2333.33
7	Toluene	345.00	1150.00
8	Cylco hexane	700.00	2333.33
9	Ethanol	240.00	800.00
10	Activated carbon	10.00	33.33

WASTE WATER DETAILS



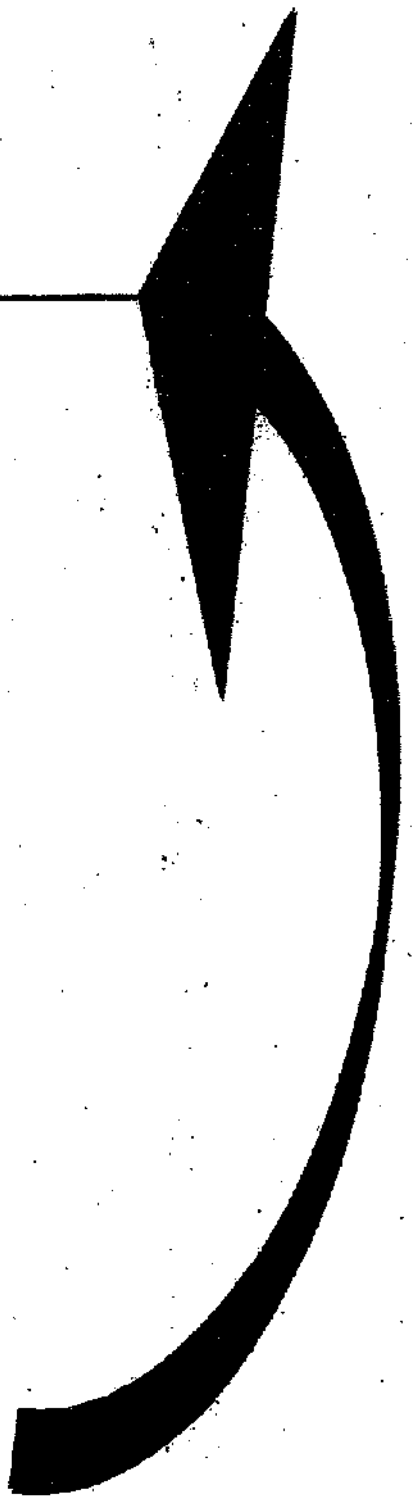
WASTE WATER DETAILS

S. No	Purpose	Effluent In KLD
1	Process	42.78
2	Washings	5.00
3	Boiler Blow down	6.00
4	Cooling towers Blow down	26.00
5	DM Plant	4.00
6	Scrubbing system	2.00
7	Domestic	2.50
8	Gardening	0.00
	Total	***88.28***

HTDS & LTDS DETAILS

S. No	Purpose	HTDS In KLD	LTDS In KLD	Effluent In KLD	Disposal Method
1	Process	42.77	0.01	42.78	HTDS Effluent sent to ETP with MEE system. LTDS effluents treated in ETP-RO Rejects to ME system and RO permeate to reuse, Condensate from MEE to reuse and MEE residue to AFTD.
2	Washings	0.00	5.00	5.00	
3	Boiler Blow down	6.00	0.00	6.00	
4	Cooling towers Blow down	0.00	26.00	26.00	
5	DM Plant	4.00	0.00	4.00	
6	Scrubbing system	2.00	0.00	2.00	
7	Domestic	0.00	2.50	2.50	Septic tank followed by Soak pit
	Total	**54.77**	**33.51**	**88.28**	

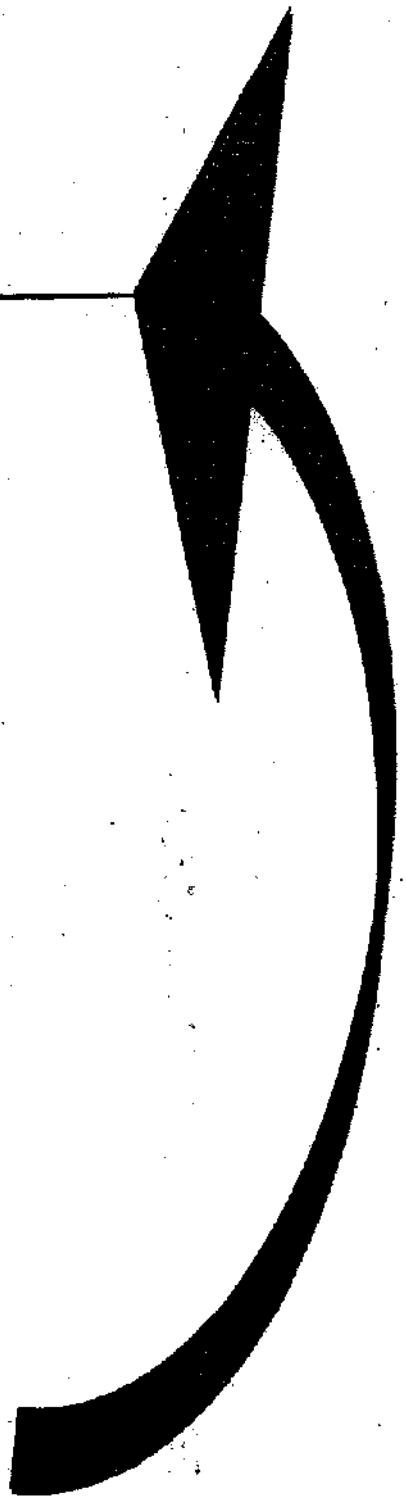
ETP FLOW CHART



FLOW CHART FOR EFFLUENT TREATMENT

Effluent Type	Treatment Flow
HTDS/HCOD	Collection → Equalization & neutralization → Stripper → MEE → ATFD → TSDF MEE Condensate will be Reused.
HTDS	Collection→ Equalization & neutralization → MEE → ATFD → TSDF MEE Condensate will be Reused.
LTDS/LCOD	Collection→ ETP (Biological Treatment) → Sand Filter → Carbon Filter → Booster pump to Membrane Filter set → RO Plant → RO Reject to MEE RO Permeate to Reused.

SPENT SOLVENTS



LIST OF SPENT SOLVENTS

S. No	Name of the product	Name of the solvent	Solvent Recovery In Kg/Batch	Solvent Recovery In Kg/day
1	Amisulpride	Acetone	597.00	49.75
		Isopropyl alcohol	142.50	11.88
2	Carbidopa	Methanol	260.00	693.33
		Toluene	304.00	810.67
		Chloroform	178.00	474.67
3	Carvedilol	Ethyl acetate	393.00	476.32
		Methanol	376.00	455.71
4	Carvedilol phosphate	Acetone	376.00	21.56
5	Cinitapride Hydrogen Tartrate	Cyclohexane	84.20	4.01
		DMF	189.00	9.01
		Methanol	222.00	10.58
6	Dapoxetine Hydrochloride	Methanol	952.20	198.38
		Ethyl acetate	1334.75	278.07
7	Epalrestat	DMF	2831.00	1179.58
		Acetic acid	758.00	315.83
8	Eszopiclone	Toluene	374.40	31.20
		EDC	41.80	3.48
		Acetonitrile	213.75	17.81
		Chloroform	1453.50	121.13
		1,4-Dioxane	28.80	2.40
9	Fluconazole	Acetone	600.00	600.00
		Ethyl acetate	1023.00	1023.00
10	Iron Sucrose	0000	0000	000000
11	Itopride Hydrochloride	Toluene	1404.00	1006.67
		Chloroform	427.00	306.16
		IPA	978.80	701.80
		Methanol	481.00	344.88
12	Ketorolac tromethamine	Methanol	251.00	324.88
		Acetone	2165.00	2802.23
13	Levocetrizine Dihydrochloride	Toluene	1440.00	288.00
		MDC	1767.00	353.40
		Acetone	442.00	88.40
14	Levosulpride	Ethylene glycol	276.00	101.48
		Methanol	1817.74	668.32
15	Linezolid	Methanol	715.00	2383.33
		MDC	2548.00	8493.33
		Ethyl acetate	765.00	2550.00

		Acetone	1471.00	4903.33
16	Mosapride citrate dihydrate	MDC	1772.00	1575.31
		Acetone	224.00	199.14
		Methanol	199.00	176.91
17	Ondansetron Hydrochloride Dihydrate	Methanol	68.00	75.55
18	Pregabalin	Methanol	1390.00	2438.53
19	Racecadotril	Isopropyl alcohol	1073.50	1341.88
		Toluene	364.80	456.00
		n-Hexane	460.80	576.00
		Methanol	978.50	1223.13
20	Tamsulosin Hydrochloride	Methanol	182.40	15.20
		Acetone	294.50	24.54
21	Tizianidine Hydrochloride	Methanol	5241.00	174.70
22	Topiramate	Isopropyl alcohol	119.00	476.00
		n-Hexane	79.00	316.00
		Ethyl acetate	256.00	1024.00
		Toluene	1652.00	6608.00
		MDC	632.00	2528.00
23	Zopiclone	Toluene	720.00	26.64
		EDC	107.00	3.96
		Acetonitrile	212.00	7.84
		Chloroform	4627.00	171.20
		1,4-Dioxane	47.00	1.74
		MDC	3335.00	123.40
		MTBE	184.00	6.81
24	Zotepine	Toluene	326.00	1086.67
		Cyclo hexane	665.00	2216.67
		Ethanol	228.00	760.00
		MIBK	665.00	2216.67
	Total		***55783.94***	***57955.07***

POLLUTION LOAD DETAILS

Enclosure - 6

Consolidated statement of M/.Symed labs Limited Unit-4

S.No	Product Name	Prodn /Month	Water Input	Water In Effluent	Inorganics In water	Organics in water	TDS	COD	HTDS	LTDS	Total Effluent	Organic	Inorganic	Spent carbon	Total solid	Process	Fugitive
		Kg/Month	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day	Kg/Day
1	Amisulpride	500.00	100.00	100.00	18.32	2.16	18.32	3.06	120.49	0.00	120.49	2.65	0.00	0.75	3.40	1.99	3.25
2	Carvedilol	2000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.48	8.48	0.00	47.27
3	Carvedilol Phosphate	100.00	2.87	2.87	0.03	0.06	0.03	0.13	2.96	0.00	2.96	0.03	0.00	0.00	0.03	0.00	1.09
4	Carbidopa	2000.00	7080.00	7826.32	184.69	80.66	184.69	124.08	8091.68	0.00	8091.68	74.37	0.00	13.33	87.70	32.32	94.67
5	Cinitapride Hydrogen tartarate	50.00	36.90	36.93	2.05	0.05	2.05	0.07	39.03	0.00	39.03	0.00	0.00	0.19	0.19	0.07	1.14
6	Dapoxetine Hydrochloride	500.00	609.38	610.25	87.30	0.41	87.30	0.63	697.97	0.00	697.97	4.95	0.00	2.92	7.87	0.00	22.93
7	Epalrestat	1500.00	1787.92	1790.74	32.50	0.41	32.50	0.78	1823.65	0.00	1823.65	0.10	0.00	7.92	8.02	0.00	78.33
8	Eszopiclone	25.00	175.83	175.44	37.66	0.41	37.66	1.01	213.52	0.00	213.52	3.15	0.00	0.83	3.98	3.77	30.41
9	Fluconazole	3000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	22.55	130.00	10.00	162.55	0.00	83.00
10	Iron sucrose	10000.00	5500.00	5437.63	304.17	0.00	304.17	0.00	5741.80	0.00	5741.80	0.00	0.00	0.00	0.00	18.73	0.00
11	Itopride Hydrochloride	2000.00	430.11	430.11	21.71	0.71	21.71	2.24	452.54	0.00	452.54	0.00	0.00	11.47	11.47	10.80	119.71
12	ketrolac tromethamine	4000.00	81.55	81.55	0.00	2.58	0.00	4.80	84.14	0.00	84.14	0.00	0.00	16.83	16.83	0.00	161.81
13	Levocetirizine Di Hydrochloride	300.00	454.00	454.39	5.86	0.20	5.86	0.62	460.45	0.00	460.45	0.00	0.00	0.80	0.80	0.00	38.20
14	Levosulpride	1500.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.84	1.84	0.00	40.07
15	Linezolid	9000.00	4740.00	4756.00	265.27	56.67	265.27	67.47	5077.93	0.00	5077.93	0.00	0.00	36.00	36.00	0.00	960.00
16	Mosapride Citrate Dihydrate	2000.00	1986.67	1984.80	16.89	30.22	16.89	79.95	2031.91	0.00	2031.91	0.00	0.00	14.22	14.22	0.00	101.33
17	Ondansetron Hydrochloride Dihydrate	500.00	691.11	689.48	5.44	3.15	5.44	10.37	698.08	0.00	698.08	0.70	0.00	25.00	25.70	0.00	3.33
18	Pregabalin	5000.00	2494.04	2494.04	156.49	1.75	156.49	2.63	2652.28	0.00	2652.28	7.19	0.00	14.04	21.23	0.00	128.07
19	Racecadotril	3000.00	1625.00	1625.00	242.90	3.75	242.90	7.65	1871.65	0.00	1871.65	3.98	0.00	12.50	16.48	0.00	178.00
20	Tamsulosin Hydrochloride	50.00	1.83	1.83	0.86	0.16	0.86	0.31	2.86	0.00	2.86	0.02	0.00	0.00	0.02	0.00	1.93
21	Tizanidine Hydrochloirde	50.00	181.67	181.91	4.00	0.91	4.00	1.02	176.12	10.70	186.82	1.18	0.00	5.17	6.35	0.00	9.17
22	Topiramate	3000.00	7952.00	7992.80	658.16	8.00	658.16	22.40	8658.96	0.00	8658.96	264.20	0.00	16.00	280.20	0.00	580.00
23	Zotepine	1000.00	3666.67	3668.50	182.77	6.67	182.77	20.80	3857.93	0.00	3857.93	0.90	0.00	33.33	34.23	4.50	330.00
24	Zopiclone	50.00	12.22	12.14	5.67	0.04	5.67	0.12	17.85	0.00	17.85	0.00	0.00	0.22	0.22	0.44	2.07
	Total	***51125.00***	***39609.77***	***40352.73***	***2232.74***	***198.96***	***2232.74***	***350.14***	***42773.80***	***10.70***	***[illegible]***	***385.97***	***130.00***	***231.84***	***747.81***	***72.62***	***3015.78***

	Prodn/Month
	Water Input
	TDS
	COD
	HTDS
	LTDS
	Total Effluent
	Organic
	Inorganic
	Spent carbon

COPY OF CFO

ANDHRA PRADESH POLLUTION CONTROL BOARD
PARYAVARAN BHAVAN, A-3, INDUSTRIAL ESTATE,
SANATHNAGAR, HYDERABAD - 500 018.

Phone: 040-23887500
Fax: 040- 23815631
Grams : Kalusya Nivarana
Website : appcb.ap.nic.in

Enclosure-7

CONSENT & AUTHORISATION ORDER
BY REGISTERED POST WITH ACKNOWLEDGEMENT DUE

Consent Order No : APPCB/PTN/NLG/4/CFO/HO/201 - 3309 **Date: 25.10.2012**

Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof, Operation of the plant under section 21 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof and Authorisation / Renewal of Authorisation under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary, Movement) Rules 2008 & Amendments thereof).

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974, under section 21 of Air (Prevention & Control of Pollution) Act 1981 and Authorisation under the provisions of HW (MH & TM) Rules, 2008 (hereinafter referred to as 'the Acts', 'the Rules') and the rules and orders made there under to

M/s. Sharanaa Pharma (P) Ltd.,
Sy.No.163/A & 164/A,
Pittampally (V), Chityal (M),
Nalgonda district – 508 114
E-mail: pharma.sharanaa@gmail.com

(Hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant to discharge the effluents from the outlets and the quantity of emissions per hour from the chimneys as detailed below):

i) Out lets for discharge of effluents:

Outlet No.	Outlet Description	Max Daily Discharge	Point of Disposal
1.	Process - 5 KLD + Washings & QC Lab – 1.0 KLD + Boiler & Cooling tower blow down – 0.8 KLD + DM Plant regeneration – 0.1 KLD	6.9 KLD	▪ Forced evaporation in the Stripper, Double Effect Evaporator (DEE). ▪ The condensate first forerun to distillate for recovery of solvents at onsite & to reuse, ▪ The secondary condensate to re-use for make-up of Cooling Tower. ▪ RO Reject to DEE and permeate for recycling in cooling Towers.
2.	Domestic	0.5 KLD	

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow
1.	Attached to 1 TPH coal fired boiler	–
2.	Attached to 125 KVA D.G. Set	–

iii) HAZARDOUS WASTE AUTHORISATION (FORM – II) [See Rule 5 (4)]

1. Number of Authorisation and date of issue - APPCB/NLG/NLG/160/HWM Dt: 25/10/2012.

2. **M/s. Sharanaa Pharma (P) Ltd., Sy. No. 163/A & 164/A, Pittampally (V), Chityal (M), Nalgonda District is hereby granted an authorization to operate a facility for collection, reception, storage, treatment, transport and disposal of Hazardous Wastes namely:**

- **HAZARDOUS WASTES WITH DISPOSAL OPTION:**

S.No	Name of the Hazardous waste	Stream	Quantity of Hazardous waste	Disposal Option
1.	Process organic residue	36.4 of Schedule – I	130 kg/day	TSDF, Dundigal, Rangareddy District for incineration / Authorised cement plants for co-processing.
2.	In-organic residue / FE residue	34.3 of Schedule – I	273 kg/day	TSDF, Dundigal, Rangareddy District for secured land filling.

3. The authorisation is subject to the terms and conditions enclosed at Schedule - C to such conditions as may be specified in the rules from time to time under the Environment (Protection) Act, 1986.

This consent order is valid for manufacturing the following products with quantities indicated only.

S. No.	Products*	Quantity	
1	4-O-Methyl-3,5, Dimethyl-1-Chloro methyl pyridine (Chloro compound) (Involving 5 stages for manufacturing of the intermediates used as intermediates in the 7th stage of manufacture of Omeprazole bulk drug, which has total of 8 stages for manufacture of bulk drug)	16.128 TPA (or) 1,344 TPM	***The industry is permitted to manufacture only two products at any given point of time.**
2	4-(2,2,2-Tri Fluoro Ethoxy)-2-Choloro Methoyl-3 (Involving 4 stages for manufacturing of the intermediates used as intermediates in the 5th stage of manufacture of Lansoprazole bulk drug, which has total of 6 stages for manufacture of bulk drug)	49 TPA (or) 4.1 TPM	
3	Cis-(2,4-Dichlorophenyl1)2-(1H-1,2,4-Triazole-1-yl) Methyl 1-1, 3-Dioxolan-4-yl methane sulfonate (Involving 2stages for manufacturing of the intermediates used as intermediates in the 10th stage of manufacture of Itraconazole bulk drug, which has total of 10 stages for manufacture of bulk drug)	4.85 TPA (or) 0.4 TPM	
4	4-O-Methyl-3,5, Dimethyl-1-Chloro methyl pyridine (Chloro compound) (Involving 5 stages for manufacturing of the intermediates used as intermediates in the 7th stage of manufacture of Omeprazole bulk drug, which has total of 8 stages for manufacture of bulk drug)	60 kg/day (or) 1.8 TPM	
5	2-[(Dimethyl Amino) Methyl]-1-[3methoxy phenyl] cyclohexanol (Involving 3 stages for manufacturing of the intermediates used as intermediates in the 4th stage of manufacture of Tramadol HCl bulk drug, which has total of 4 stages for manufacture of bulk drug)	166.67 kg/day (or) 5.0TPM	

Product Refer Note

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

This combined order of consent & Hazardous Waste Authorization should be valid for a period ending with the **30th day of April, 2013.**

Sd/-
MEMBER SECRETARY

To

M/s. Sharanaa Pharma (P) Ltd.,
Sy.No.163/A & 164/A,
Pittampally (V), Chityal (M),
Nalgonda district – 508 114

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

P. Muralisamy Reddy
SENIOR ENVIRONMENTAL ENGINEER (CFO)

SCHEDULE – A

1. The applicant should make **applications online** for renewal of Consent (under Water and Air Acts) and Authorisation under HWM **Rules at least 120 days before the date of expiry of this order,** along with prescribed fee under Water and Air Acts for obtaining Consent & HW Authorisation of the Board and detailed compliance to CFO condition.
2. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules 1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of the Water(Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air(Prevention and Control of Pollution) Act, 1981.
3. The industry should immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions etc.
4. a) All the fugitive emissions should be controlled with proper measures.
   b)The applicant should also install the equipment such as wind speed recorder, wind direction recorder.
5. The applicant should not change or alter either the quality or the quantity or the rate of the discharge or the route of discharge and should not change or alter either the prescribed quality or the rate of emission without the previous written permission of the Board.
6. The applicant should, not later than 30 days from the date of issue of this consent order, certify in writing to the Board that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent. In absence of alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production should be stopped.
7. Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and/ or violation of standards stipulated in this order or the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident, or other unforeseen act or event, the person-in-charge of the premises, from where such discharge / emission occurs or is apprehended to occur should forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax / email under intimation to the Collector and District Magistrate.
8. In case of such episodal discharges / emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge / emission below the limits prescribed in this order.
9. A good house keeping should be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers and drains should be leak proof. Floor washings should be admitted into the effluent collection system only and should not be allowed to find their way into storm drains or open areas.

10. a) The industry should carryout analysis of waste water discharges or emissions through chimneys, for the parameters mentioned in Schedule – B of this order at regular intervals.
    b) The industry should maintain following records, accessible to the Board, whenever required.
        1. Analysis reports of waste water/ emissions.
        2. Log book for operation of pollution control systems.
        3. Inspection book
11. Separate power connection with energy meter should be provided for the Pollution Control Equipments and record of power consumption and chemicals consumption for the operation of pollution control equipment should be maintained separately.
12. The applicant should comply with the directives/orders issued by the Board in this order and at all subsequent times without any negligence on his part. The applicant should be liable for such legal action against him as per provisions of the Law/Act in case if non-compliance of any order/directive issued at any time and/or violation of the terms and conditions of this consent order.
13. The applicant should furnish to the visiting officer and / or the Board any information regarding the construction, installation or operation of the effluent treatment system / air pollution control equipment / secured storage area of Hazardous Waste and such other particulars as may be pertinent for preventing and controlling pollution.
14. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability.
15. All the rules & regulations notified by Ministry of Environment and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes should be followed.
16. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 should be followed.
17. The occupier should educate the workers and nearby public of possible accidents and remedial measures.
18. For any accident or spillage of hazardous wastes causing damage to the Environment, the occupier or the transporter as the case should be held responsible.
19. In case of closure of industry, the un-used/not consumed raw materials falling under the category of Hazardous Chemicals and mentioned in Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment Rules, 2003 should be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident. In case the above hazardous chemicals have lost their properties originally acquired, then they should be treated, as Hazardous Waste and they should be disposed off only to the agencies authorized by APPCB in a safe manner.
20. The occupier should prepare/update Emergency preparedness plan for safe handling of hazardous waste from time to time and submit the same to APPCB. Emergency preparedness plan must be implemented immediately whenever there is fire, explosion or release of hazardous waste or hazardous waste constituents, which could endanger to human health or environment.
21. Packaging, labeling and transportation of Hazardous Wastes should be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling should be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.
22. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter should carry a Transport Emergency (TREM) Card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.
23. Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes should be thoroughly detoxified before selling to the agencies authorized by APPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste containers / Container Liners should be maintained in the following way:
    I) Number of containers received.
    II) Date and method of detoxification.
    III) Name of agencies to whom containers were sold with quantities.
    IV) Transportation particulars.
24. No Hazardous Wastes should be mixed with any other wastes or should be discharged to a common, other internal, external sewerage or other drainage system without prior approval of APPCB.
25. If HDPE bags are used for storing Hazardous Wastes, it should be ensured that they are perfectly sealed mechanically or double hot sealed. If MS/HDPE bags or drums are used for storing Hazardous Wastes, these drums / bags should be ensured that they are perfectly sealed.
26. The person authorized should not rent, lend, sell, transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.

27. Any unauthorized change in personnel, equipment as working condition as mentioned in the application by the person authorized should constitute a breach of his authorisation.
28. The industry should comply with the provisions of Batteries (Management & Handling) Rules, 2001.
29. The industry should put up two sign boards (6x4 ft. each) at publicly visible places at the main gate. The first sign board should provide information on specific conditions of CFO and Hazardous Waste Authorisation. The second sign board should display online data on quantity and nature of hazardous chemicals being used in the plant, as well as water, air emissions and solid waste generated within the factory premises.
30. The applicant should exhibit the Consent & HW Authorisation order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.
31. Not withstanding anything contained in this conditional letter or consent, the Board hereby reserves the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and its amendments thereof and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and its amendments thereof to review any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
32. The authorisation issued under Hazardous Waste (Management, Handling & Transboundary Movement) Rules, 2008 and its amendments thereof, should comply with the provision of the Environment (Protection) Act, 1986.

SCHEDULE - B

Special Conditions

1. The industry should take steps to reduce water consumption to the extent possible and consumption should NOT exceed the quantities mentioned below:

S. No.	Purpose	Quantity
1	Process & Washings	9.39 KLD
2	Boiler & Cooling tower makeup	14.00 KLD
3.	DM Plant regeneration	0.1 KLD
4.	Domestic	0.5 KLD
5.	Gardening	2.0 KLD
	Total:	**24.99 KLD**

2 The industry should file the water cess returns in Form-I as required under section (5) of Water (Prevention and Control of Pollution) Cess Act, 1977 on or before the **5th of every calendar month**, showing the quantity of water consumed in the previous month along with water meter readings. The industry should remit water cess as per the assessment orders as and when issued by Board.
3. The emissions should not contain constituents in excess of the prescribed limits mentioned below.

Chimney No.	Parameter	Emission Standards
1	Particulate Matter	115 mg/Nm^3

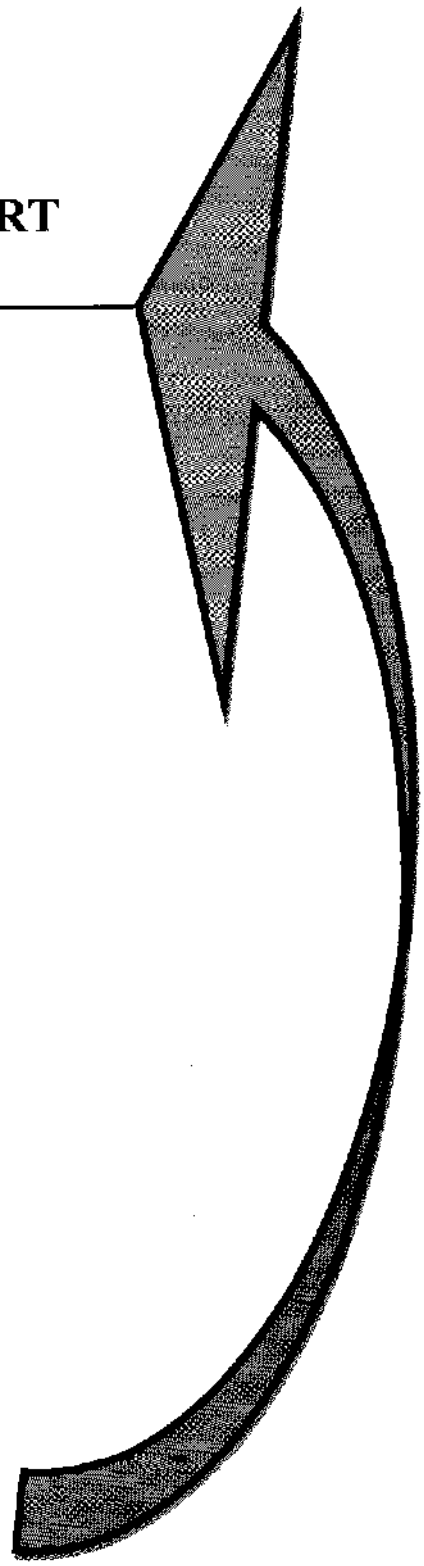
4. The industry should comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets more than 800 KW should comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.
5. The industry should comply with ambient air quality standards of PM_{10} (Particulate Matter size less than 10µg) - 100 µg/ m^3; $PM_{2.5}$ (Particulate Matter size less than 2.5 µg) - 200 µg/ m^3; SO_2 - 80 µg/ m^3; NO_x - 80 µg/m^3, outside the factory premises at the periphery of the industry.
   Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No.B-29016/20/90/PCI-I, dated 18.11.2009

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

6. The industry should not increase the capacity beyond the permitted capacity mentioned in this order, without obtaining CFE & CFO of the Board.
7. **The industry should comply with the Task Force directions issued from time to time.**

8. ***The industry should earmark an amount of Rs. 7.00 Lakhs in 2012 and further Rs 1.4 lakhs per annum for 10 years towards the Enterprise Social Responsibility (ESR) activities. The industry should earmark this amount towards the Enterprise Social Responsibility (ESR) activities and spend the amount under ESR activities through ESR/CSR Cell in the office of the District Collector.***
9. The industry should store the spent solvents in a raised concrete platform to avoid leaching of spillovers into the soil.
10. The industry should provide separate water meters with necessary pipeline for assessing the quantity of water used for each of the purposes mentioned below.
    a. Industrial cooling, boiler feed.
    b. Domestic purposes.
    c. Processing, whereby water gets polluted and pollutants are easily biodegradable.
    d. Processing, whereby water gets polluted and pollutants are not easily biodegradable.
11. The industry should maintain the following records and the same should be made available to the Board Officials during the inspection.
    a. Daily production details, RG-I records and Central Excise Returns.
    b. Quantity of Effluents generated and forced evaporated.
    c. Log Books for pollution control systems.
    d. Daily solid waste generated and disposed to TSDF.
12. The industry should maintain log books on the following.
    a. Hydraulic loads of effluent generation
    b. Characteristics of effluents
    c. Quantity of effluents forced evaporated.
    d. Condensate generation and reuse
    e. Furnish consolidated daily records on the above periodically once in **three months** to the RO, Nalgonda.
13. Rain water should not be allowed to mix with either trade or domestic effluents.
14. The industry shall install and operate the multi stage scrubber with online pH meter for scrubbing of process emissions at all emission sources. The details of chemicals consumption used in the scrubber shall be recorded & kept accessible for the inspecting officials of the Board. Industry shall control fugitive emissions by properly maintaining chilled brine circulation, closed room operations and condensers with receivers.
15. The industry shall not send the spent / mixed solvents to the recyclers. They shall process the same at solvent recovery plant within the plant premises. Solvents shall be recovered to the maximum extent possible and shall be reused.
16. The evaporation losses in solvents should be controlled by taking the following measures:
    i. Chilled brine circulation to effectively reduce the solvent losses into the atmosphere.
    ii. Transfer of solvents by using instead of manual handling.
    iii. Closed centrifuges be used due to which solvent losses will be reduced drastically.
    iv. The reactor vents connected with primary & secondary condensers to catch the solvent vapours.
    v. All the solvent storage tanks connected with vent condensers to prevent solvent vapours.
17. Solvent shall be taken from underground storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap received and condenser operated on chilled water.
18. Proper earthling shall be provided in all the electrical equipment wherever solvent handling is done.
19. *The industry should maintain Stripper, Double Effect Evaporator, RO, Nutch Filter for disposal of effluents and maintain zero discharge continuously and report the compliance to RO, Nalgonda every tow months.*
20. *The industry shall install ATFD and report compliance to RO, Nalgonda within two months.*
21. The industry should operate ETP regularly and all the units of the ETP should be impervious to prevent ground water pollution.
22. The industry should segregate the effluent into High TDS and Low TDS streams and treat them in the Stripper, Double Effect Evaporator, Press, Nutch filter, and RO.
23. The proponent should install multi stage scrubber with on line pH meters for of NH_3, SO_2, HCl, Bromine and other gaseous emissions. The scrubbed solutions should be recycled to the maximum extent.
24. The industry should under take characterization of effluents for each stream and adopt the treatment in environmentally sound manner.
25. The industry should maintain separate power consumption records pertaining to pollution control equipment.

CFO COMPLIANCE REPORT



Enclosure - 8

COMPLIANCE REPORT

S.No	CFO Conditions	Compliance
	SCHEDULE-A	
1.	The applicant shall make applications for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules at least 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts for obtaining Consent & HW Authorization of the Board	Condition has been noted and submitting for the same.
2	Any person aggrieved by the State Board under Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal (hereinafter referred to as the Appellate Authority) constituted under Section 28 of the Water (Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution)Act, 1981.	Condition will be followed
3	The industry shall immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions etc.	There is no change in raw materials used.
4	a) All the fugitive emissions shall be controlled with proper measures. b) The applicant shall also install the equipment such as wind speed recorder, wind direction recorder.	Proper measures will be taken to control fugitive emissions.
5	The applicant shall not change or alter either the quality or the quantity or the rate of the discharge or the route of discharge and shall not change or alter either the prescribed quality or the rate of emission without the previous written permission to the Board.	Condition has been noted and will be followed.
6	The applicant shall, not later than 30 day from the date of issue of this consent order, certify in writing to the Board that the applicant has installed of provided for an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production shall be stopped.	Condition will be followed.

7	Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and/ or violation of standards stipulated in this order or the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident , or other unforeseen act or event, the person – in-charge of the premises, from where such discharge/ emission occurs or is apprehended to occur shall forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax/ email under intimation to the Collector and District Magistrate.	Condition has been noted and will be followed as mentioned by you.
8	In case of such episodal discharges/ emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge/ emission below the limits prescribed in this order.	Necessary steps will be taken at such occurrences.
9	A good house keeping shall be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers, and drains shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way into the effluent collection system only and shall not be allowed to find their way into storm drains of open areas.	We are maintaining good housekeeping. Condition has been complied.
10	a)The industry shall carryout analysis of waste water discharges or emissions through chimneys , for the parameters mentioned in Schedule –B of this order at regular intervals. b) The industry shall maintain following records to accessible to the Board, whenever required. 1. Analysis reports of waste water/ emissions. 2. Log book for operation of pollution control systems. 3. Inspection book	Condition has been noted and will be followed. We are maintaining the records as mentioned by you in the consent.
11	Separate power connection with energy meter should be provided for the Pollution Control Equipments and record of power consumption and chemicals consumption for the operation of pollution control equipment should be maintained separately.	Separate power connection with energy meter has been provided

12	The applicant shall comply with the directives/orders issued by the Board in this order and at all subsequent times without any negligence on his part. The applicant shall be liable for such legal action against him as per provisions of the Law/Act in case if non-compliance of any order/directive issued at any time and /or violation of the terms and conditions of this consent order.	Condition has been noted and self explanatory.
13	The applicant shall furnish to the visiting officer and/ or the Board any information regarding the construction, installation or operation of the effluent treatment system / air pollution control equipment /secured storage area of Hazardous Waste and such other particulars as may be pertinent for preventing and controlling pollution.	Necessary information will be furnished to the concerned officer as mentioned by you.
14	The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability.	Condition has been noted and self explanatory.
15	All the rules & regulations notified by Ministry of Environment and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes shall be followed.	All the rules & regulations notified by Ministry of Environment and Forests, Government of India will be followed.
16	All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Ace, 1991 shall be followed	All the rules & regulations notified by Ministry of Law and Justice, Government of India will be followed.
17	The occupier shall educate the workers and nearby public of possible accidents and remedial measures.	Condition will be complied.
18	For any accident or spillage of hazardous wastes causing damage to the Environment, the occupier or the transporter as the case shall be held responsible.	Condition has been noted and self explanatory.
19	In case of closure of industry , the un-used /not consumed raw materials falling under the category of Hazardous Chemicals and mentioned Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment in Rules, 2003 shall be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident. In case the above hazardous	Condition will be followed.

	chemicals have lost their properties originally acquired , then they shall be treated, as Hazardous Waste and they should be disposed off only to the agencies authorized by APPCB in a safe manner.	
20	The occupier shall prepare/update Emergency preparedness plan for safe handling of hazardous waste from time to time and submit the same to APPCB. Emergency preparedness plan must be implemented immediately whenever there is fire, explosion or release of hazardous waste or hazardous waste constituents, which could endanger to human health or environment.	Emergency preparedness plan will be prepared and will be submitted.
21	Packaging , labeling and transportation of Hazardous Wastes shall be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling shall be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.	Packaging , labeling and transportation of Hazardous Wastes will be in accordance with the provisions of the rules issued by the Central Govt.
22	The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter shall carry a Transport Emergency (TREM) Card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.	We will hire a trained driver who acts accordingly at the time of emergency.
23	Containers/ Container Liners of Hazardous Waste should be thoroughly detoxified before selling to the agencies authorized by APPCB. Proper records, specific to each Hazardous Chemical /Hazardous Waste containers / Container Liners should be maintained in the following way: I) Number of containers received. II) Date and method of detoxification. III) Name of agencies to whom containers were sold with quantities. IV) Transportation particulars.	Containers/ Container Liners of Hazardous Waste will be thoroughly detoxified and all the records will be maintained.
24	No Hazardous Wastes shall be mixed with any other wastes or shall be discharged to a	Condition will be followed.

	common, other internal, external sewerage or other drainage system without prior approval of APPCB.	
25	If HDPE bags are used for storing Hazardous Wastes, it should be ensured that they are perfectly sealed mechanically or double hot sealed. If MS/HDPE bags or drums are used for storing Hazardous Wastes, these drums/bags should be ensured that are perfectly sealed.	Necessary steps will be taken to comply the condition.
26	The person authorized shall not rent, lend , sell, transfer their industrial premises without obtaining prior permission of the State Pollution Control Board.	Condition has been noted.
27	Any unauthorized change in personnel , equipment as working condition as mentioned in the application by the person authorized shall constitute a breach of his authorization,	Condition has been noted.
28	The industry shall comply with the provisions of Batteries (Management &Handling) Rules, 2001.	Condition will be complied.
29	The industry shall put up two sign boards (6x4 ft. each) at publicly visible places at the main gate. The first sign board shall provide information on specific conditions of CFO and Hazardous Waste Authorization. The second sign board shall display online data on quantity and nature of hazardous chemicals being used in the plant, as well as water, air emissions and solid waste generated within the factory premises.	Condition will be followed.
30	The applicant shall exhibit the Consent &HW Authorization order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.	Consent will be exhibited as mentioned by you.
31	Not withstanding anything contained in this conditional letter or consent , the Board hereby reserves the right and powers under Section 27(2) of the Water (Prevention &Control of Pollution) Act, 1974 and its amendments thereof and under Section 21 of the Air (Prevention &Control of Pollution)Act, 1981 and its amendments thereof to review any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.	Condition has been noted and self explanatory.

32	The authorization issued under Hazardous Waste (Management and Handling) &) Rules, 1989 and its amendments thereof, shall comply with the provision of the Environment (Protection)Act, 1986.	Condition has been noted.
	SCHEDULE-B	
1.	The industry should take steps to reduce water consumption to the extent possible and the consumption shall NOT exceed the quantities mentioned below:	Water consumption will be under the limits as mentioned by you.
2.	The industry should file the water Cess returns in Form-I as required under section (5) of Water (Prevention and Control of Pollution) Cess Act, 1977 on or before the 5th of every calendar moth, showing the quantity of water consumed in the previous month along with water meter readings. The industry shall remit water Cess as per the assessment orders as and when issued by Board	Water cess will be filed within the stipulated period as mentioned by you.
3.	The emissions should not contain constituents in excess of the prescribed limits mentioned below	Emissions will be under limit s only.
4.	The industry should comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E) dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.	Condition has been noted.
5.	The industry should comply with ambient air quality standards of PM 10 (Particulate Matter size less than 10µg) -100µg / m3; PM2.5 (Particulate Matter size less than 2.5 µg) – 200 µg/ m3;SO2 -80 µg /m3; NOX -80 µg/m3, out side the factory premises at the periphery of the industry. Standards for other parameters as mentioned in the National Ambient Air Quality Standards CPCB Notification No. B-29016/20/9/PCI-I, dated 18.11.209 Noise Levels: Day time –(6 AM to 10 PM) -75 Db (A) Night time-(10PM to 6PM)- 70 Db(A)	Ambient air quality standards will be maintained as mentioned by you in the consent.
6.	The industry should not increase the capacity beyond the permitted capacity mentioned in this order, without obtaining CFE and CFO of the Board.	Production capacity will be within the limits as mentioned by you.
7.	The industry should comply with the Task Force directions issued from time to time.	Task force directions has been complied.
8	The industry should earmark an amount of Rs. 7.00 Lakhs in 2012 and further Rs 1.4 Lakhs per annum for 10 years towards the Enterprise Social Responsibility (ESR) activities. The industry should earmark this amount towards the Enterprise Social Responsibility	Condition will be followed.

	(ESR) activities and spend the amount under ESR activities through ESR/CSR Cell in the office of the District Collector.	
9	The industry should store the spent solvents in a raised concrete platform to avoid leaching of spillovers into the soil.	Condition will be followed.
10	The industry should provide separate water meters with necessary pipeline for assessing the quantity of water used for each of the purposes mentioned below. i. Industrial cooling, boiler feed. ii. Domestic purposes iii. Processing, whereby water gets polluted and pollutants are easily biodegradable. iv. Processing, whereby water gets polluted and pollutants are not easily biodegradable.	Separate water meters has been provided.
11	The industry should maintain the following records and the same should be made available to the Board Officials during the inspection. a. Daily production details, RG-I records and Central Excise Returns. b. Quantity of Effluents generated and force evaporated c. Log Books for pollution control systems d. Daily solid waste generated and disposed to TSDF.	All the records mentioned in the consent will be maintained.
12	The industry should maintain log books on the following a. Hydraulic loads of effluent generation b. Characteristics of effluents c. Quantity of effluents forced evaporated d. Condensate generation and reuse e. Furnish consolidated daily records on the above periodically once in three months to the RO, Nalgonda.	Log books will be maintained.
13	Rain water should not be allowed to mix with either trade or domestic effluents.	Condition will be followed.
14	The industry shall install and operate the multi stage scrubber with online pH meter for scrubbing of process emissions at all emission sources. The details of chemicals consumption used in the scrubber shall be recorded & kept accessible for the inspecting officials of the Board. Industry shall control fugitive emissions by properly maintaining chilled brine circulation, closed room operations and condensers with receivers.	Multi stage scrubber has been installed.
15	The industry shall not send the spent / mixed solvents to the recyclers. They shall process the same at solvent recovery plant within the plant premises. Solvents shall be recovered to the maximum extent possible and shall be reused.	Condition will be followed.
16	The evaporation losses in solvents should be controlled	All the measures mentioned in the

	by taking the following measures i. Chilled brine circulation to effectively reduce the solvent losses into the atmosphere. ii. Transfer of solvents by using instead of manual handling iii. Closed centrifuges be used due to which solvent losses will be reduced drastically. iv. The reactor vents connected with primary & secondary to catch the solvent vapours v. All the solvent storage tanks connected with vent condensers to prevent solvent vapours.	consent will be followed.
17	Solvent shall be taken from underground storage tanks to reactors through closed pipeline storage tanks shall be vented through trap received and condenser operated on chilled water	Condition will be followed.
18	Proper earthling shall be provided in all the electrical equipment wherever solvent handling is done.	Earthing has been provided.
19	The industry should maintain stripper, Double Effect Evaporator, Ro, Nutch Filter for disposal of effluents and maintain zero discharge continuously and report the compliance to RO, Nalgonda every tow months.	Condition will be followed.
20	The industry shall install ATFD and report compliance to RO, Nalgonda within two months	ATFD has been installed.
21	The industry should operate ETP regularly and all the units of the ETP should be impervious to prevent ground water pollution.	Condition has been complied.
22	The industry should segregate the effluent into High TDS and Low TDS streams and treat them in the Stripper, Double Effect Evaporator, Press, Nutch filter, and RO.	Effluent segregation will be done.
23	The proponent should install multi stage scrubber with on line Ph meters for of NH_3, SO_2, HCl, Bromine and other gaseous emissions. The scrubbed solutions should be recycled to the maximum extent.	Multi stage scrubber has been installed.
24	The industry should under take characterization of effluents for each stream and adopt the treatment in environmentally sound manner.	Condition has been noted and will be followed.
25	The industry should maintain separate power consumption records pertaining to pollution control equipment.	Separate power consumption records will be maintained.
26	The industry should provide digital flow meter with totalizer to quantify the effluents evaporating in forced evaporation system within three months and report the compliance to the Board.	Digital flow meter has been provided.
27	The industry should provide vent condensers for all the storage tanks to prevent escaping of fugitive emissions and maintain the same effectively	Vent condensers for all the storage tanks has been provided.
28	The First Fore run of condensate from forced	Condition will be followed.

	evaporation system should be quantified and should furnish the details of characteristics and mode of disposal to the RO , Nalgonda.	
29	The details of chemicals consumption used in the scrubber should be recorded and kept accessible for the inspection officials of the Board.	chemicals consumption used in the scrubber will be recorded
30	The industry should construct elevated lined platform with dyke wall and leachate collection sump for storage of solvent drums, raw material drums, waste drums, waste etc. under shed. In no circumstances the drums should be stored on a naked open ground.	Condition will be followed.
31	The industry should evaluate the performance of solvent recovery system for each stream – wise and should furnish plan of action to maintain the efficiency of solvent recovery more than 95% for each stream wise	Condition will be followed.
32	There should not be any spillages / chemicals /effluents on ground. The drums containing chemicals /& wastes should be stored on elevated platform with a provision to collect leachate / spillages in the collection pit. In no case the drums should be stored on the naked open ground.	Condition will be followed.
33	The industry should take all safety measures and provide fire fighting equipment in the plant.	Fire fighting equipment has been provided.
34	The industry should establish appropriate RWH structure on the available up – stream portion of the plant site.	Condition will be followed.
35	The industry should not discharge any wastewater outside the factory premises and maintain zero discharge of effluents.	There will be no discharge any wastewater outside the factory premises and zero discharge of effluents will be maintained.
36	Thick green belt should be developed & maintained by the industry with tall growing trees in the vacant spaces of the unit covering an area of 33% of total area.	Green belt will be developed.
37	System of leak detection and repair of pump / pipeline shall be installed in the plant and immediate response team shall be identified for preventive maintenance.	System of leak detection has been installed.
38	The industry shall isolate the storage of highly inflammable chemicals solvents and other raw materials from the rest of the facilities in the plant premises.	Condition has been noted and will be followed.
39	The industry should ensure implementation of requisite measures to prevent air pollution & odour nuisance in the surrounding area. If it is found any activity of the industry is causing odour nuisance & air pollution, this consent order now issued will be revoked without further intimation.	Condition will be followed.
40	The industry should submit mock drill report carried out at least once in six months, as required under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989.	Condition will be followed.

41	The industry should comply with the Task Force directions issued from to time.	Condition has been noted.
42	The industry has submitted the Bank Guarantee of Rs. 2.0 lakhs with a validity period upto 23.12.2012. The Bank Guarantee submitted will be forfeited in favour of the Board if the industry fails to comply with Board direction/ standards.	Condition has been complied.
43	Industry shall comply with directions issued by the Board to achieve treatment scheme of Zero Effluent discharge vide Task Force No. NLG/PCB/TF-BO/2012-1291, Dated 23-06-2012 and furnish compliance report within one month.	Directions will be complied.
44	The applicant should submit Environment statement in Form V before 30th September of every year as per Rule No. 14 of E (P) Rules, 1986 & amendments thereof.	Environment statement will be submitted within the stipulated period.
45	The conditions are without prejudice to the rights and contentions of this Board in any Hon'ble Court of Law.	Condition has been noted.
46	The industry should maintain compliance of CFE order dt 14.11.2005	Condition will be followed.
47	The applicant should submit Environment statement in Form V before 30th September of every year as per Rule No. 14 of E (P) Rules, 1986 & amendments.	Environment statement will be submitted within the stipulated period.
	SCHEDULE-C	
1	The Industry shall give top priority for waste minimization and cleaner production practices.	Waste minimization will be given importance.
2.	The industry shall not store hazardous waste for more than 90 days as per the Hazardous Wastes (Management. Handling and Transboundary Movement) Rules, 2008 and amendments thereof.	Condition will be followed.
3.	The Industry shall store Used /Waste oils and Used Lead Acid Batteries in a secured way in their premises till its disposal.	Condition will be followed.
4.	The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors/Recyclers.	Waste oils will be disposed to authorized reprocessors/recyclers.
5.	The industry shall dispose Used Lead Acid Batteries to the manufactures/ dealers on buyback basis.	Used Lead Acid Batteries will be disposed to the manufactures/ dealers on buyback basis.
6.	The industry shall not dispose spent solvents / mixed spent solvents to the traders.	We will not dispose spent solvents / mixed spent solvents to the traders.
7.	The industry shall take necessary practical steps for prevention of oil spillages and carryover of oil from the premises.	Necessary steps will be taken for prevention of oil spillages and carryover of oil from the premises.
8.	The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board Office and concerned Regional Office.	We will maintain 6 copy manifest system.
9.	The industry shall maintain good house keeping & maintain proper records for Hazardous Wastes stated in Authourisation.	We are maintaining good house keeping and proper records of hazardous wastes.

10	The industry shall maintain proper records for Hazardous Wasted stated in Authorisation in FORM-3 i.e., quantity of Incinerable waste, land disposal waste, recyclable waste etc., and file annual returns in Form -4 as per Rule 22(2) of the Hazardous Wastes (Management, Handling & Transboundary Movement)Rules, 2008 and amendments thereof.	Records will be maintained as mentioned by you.
11	The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule B & C of this Order on half yearly basis to Board Office, Hyderabad and concerned Regional Office.	Condition has been noted and submitting for the same.
12	The industry shall dispose of e-waste to the authorized recyclers only.	E-waste will be disposed to the authorized recyclers only.
13	The industry shall conform to the co-processing guidelines of CPCB in sending wastes to co-processing for cement plants.	Condition will be followed.

LAND DOCUMENTS

Enclosure-9

ORIGINAL

దస్తావేజులు మరియు రుసుముల రశీదు

నెం. 11241

శ్రీమతి / శ్రీ G Prasantha Kumar MD

ఈ దిగువ ఉదహరించిన దస్తావేజులు మరియు రుసుము స్వీకరించబడినవి. Sharada pharma

దస్తావేజు స్వభావము	Sale	
దస్తావేజు విలువ	7,50,00,000	
స్టాంపు విలువ రూ.	100	
దస్తావేజు నెంబరు	P.1413	Cash
రిజిస్ట్రేషన్ రుసుము	3,75,000	2
GHMC (T.D.)		
యూజర్ చార్జీలు	2357,400	1
అదనపు షీట్లు	100	100
ఇతరములు	DD# 596484 Dt 16/12/18 SBH	
మొత్తం	27,32,500	

(అక్షరాల One Hundred) రూపాయలు మాత్రమే)

తేది 16/12/18

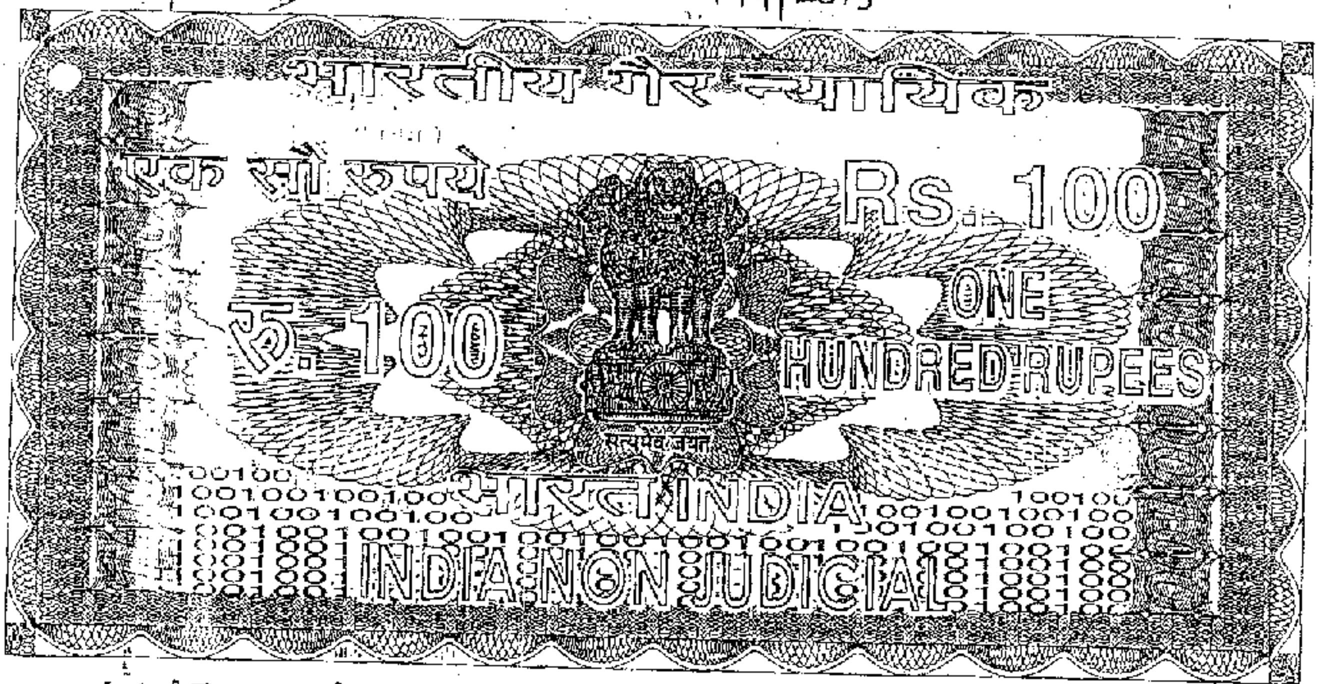
చలాను తేది

సబ్ రిజిస్ట్రారు

If Document is not claimed within 10 days from the date of Registration, safe custody fee of Rs. 50/- for every thirty days or part thereof, if in excess of 10 days subject to maximum of Rs. 500/- will be levied.

P. 44/13

6444/2013



ఆంధ్రప్రదేశ్ आन्ध्र प्रदेश ANDHRA PRADESH

S. No. 15691 Dt. 16/12/2013 Rs. 100/-

Sold to D. Mohan Rao S/o. D. Lingaiah

For whom Symed Labs Limited R/o. Hyderabad

BG 796821

Junior Assistant
EX-OFFICO STAMP VENDOR
S.R.O. CHOUTUPPAL

SALE DEED

THIS DEED OF SALE ("Sale Deed") is made and executed on this 16th day of December, 2013 by and between :

SHARANAA PHARMA PVT LTD, a Private Limited Company, incorporated under the Companies act, 1956 having its Registered Office at Plot No. 11, 1st Floor, Main Road, Krishna Reddy Nagar, New Bowenpally, Secunderabad (AP)-500 012 represented by its Managing Director Mr. G. Prasanth Kumar , S/o Dhanunjaya. aged about 50 years, resident of Plot No: 100, Road No:3, West Mared pally, Secunderabad(AP)., India duly authorized by the Ordinary Resolution passed by the Members of the Company at their Extra Ordinary General Meeting held on July 15, 2013 and subsequent Resolution passed by the Board of Directors at their Meeting held on July 15,2013 which are duly filed with the Office of the Registrar of Companies, Andhra Pradesh vide Receipt No. B 80279979, Dt. 26-07-2013 (Hereinafter referred to as "**VENDOR**" which expression shall mean and include its executors, legal representatives, assignees and administrators of the One Part).

For SHARANAA PHARMA PVT. LTD.

Authorised Signatory

IN FAVOUR OF

SYMED LABS LIMITED, a Public Limited Company, incorporated under the Companies Act, 1956 having its registered office at H.NO.8-3-166/6&7, IInd Floor, Erra gadda, Hyderabad 500 018 represented by its Managing Director Dr D Mohan Rao, S/o D. Lingaiah aged about 55 years, resident of D. No: 202, 8-2-293/82/A/202, Opp Jubilee International Club, Road No: 14, Jubilee Hills, Hyderabad – 500 038 duly authorized by the Resolution by the Board of Directors at their Meeting held on 10-08-2013 (Hereinafter referred to as : "VENDEE" which expression shall mean and include its executors, legal representatives, assignees and administrators of the other part).

WHEREAS:

A. The VENDOR had purchased Acres 2-24 Guntas of land along with RCC Building situated in Sy. No. 163 AND 163/A, Pittampally Village and Gramapanchayat, Chityal Mandal, Nalgonda District. The VENDOR subsequently constructed further buildings and structures having a total built up area around RCC 23,410 Sq.Ft. The VENDOR also has installed Plant and Machinery in the said buildings and structures. The details of which provided in Schedule Property.

B. The Schedule property was purchased by the Vendor admeasuring Ac. 2-00 Gts. in Sy.No. 163/A, Ac. 0-21 Gts. in Sy.No. 163 from Samidi Shekhar Reddy Vide Sale Deed Doct. No. 2547/2005, dt. 12-09-2005 and Rectification Deed Doct. No. 1211/2010, dt. 20-03-2010, Registered at S.R.O. Choutuppal, and Ac. 0-03 Gts. in Sy.No. 163 purchased from Samidi Vanaja Vide Sale Deed Doct. No. 1210/2010, Dt. 20-03-2010, Registered at S.R.O. Choutuppal.

C. AND WHEREAS the Board of Directors of "VENDOR" have decided to sell the said Schedule Property together with Land and Buildings, Plant and Machinery with all valid licenses and approvals and an Ordinary Resolution is passed approving the same in the Extra Ordinary General Meeting of Members held on 15-07-2013 and subsequently the Board of Directors at their Meeting held on 15-07-2013 authorizing Mr. G. Prasanth Kumar, Managing Director to negotiate the price for selling the schedule property.

For SHARANAA PHARMA PVT. LTD.

Authorised Signatory

D. AND WHEREAS the VENDOR herein has offered to sell the said property more fully described in the Schedule of Property mentioned hereunder to the VENDEE for a total sale consideration of Rs.7,50,00,000/- (Rupees Seven Crores fifty lacs only) and the VENDEE herein has agreed to purchase the Schedule Property for the said sale consideration from the VENDOR The VENDEE has already paid Rs.7,50,00,000/- (Rupees Seven Crores fifty lacs only) before the execution of this Sale Deed to the VENDOR and the VENDOR has admitted and acknowledged the receipt of the said total Sale consideration towards execution of sale of the schedule property and the VENDOR has also delivered the physical possession of the Schedule Property.

Whereas the Vendor has received the said consideration as follows:

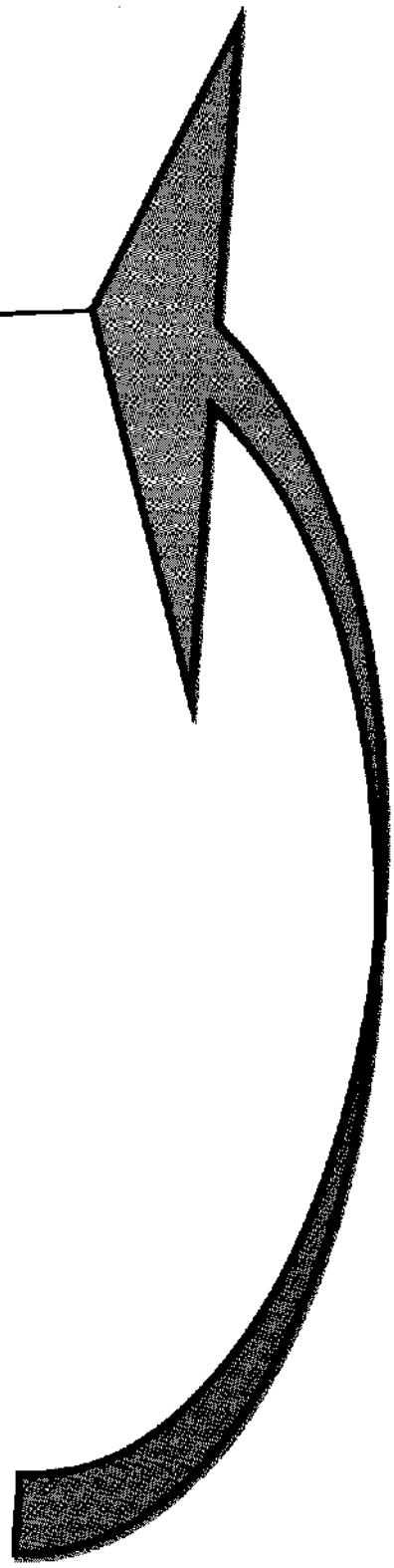
1. Rs. 10,00,000/- (Rupees Ten Lakhs only) received vide Cheque No. 004932, Dt. 11-07-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
2. Rs. 90,00,000/- (Rupees Ninety Lakhs only) received vide Cheque No. 004604, Dt. 19-08-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
3. Rs. 50,00,000/- (Rupees Fifty Lakhs only) received vide Cheque No. 006058, Dt. 23-09-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
4. Rs. 50,00,000/- (Rupees Fifty Lakhs only) received vide Cheque No. 006135, Dt. 27-09-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
5. Rs. 1,00,00,000/- (Rupees One Crore only) received vide Cheque No. 883070, Dt. 28-10-2013 of State Bank of Hyderabad, Sanath Nagar Branch, Hyderabad.
6. Rs. 50,00,000/- (Rupees Fifty Lakhs only) received vide Cheque No. 005523, Dt. 20-11-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
7. Rs. 10,00,000/- (Rupees Ten Lakhs only) received vide Cheque No. 007217, Dt. 12-12-2013 of Andhra Bank, S.C.F. Branch, Somajiguda, Hyderabad.
8. Rs. 2,71,22,274 (Rupees Two Crores Seventy One Lakhs Twenty Two thousand Two hundred and Seventy Four only) received vide Cheque No. 883088, Dt. 16-12-2013 of State Bank of Hyderabad, Sanath Nagar Branch, Hyderabad.
9. Rs. 1,11,27,726/- (Rupees One Crore Eleven Lakhs Twenty Seven thousand Seven hundred Twenty Six only) received vide Cheque No. 883089, Dt. 16-12-2013 of State Bank of Hyderabad, Sanath Nagar Branch, Hyderabad.
10. Rs. 7,50,000/- (Rupees Seven Lakhs Fifty thousand only) deducted as a T.D.S. under section 194-IA. (Payment on transfer of certain immovable property other than agricultural land).

This Deed of sale between the VENDOR and the VENDEE is subject to the following terms and conditions mutually agreed by them.

For SHARANAA PHARMA PVT. LTD.

Authorised Signatory

ACCREDITATION DETAILS



Annexure I-A

Name of the Consultant: **Rightsource Industrial Solutions Pvt. Ltd.**

2nd Floor, "Sri Laxmi Srinivasa Nilayam", Plot No. 7,
Road No. 1, Czech Colony, Santhnagar,
Hyderabad - 500018

Sectors Approved – 01 No.

Sl. No.	Sector No.	Name of Sector	Category A/B
1	21	Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates)	A

Total = 01 Sector*

**Sectors allocated to individual EIA Coordinators are mentioned in Annexure I-B*

(Vipin Sahni)
Director