APPLICATION FOR APPROVAL
OF
TERMS OF REFERENCE

FOR
OBTAINING ENVIORONMENT CLEARANCE

OF

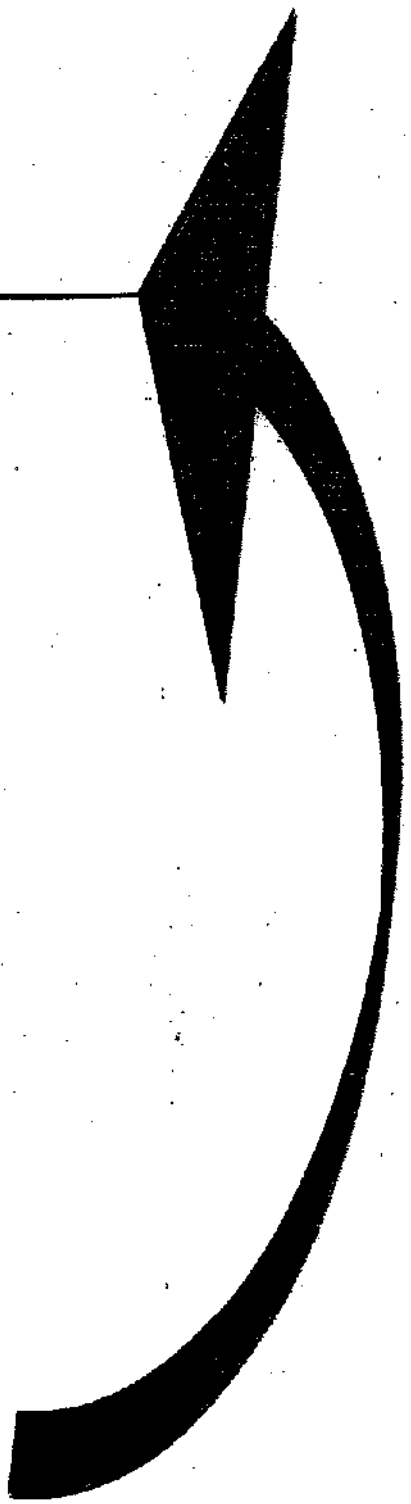
VINEET LIFE SCIENCES PVT. LTD.

SURVEY. NO'S: 1019, 1020 /A-2, 1020 /B, & 1021,
JANGAMAHESWRAPADU (V), DURGI (M),
GUNTUR (DT), ANDHRA PRADESH

Prepared By:

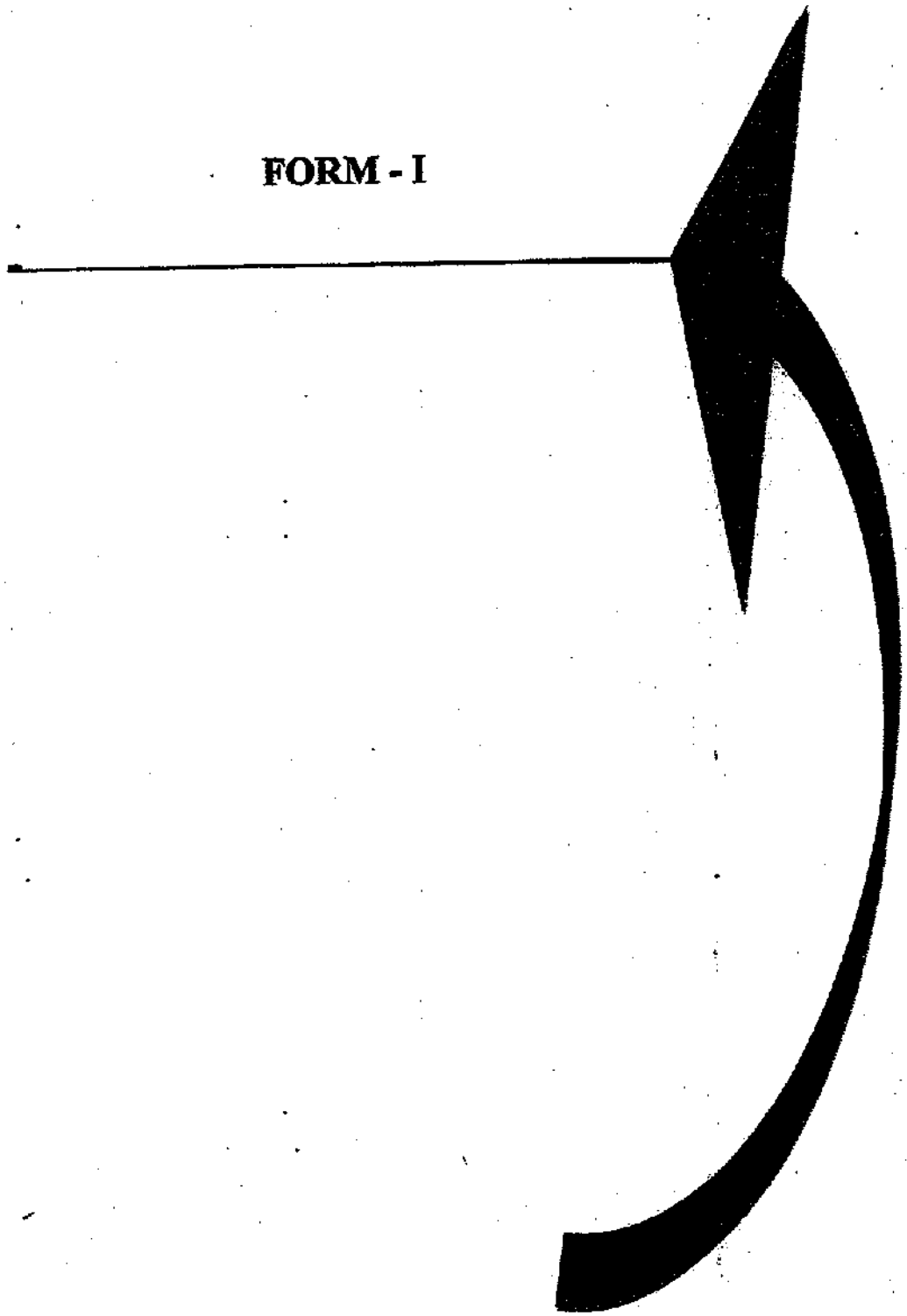
Rightsource Industrial Solutions Pvt. Ltd
Plot no: 203, House.No:5-36/203, Prashanthi nagar,
IDA, Kukatpally, Hyderabad – 500072.
PH: 040-65873137, 23070602, 23075699, 40126589.
FAX: 040-23070602. MAIL: info@rightsource.co.in

LIST OF CONTENTS



LIST OF CONTENTS

FORM - I



APPENDIX - I
FORM -1

I) Basic information

S. No	ITEM	DETAILS
1.	Name of the project/s	**M/s. VINEET LIFESCIENCES PVT. LTD**.
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	Bulk Drugs & Intermediates – 600 TPA Proposed products with capacities are Enclosed as **Annexure - I**
4.	New/Expansion/Modernization	New
5.	Existing Capacity/Area etc.	N.A
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	Latitude : 16^{o}22'17.87'' North Longitude :79^{o}32'15.25'' East Survey No's: 1019,1020/A-2,1020/B & 1021 Jangamaheswrapadu (V), Durgi (M), Guntur (Dt), Andhra Pradesh. Topo Map Enclosed as **Annexure-II**
10.	Nearest railway station / airport Along with distance in kms.	Macherla Railway Station – 16 KMs Gannavram Air Port - 135 KMs State Highway No.89 - 5.8 KMs
11.	Nearest Town, City & Distric Headquarters Along with distance in Kms.	Macherla - 15 Kms Vijayawada – 113 Kms District Head Quarter Durgi – 5 Kms.
12.	Village Panchayats, Zilla Parishad, Municipal Corporation, Local Body (Complete postal addresses with telephone nos. to be given)	Village Panchayats Jangamaheswrapadu (V), Durgi (M), Guntur (Dt),
13.	Name of the applicant	K. Murali Mohan
14.	Registered Address	**M/s. Vineet LifeSciences Pvt. Ltd.**
15.	Address for correspondence:	M/s. Rightsource Industrial Solutions Pvt. Ltd. Plot No.203,H.No.536/203,Prashantinagar, IDA, Kukatpally, Hyderabad-500072.
	Name	K. Murali Mohan
	Designation (Owner/Partner/CEO)	Director
	Address	**M/s. Vineet LifeSciences Pvt. Ltd.** Flat No.202, Sridevi Residency, Siva Ganga Colony, L.B Nagar, Hyderabad, AndhraPradesh.
	Pin Code	500072
	E-mail	info@rightsource.co.in

	Telephone No.	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, 972? (c) The C.R.Z Notification, 1991?	Not Applicable
22.	Whether there is any Government Order/Policy relevant/relating to the site?	No
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)	Yes	The Terrain of this land is at an elevation of 191 Mtrs. Permanent change in the land use. Construction of Buildings for manufacturing of Bulk Drugs & Intermediates are in 3.40 Acres (13,759.80 SQM) of land.

			There are no adverse impacts on land use as the land is very small and presently it is non agriculture land. But it is required to convert the land as industrial Land.
1.2	Clearance of existing land, vegetation and buildings?	No	N.A.
1.3	Creation of new land uses?	Yes	Total Plot Area : 13,759.80 SQM Built Up Area : 3313.60 SQM Green Belt : 4790.55 SQM Roads Area :1979.47 SQM Open Area :3676.17 SQM
1.4	Pre-construction investigations e.g. bore houses, soil testing?	Yes	Bore well and Soil.
1.5	Construction works?	Yes	Construction of Production Block-I&II, Solvent storage yard, MEE / ETP, Boiler House, Coal Sheds & other amenities will be involved. 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 earth works 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	**Construction Phase:** Temporary shed will be used to store materials like Cement etc., **Operational Phase:** A Designated ware house of 400 SQM is built to store the raw materials and goods. All the solvent/Diesel used in the process will be stored in either storage tanks or in the drums under a Roof with a leachate collection System as per the PESO Norms.

			Coal is stored on a designated platform with roof nearer to the boiler house.
1.15	Facilities for treatment or disposal of solid waste or liquid effluents?	Yes	All the Liquid Waste generated from the proposed plant will be mitigated in plant premises by installing 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	No
1.20	New or diverted transmission lines or pipelines?	No	No
1.21	Impoundment, damming, culverting, realignment or other changes to the hydrology of watercourses or aquifers?	No	No
1.22	Stream crossings?	No	No
1.23	Abstraction or transfers of water from ground or surface waters?	Yes	Water will be drawn from the Bore well in proposed site with an approval from the SGWD. 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	No	Nil (There will not be any changes in water bodies or the land surface

	or run-off?		affecting drainage or run-off)
1.25	Transport of personnel or materials for construction, operation or decommissioning?	Yes	The construction material shall be drawn from local sources within 15Km. There is no transport of personnel as the construction workers shall be drawn from nearby villages. A Mini Bus will be providing to the employees from the nearby residential area during the operational phase.
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?	No	Not Applicable
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)	Yes	3.4 Acres of land is used for the proposed activity. Presently the land is single crop dry land but presently there is non-agriculture in the proposed site .But it is required to convert the land as non agricultural purpose from the concerned department.
2.2	Water (expected source & competing users) unit: KLD	Yes	**Construction Phase:** Approximately 10 KLD of water is used in this phase and will be met from the bore well located in the plant premises **Operational phase:** Maximum of 112.78 KLD of water is required in this phase but will be

			reduced this fresh water requirement by using the recovered and recycled water. 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)	Yes	From the Local Sources Approximately Stone - 20mm – 250 M^3 40mm – 150 M^3 Sand – 1000 Tones.
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-APCPDCL–**800 KVA** • Generator: **380 & 250KVA** as stand by. Fuel: HSD about 60.8 & 40 Liters per Hour • Steam: from Boiler **2.0 & 3.0 TPH** Coal Fired Boiler • Coal to the maximum of **12.5 TPD** is required and will be procured from the local sources.
2.7	Any other natural resources (use appropriate standard units)	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, and 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 wastess	No	No demolition waste will be generated. Construction waste such as dugout soil will be used as replenishment.
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	The noise generating from the earth moving equipment is very low as it is a small construction activity.
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 earth moving 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 is 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 environment e.g. * Supporting infrastructure (roads, power supply, waste or waste water treatment, etc.) * Housing development * Extractive industries * Supply industries * Other	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
9.2	Lead to after-use of the site, which could have an impact on the environment	Yes	Site will be permanently used for manufacturing bulk drugs with taking proper Environmental protection and mitigation measures to avoid impacts on biotic and abiotic environment.
9.3	Set a precedent for later developments	No	Since area is small, there will not be much development at latter stages. Green belt development is envisaged.

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	None	-
10.2	Areas which are important or sensitive for ecological reasons – Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	**Reserved Forest** **Water Bodies**	Kakirala RF – 0.58 KMs.(E) Mutukuru RF – 1.2 KMs (S) Bollapalle RF–6.8KMs (SE) Bugga Dam Reservoir -7.5 KMs(N)
10.3	Areas used by protected, important or sensitive species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	None	-
10.4	Inland, coastal, marine or underground waters	None	-
10.5	State, National boundaries	None	-
10.6	Routes or facilities used by the public for access to recreation or other tourist, pilgrim areas	None	-
10.7	Defense installations	No	None
10.8	Densely populated or built-up area	Yes	Durgi –5 Kms
10.9	Areas occupied by sensitive man-made land uses (hospitals, places of worship, community facilities)	Yes	Obulesunipalle – 5.81 KMs Durgi - 6.36 Kms Dharmavaram - 9.13 KMs Atmakur – 8.35KMs Rayavaram – 11.61 KMs Mutukuru - 6.07 KMs
10.10	Areas containing important, high quality or scarce resources (ground water resources, surface resources, forestry, agriculture, fisheries, tourism, minerals).	**Reserved Forest** **Water Bodies**	Kakirala RF – 0.58 KMs.(E) Mutukuru RF -1.2 KMs (S) Bollapalle RF–6.8 KMs (SE) Bugga Dam Reservoir -7.5 KMs(N)

10.11	Areas already subjected to pollution or environmental damage. (Those where existing legal environmental standards are exceeded)	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)	None	-

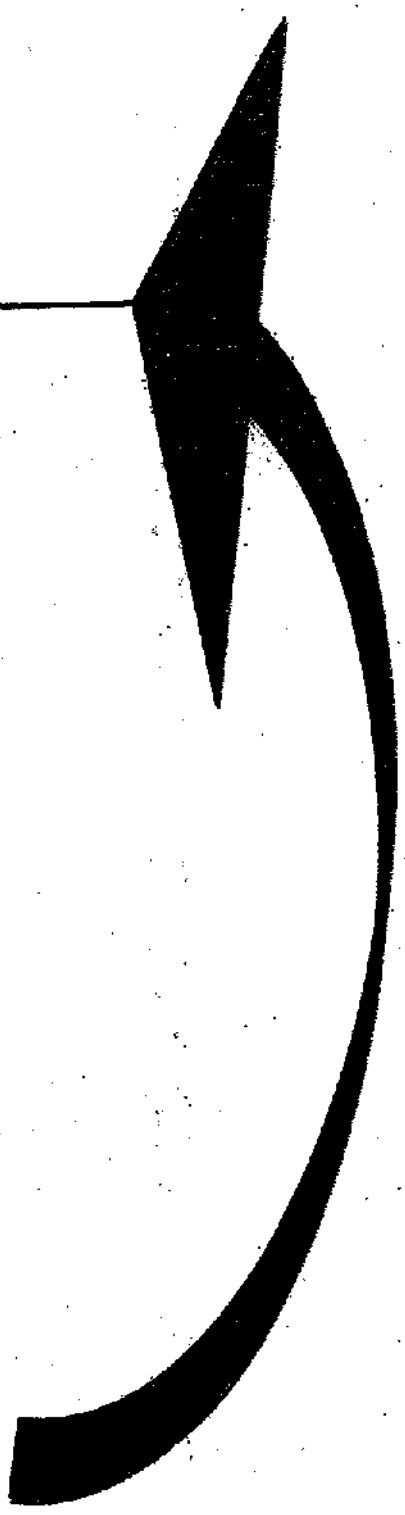
"I hereby given undertaking that the data and information given in the application and enclosures are true to the best of my knowledge and behalf and I am aware that if any part of the data and information submitted is found to be false or misleading at any stage, the project will be rejected and clearance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

Date: 15.03.2014
Place: Hyderabad

For Vineet Life Sciences Pvt. Ltd.,

K. Murali Mohan
Director

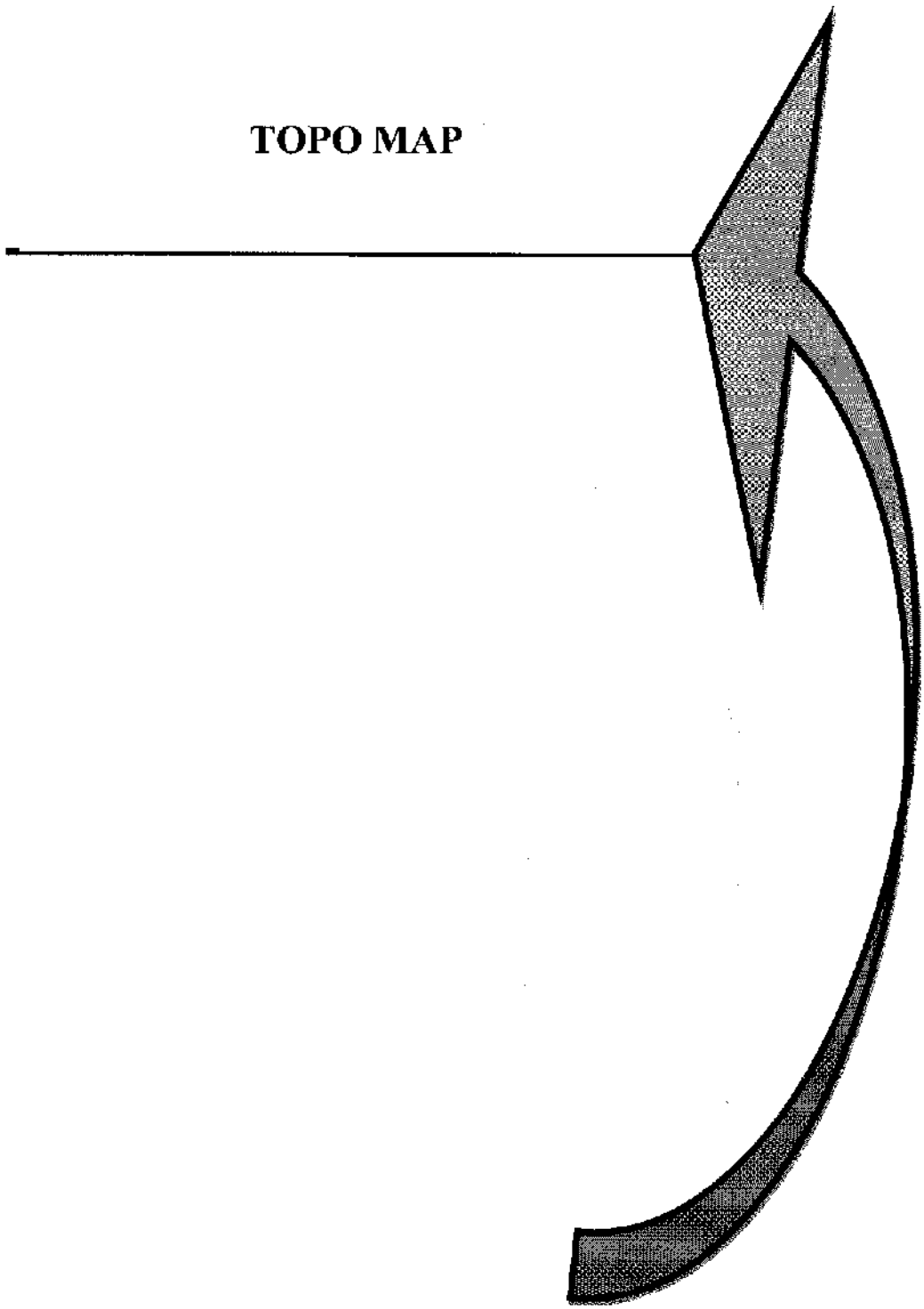
LIST OF PRODUCTS

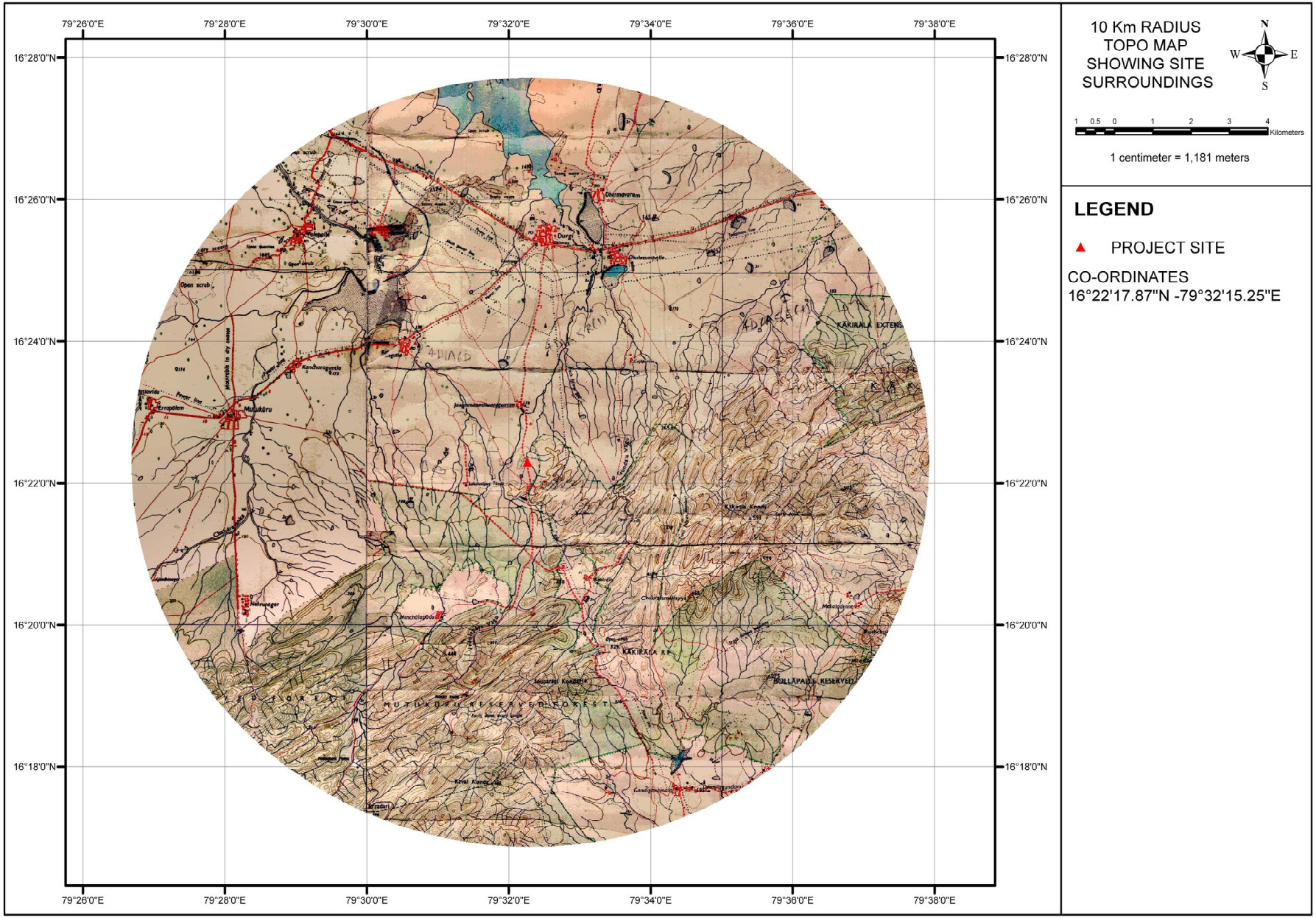


LIST OF PRODUCTS

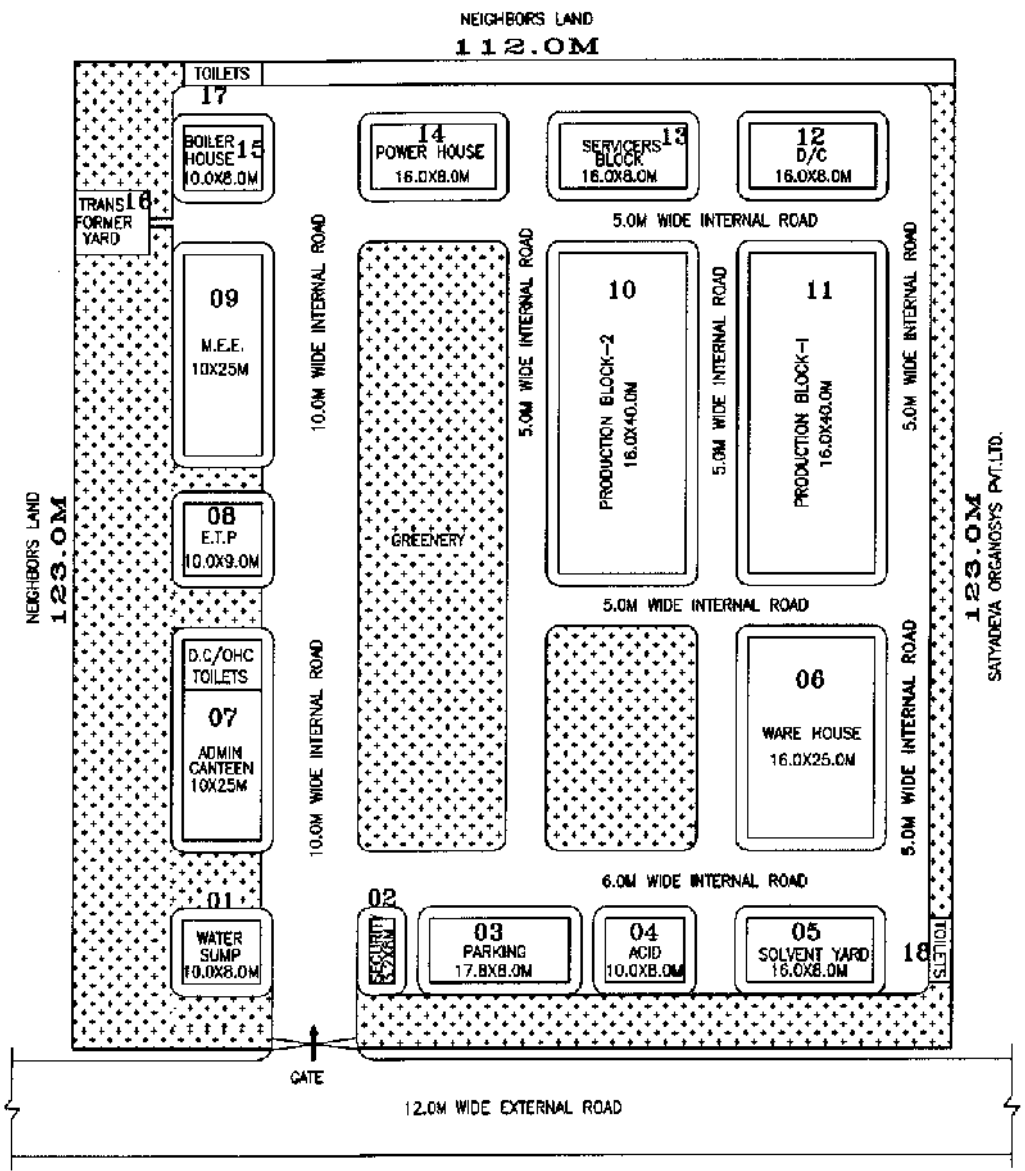
S. No	Name of the Product	CAS No's	Quantity In Kg/Month	Quantity In Kg/Day
1	Albendazole	54965-21-8	5000.00	166.67
2	Amlodipine Besylate	111470-99-6	2000.00	66.67
3	Efavirenz	154598-52-4	3000.00	100.00
4	Emtricitabine	143491-57-0	3000.00	100.00
5	Famotidine	76824-35-6	6000.00	200.00
6	Fluconazole	86386-73-4	2000.00	66.67
7	Lamivudine	134678-17-4	1500.00	50.00
8	Levosulpride	23672-07-3	2000.00	66.67
9	Lopinavir	192725-17-0	1000.00	33.33
10	n-Butyl Lithium	109-72-8	15000.00	500.00
11	Pantoprazole sodium	138789-67-1	1500.00	50.00
12	Ritanovir	155213-67-5	1000.00	33.33
13	Triclabendazole	68786-66-3	5000.00	166.67
14	Valsartan	13786-2-53-4	1000.00	33.33
15	Zidovudine	30516-87-1	1000.00	33.33
	Total		**50000.00**	**1666.67**

TOPO MAP




79°26'0"E
79°28'0"E
79°30'0"E
79°32'0"E
79°34'0"E
79°36'0"E
79°38'0"E
16°28'0"N
16°26'0"N
16°24'0"N
16°22'0"N
16°20'0"N
16°18'0"N
10 Km RADIUS
TOPO MAP
SHOWING SITE
SURROUNDINGS
N
W
E
S
1 0.5 0 1 2 3 4
Kilometers
1 centimeter = 1,181 meters
LEGEND
PROJECT SITE
CO-ORDINATES
16°22'17.87"N -79°32'15.25"E

SITE PLAN



ORG.NO: VLSPL-GEN-1

CUSTOMER:

VINEET LIFE SCIENCES PVT. LTD.
Sy.NO:1019,1020/A-2,1020/B & 1021.
JANGAMAHESWARA PADU(V), DURGI(M),
GUNTUR(Dist)

S.NO.	DESCRIPTION	L in MT	B in MT	AREA in Sq.Mts.
01	HARD WATER SUMP	10.0M	08.0M	80.0M
02	SECURITY	03.2M	08.0M	25.6M
03	PARKING	17.0M	08.0M	136.0M
04	ACID	10.0M	08.0M	80.0M
05	SOLVENT YARD	16.0M	08.0M	128.0M
06	WARE HOUSE	16.0M	25.0M	400.0M
07	CANTEEN/ADMIN D/C OHC /TOILETS	10.0M	25.0M	250.0M
08	E.T.P	10.0M	09.0M	90.0M
09	M.E.E.	10.0M	25.0M	250.0M
10	PRODUCTION BLOCK-II	16.0M	40.0M	640.0M
11	PRODUCTION BLOCK-I	16.0M	40.0M	640.0M
12	D/C	16.0M	08.0M	128.0M
13	SERVICE BLOCK	16.0M	08.0M	128.0M
14	POWER HOUSE	16.0M	08.0M	128.0M
15	BOILER HOUSE	10.0M	08.0M	80.0M
16	TRANSFORMER YARD	08.0M	09.6M	76.8M
17	TOILETS	10.0M	03.0M	30.0M
18	TOILETS	08.0M	03.0M	24.0M
			TOTAL-	3313.60M

AREA: TOTAL LAND:	3.4Acre OR 13,759.80 SQM
TOTAL BUILTUP AREA	3,313.60 SQM
GREENERY AREA	4,790.55 SQM
OPEN AREA	3,676.17 SQM
ROADS AREA	1,979.47 SQM

GENERAL NOTES

1)ALL DIMENSIONS ARE IN MM & MTS ONLY

PROPOSED [ ] EXISTING [ ] DELETION [ ]

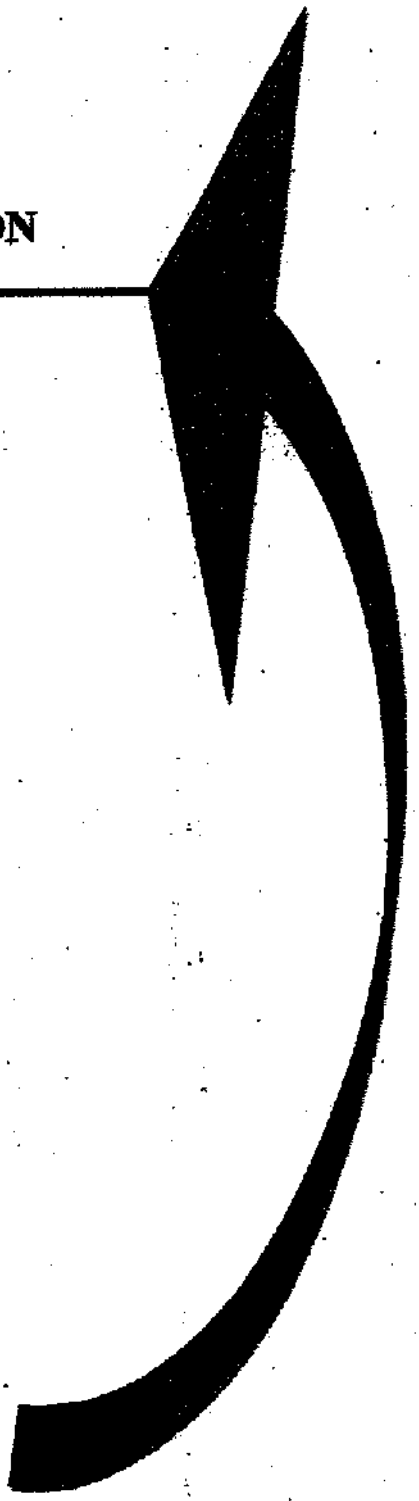
TITTLE: PLOT PLAN

ENGINEER SIGN:-

SIGN OF OCCUPIER:-

PREPARED BY:
SAI RAM DESIGNS&DRAFTING
HYDERABAD-500 043.
TEL:040-64510316(O) CELL-9948060316
email: designs@sairamdesigns.com

PROCESS DESCRIPTION



1. ALBENDAZOLE

Process Description:

Stage-1

2-Nitro-4-Thiocyano aniline reacts with 1-Bromo propane in the presence of Sodium hydroxide as base to give Stage-1 as product.

Stage-2

Stage-1 reacts with Sodium hydrogen sulphide by means of hydrolysis to give stage-2 as product.

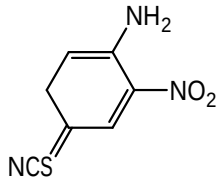
Stage-3

Stage-2 reacts with Methyl carbonyl cyanamide and Hydrochloric acid in the presence of Methanol as a solvent media to give Albendazole as product.

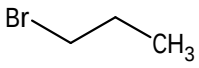
ALBENDAZOLE

Route of synthesis:

Stage-1

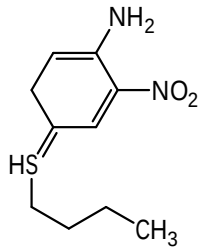


\+



\+ 2NaOH + H_2SO_4 —Water→

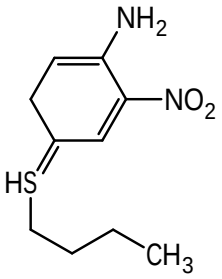
2-Nitro-4-Thiocyano aniline	1-Bromo-propane	Sodium hydroxide	Sulphuric acid
$C_7H_6N_3O_2S$	C_3H_7Br	2X40=80.00	98.07
196.20	122.99		



\+ Na_2SO_4 + HBr + $NO_2\uparrow$

4-(Butyl-I^4-sulfanylidene)-6-nitro -cyclohexa-1,5-dienylamine	Sodium sulphate	Hydrobromic acid	Nitrogen dioxide
$C_{10}H_{16}N_2O_2S$	142.04	80.91	46.00
228.31			

Stage-2



4-(Butyl-I^4-sulfanylidene)-6-nitro -cyclohexa-1,5-dienylamine

$C_{10}H_{16}N_2O_2S$

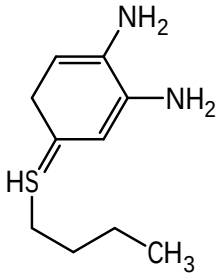
228.31

\+ 2 NaHS + $2H_2O$ —n-propanol→

Sodium hydrogen sulphide

2X56.06=112.12

18.00



4-(Butyl-I^4-sulfanylidene)-cyclohexa-2,6-diene-1,2-diamine

$C_{10}H_{18}N_2S$

198.32

\+ $Na_2S_2O_3$ + $H_2\uparrow$

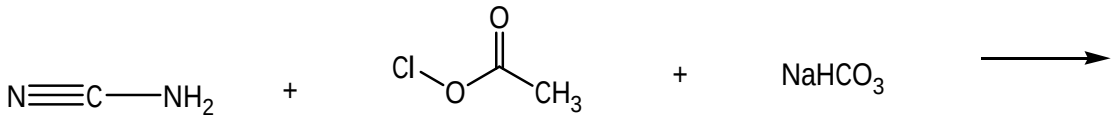
Sodium dithionate

158.10

2.00

Stage-3

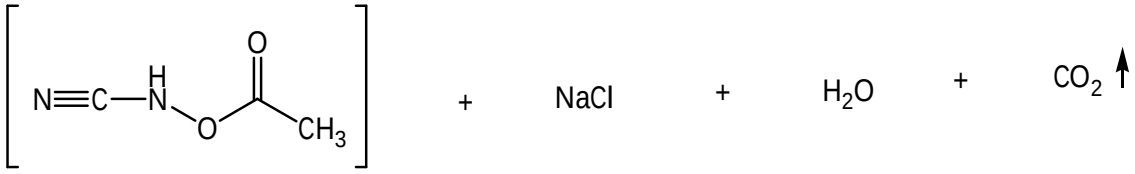
Step-A



Cyanamide
42.03

Chloro acetate
$C_2H_3ClO_2$
94.49

Sodium bicarbonate
84.00



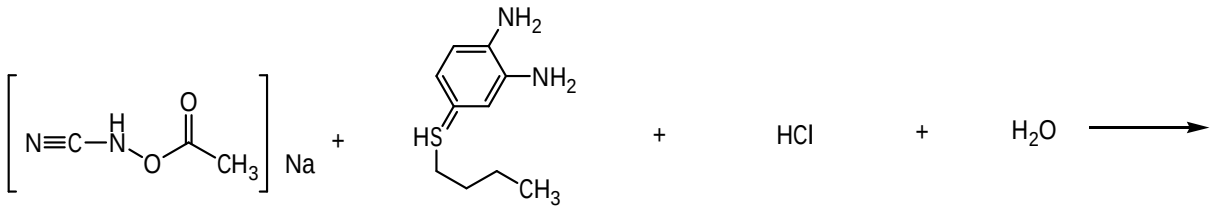
Methyl carbonyl cyanamide
$C_3H_4N_2O_2$
100.07

Sodium chloride
58.44

18.00

Carbon dioxide
44.00

Step-B

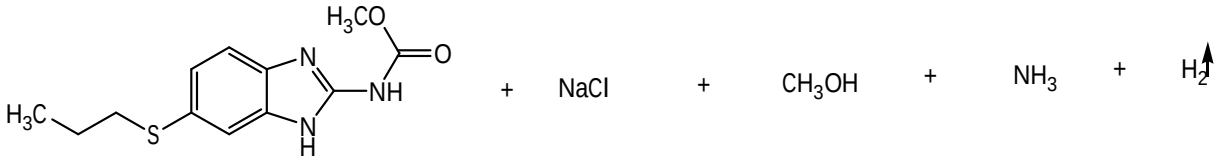


Methyl carbonyl cyanamide
$C_3H_4N_2O_2Na$
123.06

4-(Butyl-I^4-sulfanylidene)-cyclohexa-2,6-diene-1,2-diamine
$C_{10}H_{18}N_2S$
197.32

Hydrochloric acid
36.45

18.00



Albendazole
$C_{12}H_{15}N_3O_2S$
265.33

Sodium chloride
58.44

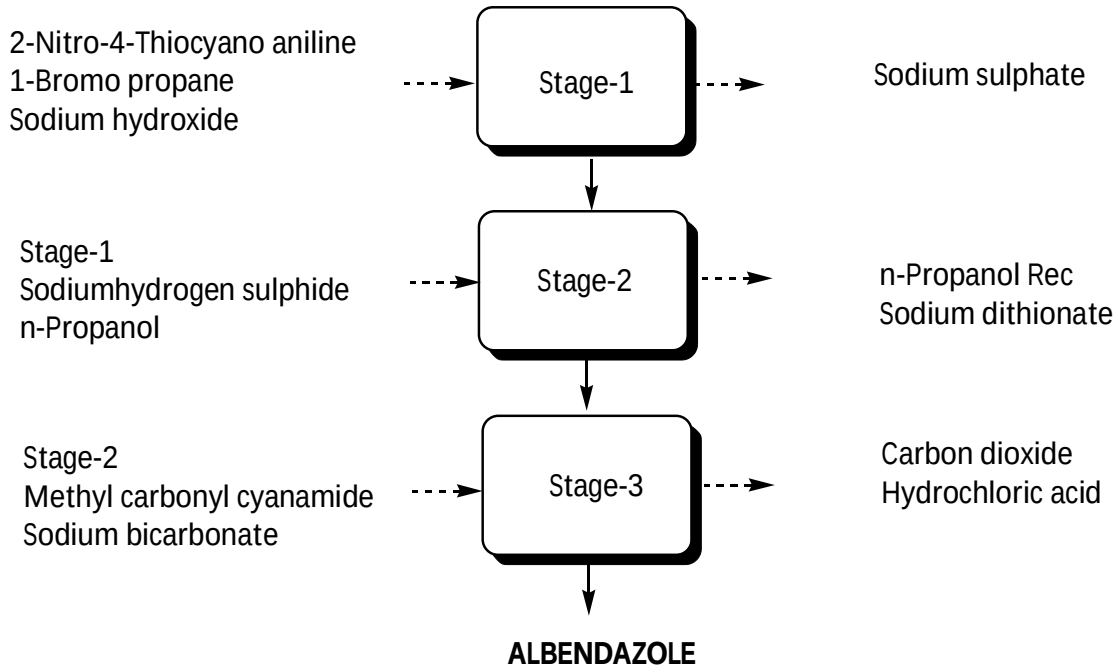
Methanol
32.04

Ammonia
17.03

2.00

ALBENDAZOLE

Flow Chart:



ALBENDAZOLE

Material Balance:

Material Balance of Albendazole Stage-1 Batch Size: 100Kgs				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
2-Nitro-4-Thiocyano aniline	74.00		Stage-1	86.11
n-Bromo propane	46.38		n-Propanol Recovery	1328.00
Sodium hydroxide	30.16		n-Propanol Loss	70.00
n-Propanol	1400.00		Effluent water	830.51
Sulphuric acid	36.98		(Water-800,Hydrobromic acid-30.51)	
Water	800.00		Inorganic Residue	53.54
			(Sodium sulphate)	
			Process emission	17.34
			(Nitrogen dioxide-17.34)	
			Organic Residue	2.02
			(Organic impurities-0.02, n-Propanol-2)	
Total	2387.52		Total	2387.52

Material Balance of Albendazole Stage-2 Batch Size: 100Kgs				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	86.11		Stage-2	74.80
Sodium hydro sulphide	42.28		n-Propanol Recovery	807.50
n-Propanol	850.00		n-Propanol Loss	42.50
Water	400.00		Effluent water	386.43
			(Water-386.43)	
			Inorganic Solid waste	59.61
			(Sodium dithionate-59.61)	
			Process Emission	0.75
			(Hydrogen)	
			Organic Residue	6.80
Total	1378.39		Total	1378.39

Material Balance of Albendazole Stage-3 Batch Size: 100Kgs				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	74.80		Albendazole	100.00
Cyanamide Solution	90.00		Methanol Recovery	710.00
Methyl chloro formate	35.58		Methanol Loss	37.50
Sodium bicarbonate	31.63		Effluent water	462.03
Methanol	750.00		(Water-393.23,Generated water-6.77,Hydrochloric acid- 13.72, Methanol-12.07,Water from Cyanamide solution-14.24,Sodium chloride-22)	
Water	400.00		Organic Residue	48.76
			(Organic Impurities-46.26, Methanol-2.50)	
			Process Emission	23.72
			(Carbon dioxide-16.56,Ammonia-6.41,Hydrogen-0.75)	
Total	1382.01		Total	1382.01

2. AMLODIPINE BESYLATE

Process Description:

Stage-1

Phthalic anhydride reacted with Mono ethanol amine in Toluene media forms phthalimido ethanol

Stage-2

Phthalimido ethanol reacted with Ethyl-4-chloro aceto acetate in presence of sodium hydride, Toluene forms ethyl phthalimido ethoxy aceto acetate.

Stage-3

Ethyl phthalimido ethoxy aceto acetate condensate with ortho chloro Benz aldehyde

Stage-4

Ethyl phthalimido ethoxy aceto acetate and ortho chloro Benz aldehyde condensate reacted methyl β-amino crotonate in Acetic acid media and further purified in Ethyl acetate and forms phthalimido Amlodipine

Stage-5

Phthalimido Amlodipine reacted with Mono methyl amine forms Amlodipine Base.

Stage-6

Amlodipine Base reacted with Benzene sulphonic acid in water media forms Amlodipine Besylate

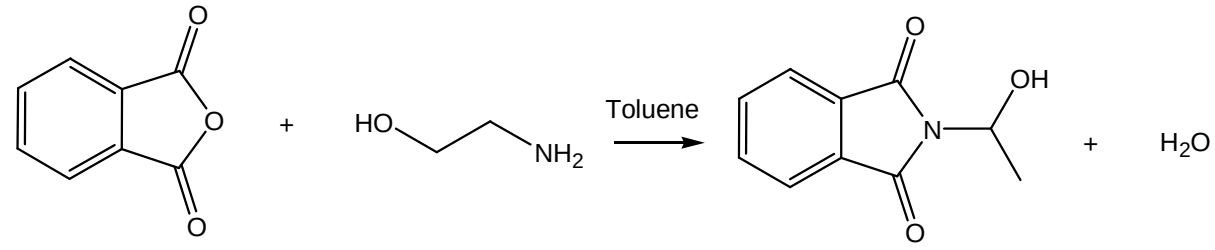
Stage-7 (Purification)

Amlodipine Besylate further purified in Methanol and Ethyl Acetate to get Pure Amlodipine Besylate Product

AMLODIPINE BESYLATE

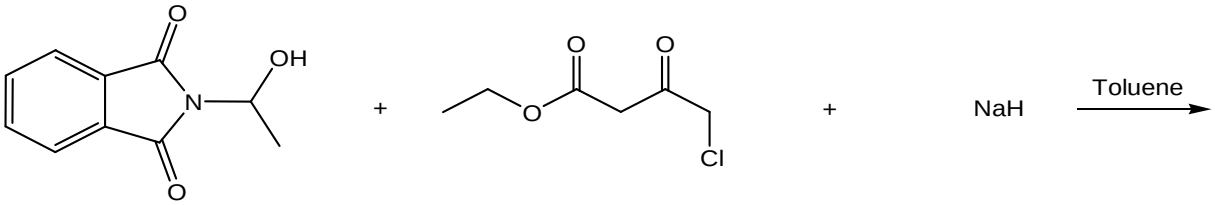
Route of Synthesis:

Stage-1

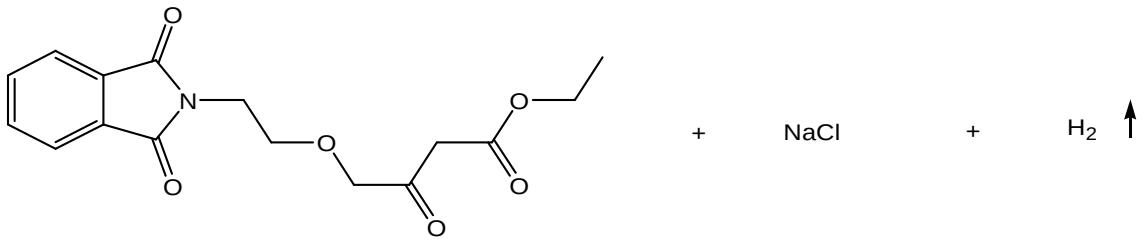


Phthalic anhydride	Mono ethanol amine	Phthalimido ethanol	Water
$C_8H_4O_3$	C_2H_7NO	$C_{10}H_9NO_3$	18.0
148.12	61.08	191.18	

Stage-2

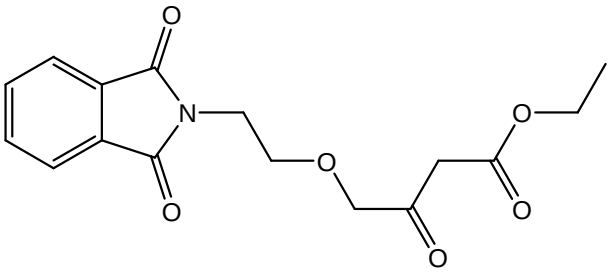


Phthalimido ethanol	Ethyl-4-chloro acetoacetate	Sodium hydride
$C_{10}H_9NO_3$	$C_6H_9ClO_3$	24.0
191.18	164.59	



Ethyl-4(2-Phthalimido)ethoxy acetoacetate	Sodium Chloride	Hydrogen
$C_{16}H_{17}NO_6$	58.44	2.0
319.31		

Stage-3

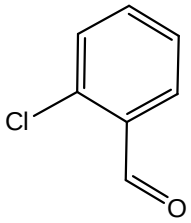


Ethyl-4(2-Phthalimido)ethoxy acetoacetate

$C_{16}H_{17}NO_6$

319.31

+

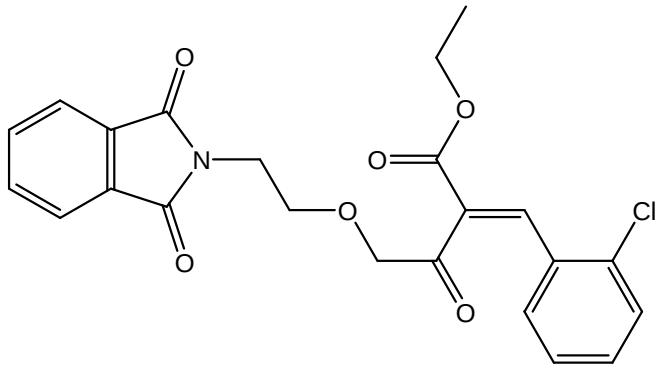


Orthochloro benzaldehyde

C_7H_5ClO

140.57

Piperadine (Catalyst)



2-(2-Chloro-benzylidene)-4-[2-(1,3-dioxo-1,3-dihydro-isoindol-2-yl)-ethoxy]-3-oxo-butyric acid ethyl ester

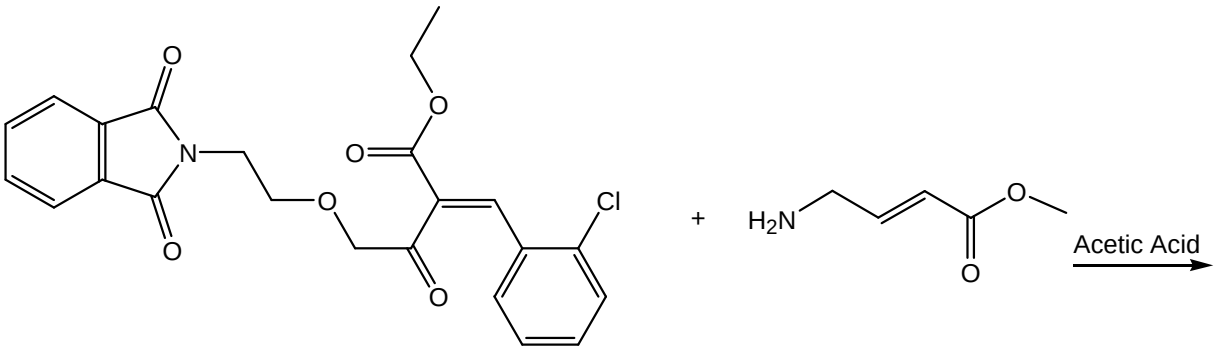
$C_{23}H_{20}ClNO_6$

441.86

+ H_2O

18.0

Stage-4



2-(2-Chloro-benzylidene)-4-[2-(1,3-dioxo-1,3-dihydro-isoindol-2-yl)-ethoxy]-3-oxo-butyric acid ethyl ester

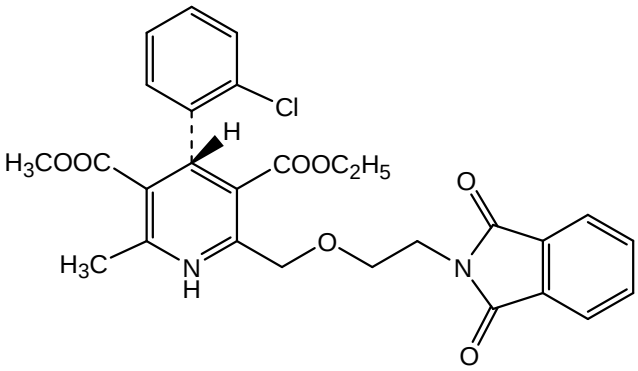
$C_{23}H_{20}ClNO_6$

441.86

Methyl Amino crotonate

$C_5H_9NO_2$

115.13



\+ H_2O

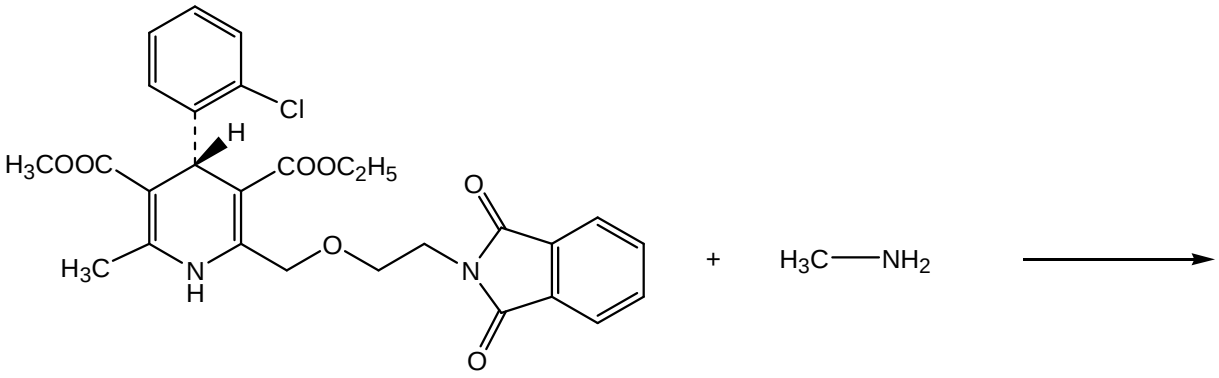
Phthalimido amlodipine

$C_{28}H_{27}ClN_2O_7$

538.98

18.0

Stage-5



Phthalimido amlodipine

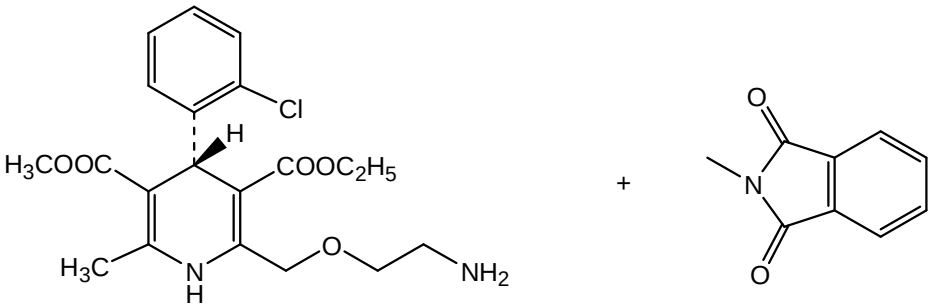
$C_{28}H_{27}ClN_2O_7$

538.98

Mono methylamine

CH_5N

31.06



Amlodipine Base

$C_{20}H_{25}ClN_2O_5$

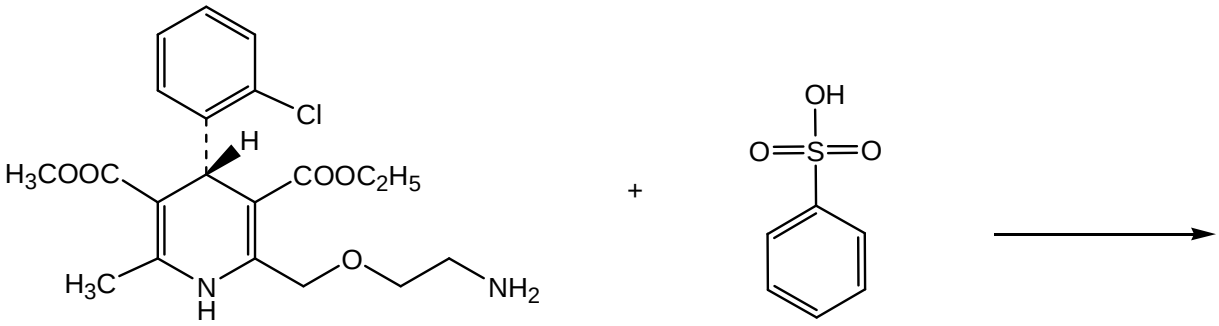
408.88

2-Methyl-isoindole-1,3-dione

$C_9H_7NO_2$

161.16

Stage-6



Amlodipine Base

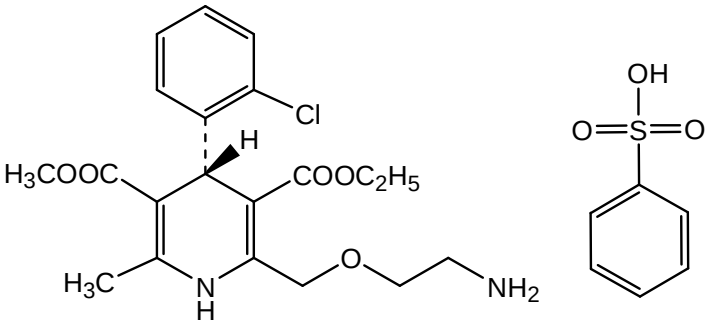
$C_{20}H_{25}ClN_2O_5$

408.88

Benzene Sulfonic Acid

$C_6H_6O_3S$

158.18

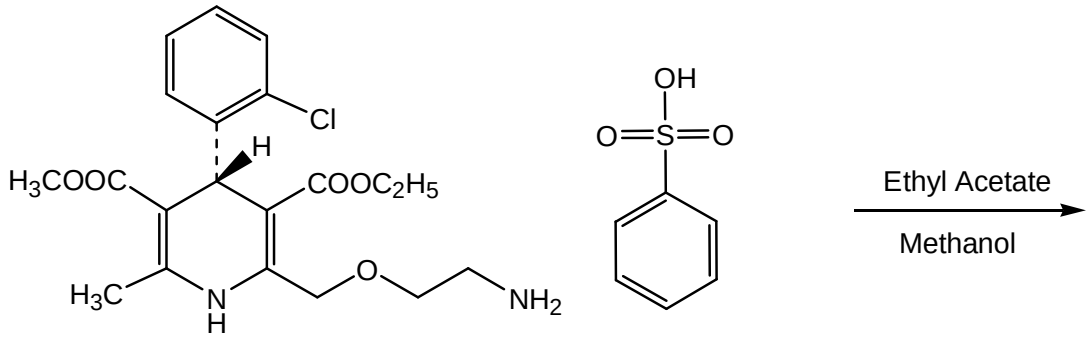


Amlodipine Besylate

$C_{26}H_{31}ClN_2O_8S$

567.05

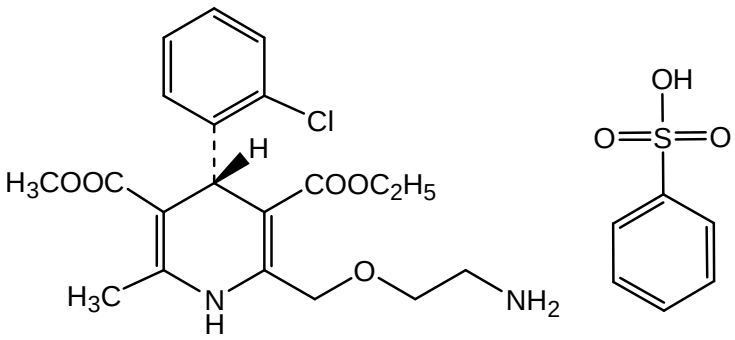
Stage-7 (Purification)



Amlodipine Besylate

$C_{26}H_{31}ClN_2O_8S$

567.05



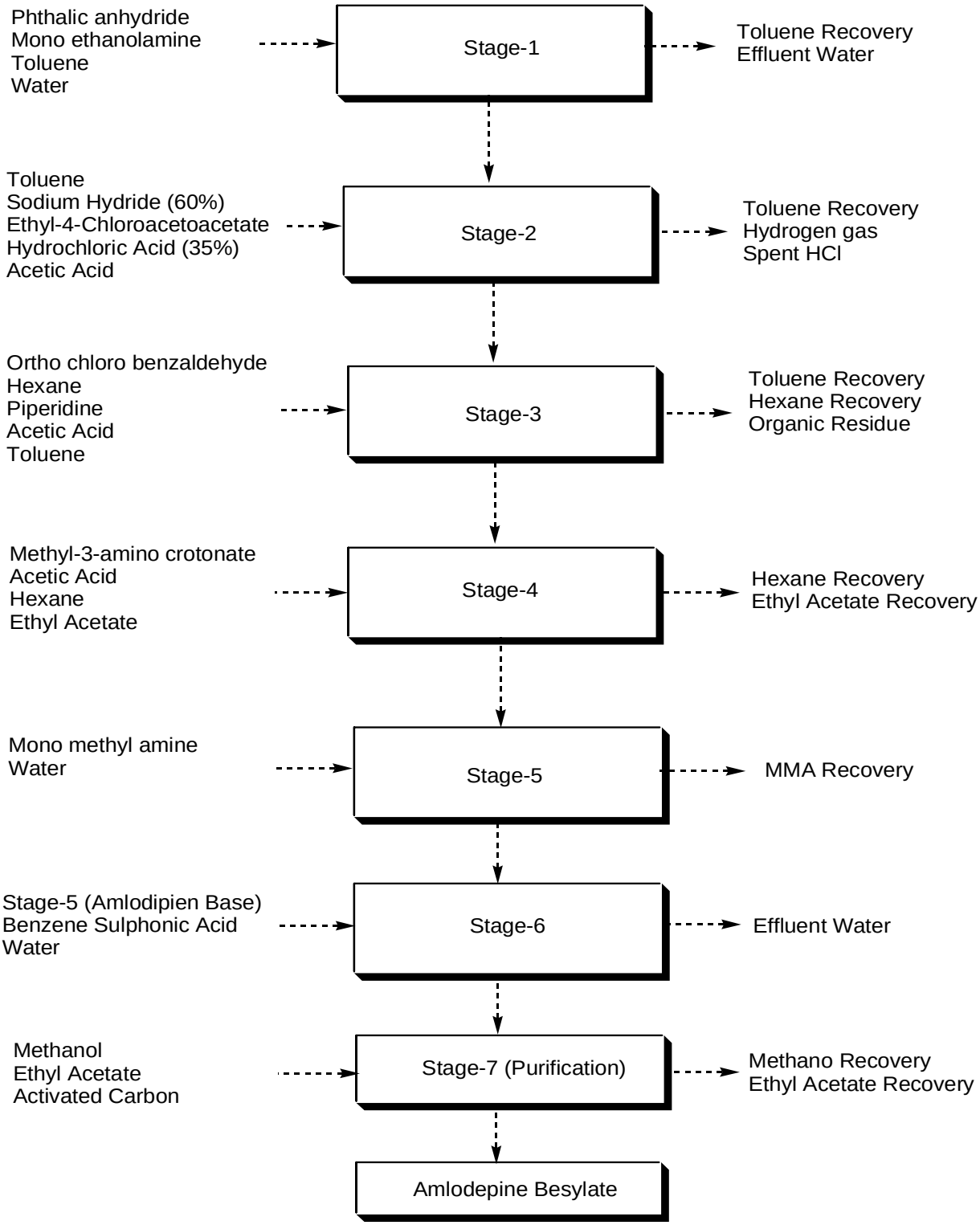
Amlodipine Besylate Pure

$C_{26}H_{31}ClN_2O_8S$

567.05

AMLODIPINE BESYLATE

Flow Chart:



AMLODIPINE BESYLATE

Material Balance:

Material balance of Amlodipine Besylate Stage-1 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Phthalic anhydride	100.50		Stage-1	120.50
Mono ethanolamine	42.00		Toluene Recovery	160.00
Toluene	170.00		Toluene Loss	7.00
Water	850.000		Effluent Water	863.78
			(Water-850, generated water-12.22,Toluene-1, Mono ethanol amine-0.56)	
			Organic Residue	11.22
			(Organic Impurities-9.22, Toluene-2)	
Total	1162.50		Total	1162.50

Material balance of Amlodipine Besylate Stage-2 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	120.50		Stage-2 in Toluene and Paraffin Oils	1550.00
Toluene	1326.00		Effluent Water	1915.77
Sodium Hydride	58.00		(Water-1630, water from HCl-82.7,Sodium chloride-151.87, Ethyl-4-chloroacetoacetate-11.2, Acetic Acid-40)	
Ethyl-4-Chloroacetoacetate	115.00		Spent Hydrochloric Acid	48.30
Hydrochloric Acid (35%)	138.00		Organic Residue	25.53
Acetic Acid	40.00		Process Emission	
Sodium Chloride	115.00		(Hydrogen)	2.90
Water	1630.00			
Total	3542.50		Total	3542.50

Material balance of Amlodipine Besylate Stage-3 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2 In Toluene and Parafin	1550.00		Stage-3 and Parafin	273.00
Ortho chloro benzaldehyde	90.00		Toluene Recovery	1289.00
Hexane	140.00		Toluene Loss	53.00
Piperidine	6.00		Hexane Recovery	131.00
Acetic Acid	4.00		Hexane Loss	7.00
Toluene	20.00		Effluent Water	702.33
Water	680.00		(Water-680,generated water-11.33,Acetic Acid-4,Toluene-1,Piperidine-6)	
			Organic Residue	34.67
			(Organic Residue-29.67, Toluene-3, Hexane-2)	
Total	2490.00		Total	2490.00

Material balance of Amlodipine Besylate Stage-4 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-3 and Parafin	273.00		Stage-4	150.00
Methyl-3-amino crotonate	160.00		Hexane Recovery	93.00
Acetic Acid	814.00		Hexane Loss	5.00
Hexane	100.00		Ethyl Acetate Recovery	358.50
Ethyl Acetate	380.00		Ethyl Acetate Loss	19.00
			Spent Acetic Acid to Auth. Prt	1071.56
			(Acetic Acid-814,Methyl-3-amino crotonate-94.87,Org. compound-129,Hexane-0.5, Paraffin-23,gen. water-10.19)	
			Organic Residue	29.94
			(Organic Impurities-25.96, Hexane-1.5, Ethyl Acetate-2.48)	
Total	1727.00		Total	1727.00

Material balance of Amlodipine Besylate Stage-5 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-4	150.00		Stage-5 (Amlodipine Base)	100.00
Mono methyl amine	700.00		MMA Recovery	646.00
Water	1500.00		MMA Loss	34.00
			Effluent Water	1556.20
			(Water-1500,MMA-11.35,2-Methyl isonidole-1,3-dione-44.85)	
			Organic Residue	13.80
			(Organic Impurities-13.8)	
Total	2350.00		Total	2350.00

Material balance of Amlodipine Besylate Stage-6 Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-5 (Amlodipien Base)	100.00		Amlodipine Besylate	130.00
Benzene Sulphonic Acid	50.00		Effluent Water	2111.30
Water	2100.00		(Water-2100,Benzene Sulfonic Acid-11.3)	
			Organic Residue	8.70
Total	2250.00		Total	2250.00

Material balance of Amlodipine Besylate Stage-7 (Purification) Batch Size: 120.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Amlodipine Besylate	130.00		Amlodipine Besylate	120.00
Methanol	673.00		Methanol Recovery	640.00
Ethyl Acetate	819.00		Methanol Loss	33.00
Activated Carbon	10.00		Ethyl Acetate Recovery	776.00
			Ethyl Acetate Loss	40.00
			Spent Carbon	10.00
			Organic Residue	13.00
			(Organic Impurities-10,Ethyl Acetate-3)	
Total	1632.00		Total	1632.00

3. EFAVIRENZ

Process Description:

Stage-1

(S)-5-Chloro-α-(Cyclopropyl ethynyl)-2-(4'-methoxy benzyl amino) (Trifluoromethyl) benzene method protected with DDQ in presence of Toluene and Methanol solvent media gives Stage-1 compound.

Stage-2

Stage-1Compound miled reduction with Sodium Borohydride in presence of Sodium Hydroxide in Methanol, Toluene, n-Hexane and Acetone solvent media gives stage-2 Compound.

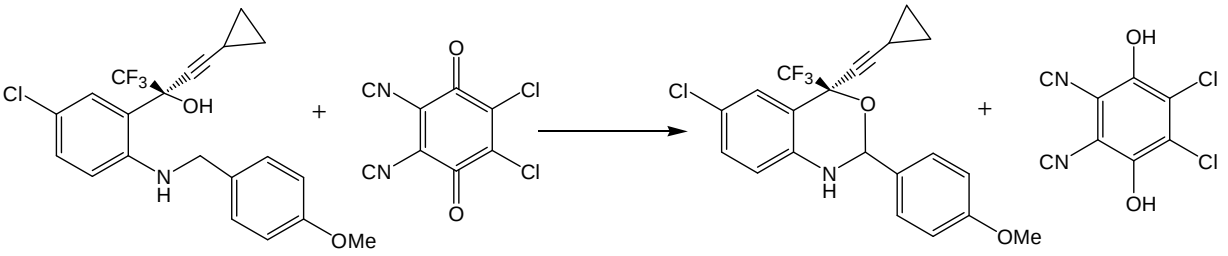
Stage-3

Stage-2 Compound reacts with Triphosgene in presence of Ethyl Acetate and n-Hexane solvent media gives Efavirenz.

EFAVIRENZ

Route of Synthesis:

STAGE-I



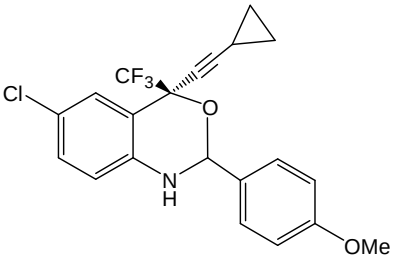
(S)-5-Chloro-1-(Cyclopropyl ethynyl) -2-(4'-methoxybenzylamino)(Trifluoro methyl)benzene methanol
(M.Wt : 409.5)

DDQ
(M.Wt : 227)

Stage-I
(M.Wt : 407.5)

DDHQ
(M.Wt : 229)

STAGE-II



Stage-I
(M.Wt : 407.5)

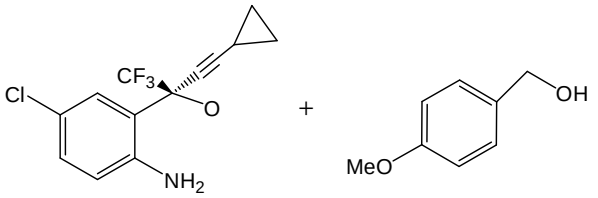
+ $NaBH_4$ + $2\ CH_3COOH$ + NaOH + $3\ H_2O$

Sodium Borohydride (M.Wt : 38)

Acetic Acid (M.Wt : 82)

Sodium Hydroxide (M.Wt : 40)

Water (M.Wt : 18)



Stage-II
(M.Wt : 289.5)

4-Methoxy benzyl alcohol
(M.Wt : 138)

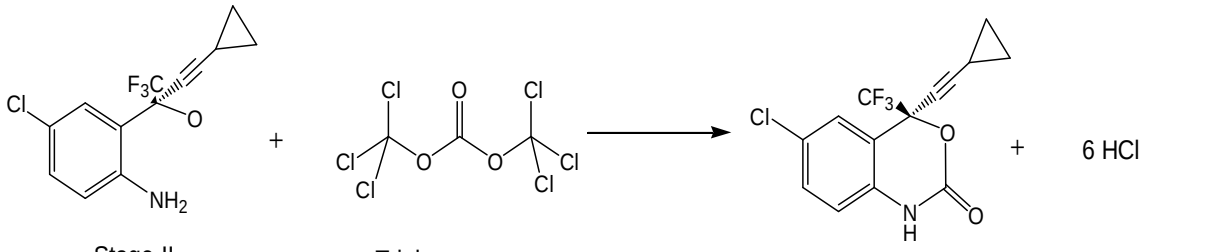
+ $2\ CH_3COONa$ + H_3BO_3 + $3\ H_2$

Sodium acetate (M.Wt : 82)

Boric acid (M.Wt : 62)

Hydrogen (M.Wt : 2)

STAGE-III



Stage-II
(M.Wt : 289.5)

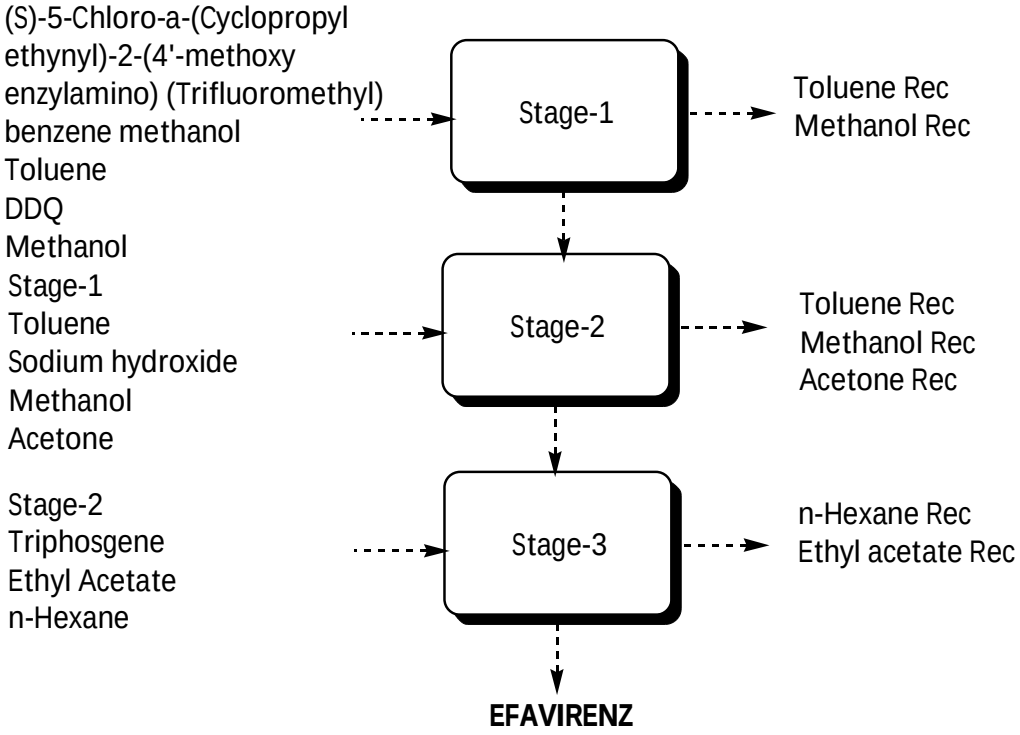
Triphosgene
(M.Wt : 297)

Efavirenz
(M.Wt : 315.5)

Hydrogen Chloride
(M.Wt : 36.5)

EFAVIRENZ

Flow Chart:



EFAVIRENZ

Material Balance:

Material Balance of Efavirenz Stage-1 Batch Size:50Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
(S)-5-Chloro-a-(Cyclopropylethynyl)-2-(4'-methoxy enzylamino) (Trifluoromethyl) benzene methanol	110.00		Stage-1 With Methanol (95+190)	285.00
Toluene	1375.00		Toluene Recovery	1279.00
DDQ	63.00		Toluene Loss	69.00
Sodium Bicarbonate	20.00		Effluent Water	1812.00
Methanol	195.00		(Sodium bicarbonate-20,Toluene-2, Methanol-5,Water-1785)	
Water	1785.00		Organic Residue	103.00
			(Organic Impurities-14.46,DDHQ-61.52,DDQ-2.02,Toluene-25)	
Total	3548.00		Total	3548.00

Material Balance of Efavirenz Stage-2 Batch Size:50Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1 with Methanol(95+190)	285.00		Stage-2	55.00
Toluene	380.00		Toluene Recovery	357.00
Sodium Borohydride	13.00		Toluene Loss	15.00
Acetic Acid	45.00		Methanol Recovery	353.00
Sodium hydroxide (10%)	380.00		Methanol Loss	19.00
Methanol	190.00		n-Hexane Recovery	214.00
n-Hexane	230.00		n-Hexane Loss	11.50
Acetone	60.00		Acetone Recovery	55.80
Water	1235.00		Acetone Loss	3.00
			Effluent Water	1614.64
			(Water-1222.41,gen.water-5.11,Boric Acid-14.45,Sodium hydroxide-17.33,water from sodium hydroxide-342,Sodium Borohydride-4.14,Methanol-8,Acetone-1.2)	
			Inorganic Solid Waste	61.50
			(Sodium Acetate)	
			Organic Residue	57.16
			(Organic Impurities-13.49,4-Methoxy benzyl alcohol-32.17,Toluene-7,n-Hexane-4.5)	
			Process Emissions	1.40
			(Hydrogen)	
Total	2818.00		Total	2818.00

Material Balance of Efavirenz Stage-3 Batch Size:50Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2	55.00		Efavirenz	50.00
Triphosgene	27.00		Ethyl Acetate Recovery	61.50
Ethyl Acetate	65.00		Ethyl Acetate Loss	3.00
n-Hexane	45.00		n-Hexane Recovery	41.80
Water	825.00		n-Hexane Loss	2.20
			Effluent Water	823.51
			(Water-823.51)	
			Organic Residue	10.94
			(Organic Impurities-9.94,n-Hexane-1)	
			Process Emissions	23.55
			(Hydrogen Chloride-19.91,Carbon Dioxide-3.64)	
Total	1017.00		Total	1017.00

4. EMTRICITABINE

Process Description:

Stage-1

5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)-[1,3]Oxa thiolane-2-carboxylic acid-2-isopropyl-5-methyl cyclo hexyl ester undergo reduction with Sodium borohydride and reacts with Isopropyl hydrochloride in the presence of Ethanol and Isopropyl alcohol as solvent media to give stage -1 as product.

Stage-2

Stage-1 undergoes neutralization with tri ethylamine in the presence of Methanol and MDC as solvent media to give stage -2 as product.

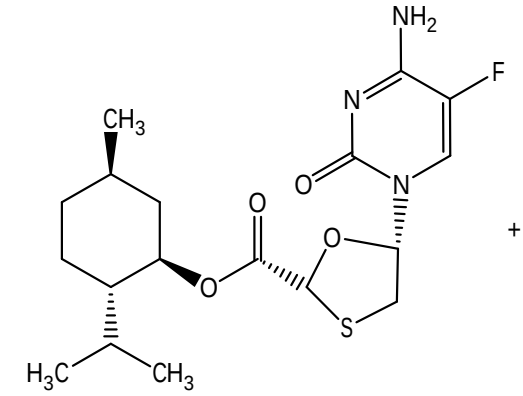
Stage-3

Stage-2 undergoes purification in the presence of Isopropyl alcohol as solvent media to give Emtricitabine as product.

EMTRICITABINE

Route of synthesis:

Stage-1



+ $NaBH_4$ + $2\ H_2O$ + $C_3H_8O.\ HCl$

5-(4-Amino-5-fluoro-2-oxo-2*H*-pyrimidin-1-yl) -[1,3]oxathiolane-2-carboxylic acid 2-isopropyl -5-methyl-cyclohexyl ester

$C_{18}H_{26}FN_3O_4S$

399.48

Sodium borohydride

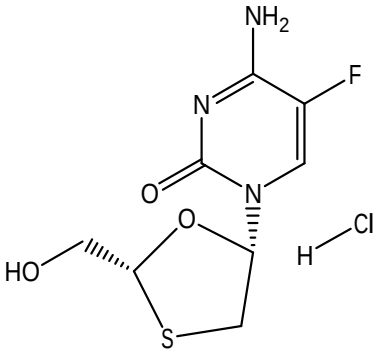
37.83

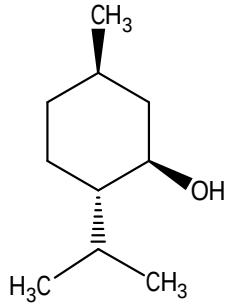
2X18=36

IPA.HCl

96.55

IPA
Ethanol
K_2HPO_4



+  + C_3H_8O + $NaBO_2$ + $2\ H_2$

4-Amino-5-fluoro-1-(2-hydroxy methyl-[1,3]oxathiolan-5-yl)-1*H*-pyrimidin-2-one

$C_8H_{11}ClFN_3O_3S$

283.70

Menthol

$C_{10}\ H_{20}O$

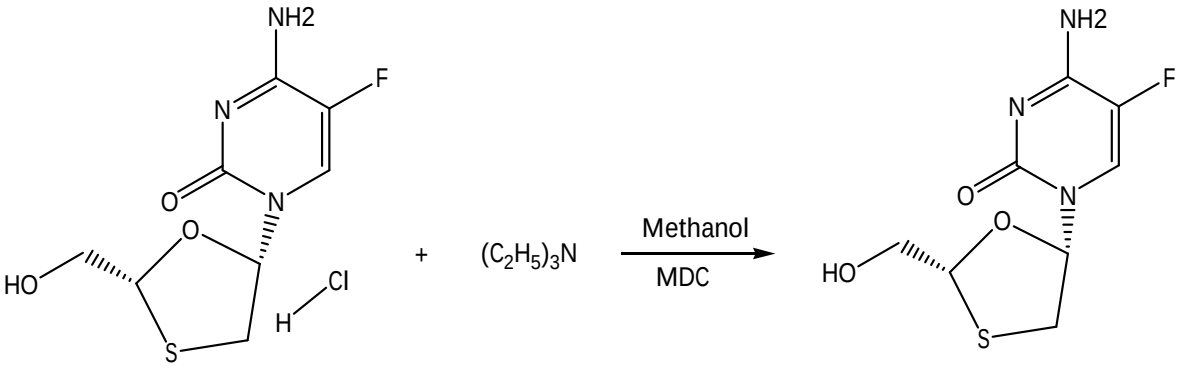
156.26

60.09

65.79

4.00

Stage-2



4-Amino-5-fluoro-1-(2-hydroxy methyl-[1,3]oxathiolan-5-yl)-1*H*-pyrimidin-2-one

$C_8H_{11}ClFN_3O_3S$

283.70

Triethyl amine

$C_6H_{15}N$

101.19

4-Amino-5-fluoro-1-(2-hydroxymethyl-[1,3]oxathiolan-5-yl)-1*H*-pyrimidin-2-one

$C_8H_{10}FN_3O_3S$

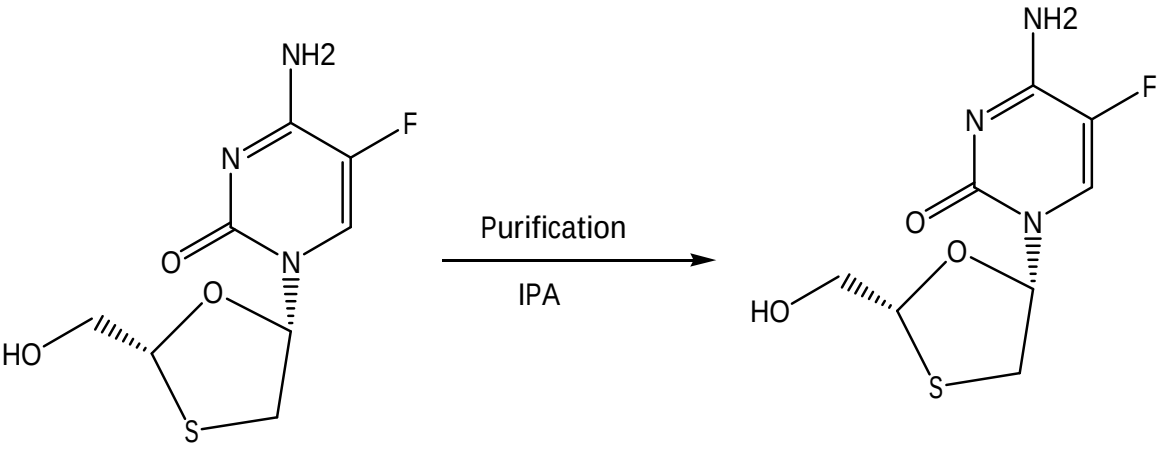
247.25

\+ $(C_2H_5)_3N.HCl$

Triethyl amine Hydrochloride

137.65

Stage-3



Emtricitabine(Crude)

$C_8H_{10}FN_3O_3S$

247.25

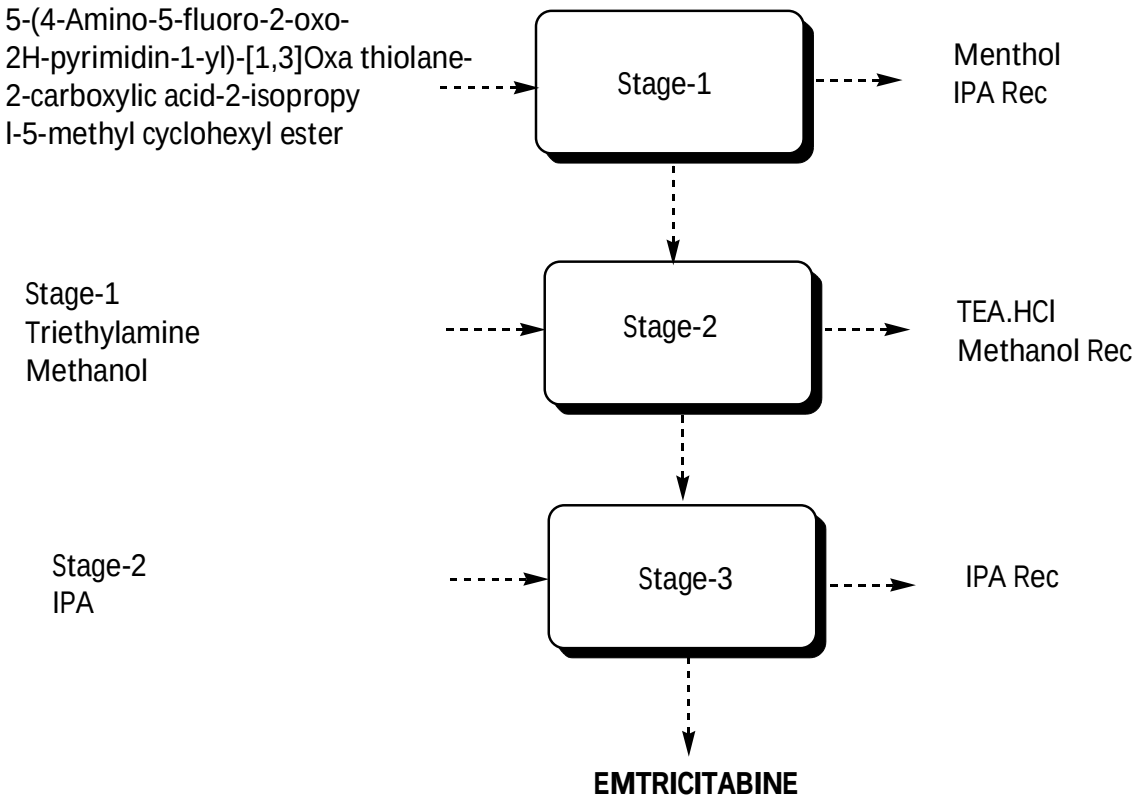
Emtricitabine(Pure)

$C_8H_{10}FN_3O_3S$

247.25

EMTRICITABINE

Flow chart:



EMTRICITABINE

Material Balance:

Material Balance Of Emtricitabine Stage-1 Batch Size:100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)-[1,3]Oxa thiolane-2-carboxylic acid-2-isopropyl-5-methyl cyclo hexyl ester	200.00		Stage-1	130.00
IPA.HCl (25%)	73.20		IPA Recovery	810.90
Dipotassium hydrogen phosphate	25.00		IPA Loss	42.00
Sodium Hydroxide flakes	5.00		Toluene Recovery	1140.00
Ethanol	950.00		Toluene Loss	58.00
Sodium borohydride	19.00		Ethanol Recovery	903.00
Toluene	1200.00		Ethanol Loss	47.00
Activated carbon	12.00		Effluent Water	1275.30
Isopropyl alcohol	800.00		(Water-1182,Sodium borate-32.9,Dipotassium hydrogen phosphate-25, Sodium hydroxide-5,HCl-28.4,IPA-2)	
Hydrochloric Acid	28.40		Spent Carbon	12.00
Water	1200.00		L-Menthol Reuse	78.23
			Organic Residue	14.17
			(Organic Impurities-12.17, Toluene-2)	
			Process Emission	2.00
			(Hydrogen)	
Total	4512.60		Total	4512.60

Material Balance Of Emtricitabine Stage-2 Batch Size: 100.0 Kg/Day				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	130.00		Stage-2	105.00
Tri ethylamine	47.00		Methanol Recovery	1137.00
Activated carbon	10.00		Methanol Loss	60.00
Methanol	1200.00		MDC Recovery	1423.00
MDC	1500.00		MDC Loss	75.00
Hyflow	5.00		Spent Carbon & Hyflow	15.00
			By-Product	63.93
			(Triethyl Amine HCl)	
			Organic Residue	13.07
			(Organic Impurities-8.07, MDC-2,Methanol-3)	
Total	2892.00		Total	2892.00

Material Balance Of Emtricitabine Stage-3 Batch Size:100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	105.00		Emtricitabine	100.00
Isopropyl alcohol	900.00		IPA Recovery	853.50
Activated carbon	10.00		IPA Loss	45.00
Hyflow	5.00		Spent Carbon & Hyflow	15.00
			Organic Residue	6.50
			(Organic Impurities-5,IPA-1.5)	
Total	1020.00		Total	1020.00

5. FAMOTIDINE

Process Description:

Stage-1

1, 3-Dichloro acetone reacts with Guanyl thiourea in the presence of Acetone as solvent media to give Stage-2 as product.

Stage-2

Stage-1 product reacts with Thiourea, N-Sulfamyl-3-chloropropionamidine, Sodium hydroxide and acetic acid in the presence of Methanol as solvent media to give Stage-2 as product.

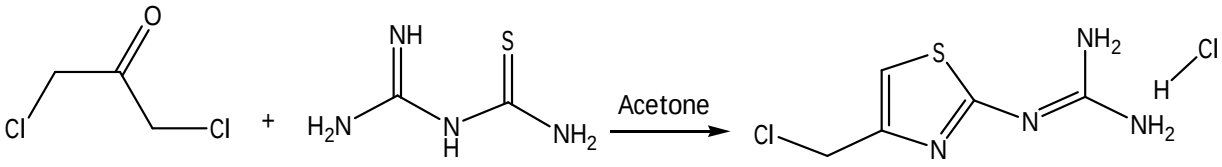
Stage-3

Stage-2 product reacts with ammonia in the presence of Methanol as solvent media to give Famotidine as product.

FAMOTIDINE

Route of Synthesis:

Stage-1



1,3-Dichloro acetone

$C_3H_4Cl_2O$

126.97

Guanyl thiourea

$C_2H_6N_4S$

118.16

N-(4-Chloromethyl-thiazol-2-yl) -guanidine; hydrochloride

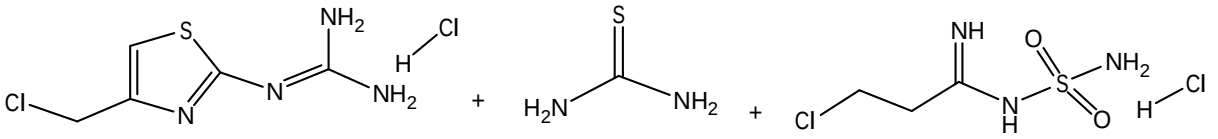
$C_5H_8Cl_2N_4S$

227.15

+ H_2O

18.0

Stage-2



N-(4-Chloromethyl-thiazol-2-yl) -guanidine; hydrochloride

$C_5H_8Cl_2N_4S$

227.15

Thiourea

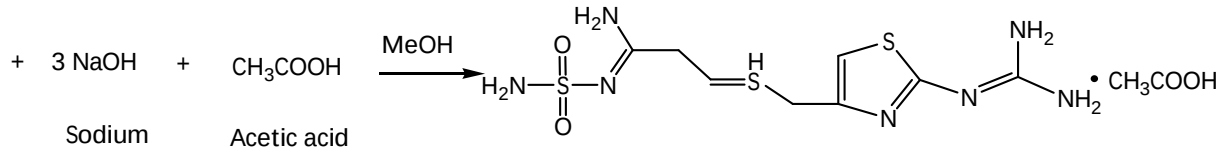
CH_4N_2S

76.12

N-Sulfamyl-3-chloropropion amidine Hydrochloride

$C_3H_9Cl_2N_3O_2S$

222.13



Sodium hydroxide

120.0

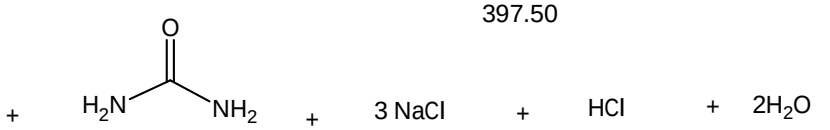
Acetic acid

60.0

N'-(aminosulfonyl)-3-[[[(2-[(diaminomethylene) amino]-4-thiazolyl]methyll]thio]- propanamide acetate

$C_{10}H_{19}N_7O_4S_3$

397.50



Urea

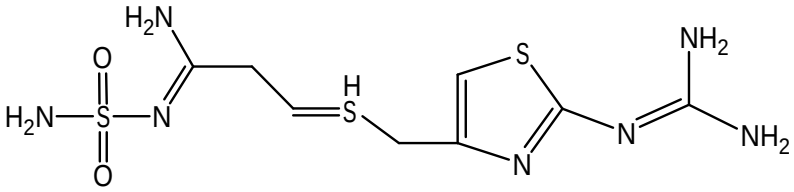
60.06

175.5

36.5

36.0

Stage-3



N'-(aminosulfonyl)-3-[[[(2-[(diaminomethylene) amino]-4-thiazolyl]methyll]thio]-propanamide acetate

$C_{10}H_{19}N_7O_4S_3$

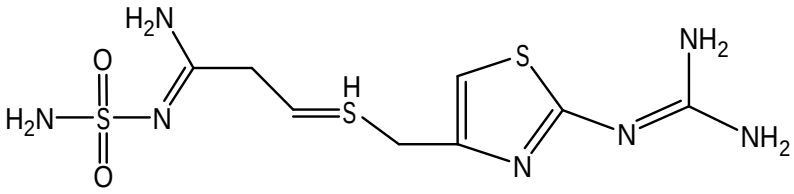
397.50

• CH_3COOH + NH_3

Ammonia

17.0

Methanol



Famotidine (Pure)

$C_8H_{15}N_7O_2S_3$

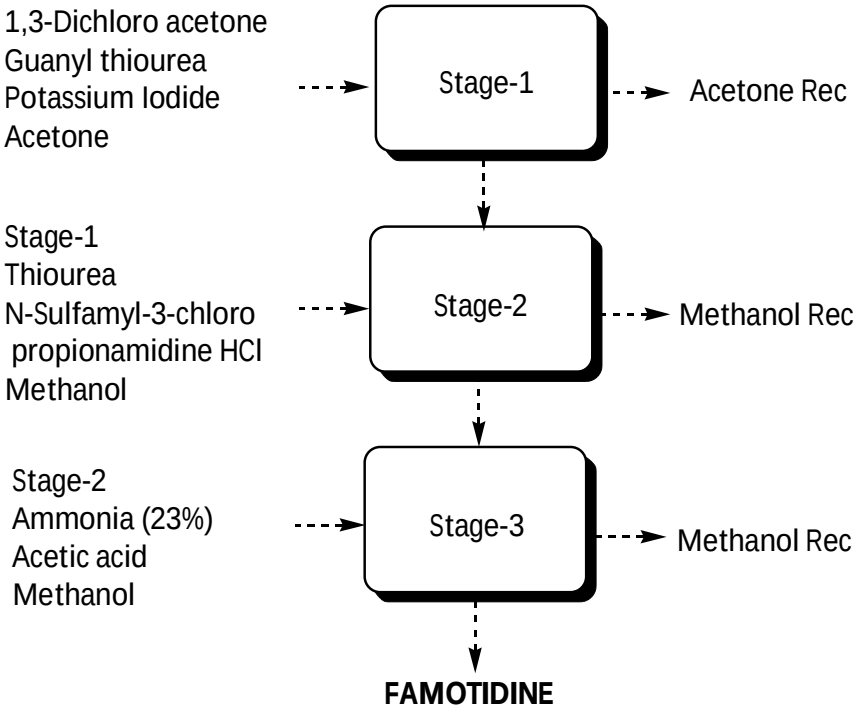
337.45

+ CH_3COONH_4

77.08

FAMOTIDINE

Flow Chart:



FAMOTIDINE

Material Balance:

Material Balance of Famotidine Stage-1 Batch Size:100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
1,3-Dichloro acetone	53.00		Stage-1	88.97
Guanyl thiourea	50.00		Acetone Recovery	161.00
Potassium Iodide	2.40		Acetone Loss	8.00
Acetone	170.00		Generated water	7.51
			Inorganic solid waste	2.40
			(Potassium Iodide)	
			Organic solid waste	7.52
			(Organic Impurities-6.52, Acetone-1)	
Total	275.40		Total	275.40

Material Balance of Famotidine Stage-2 Batch Size:100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	88.97		Stage-2	125.70
Thiourea	25.13		Methanol Recovery	3228.00
Sodium hydroxide	40.00		Methanol Loss	169.00
N-Sulfamyl-3-chloro propionamidine HCl	74.00		Generated water	12.00
Acetic acid	20.00		Inorganic solid waste	70.60
Methanol	3397.00		(Sodium chloride-58.5, Hydrochloric acid-12.1)	
			Organic solid waste	39.80
			(Acetic acid-20,Urea-19.8)	
Total	3645.10		Total	3645.10

Material Balance of Famotidine Stage-3 Batch Size:100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	125.70		Famotidine	100.00
Ammonia (23%)	24.00		Methanol Recovery	36.00
Acetic acid	5.00		Methanol Loss	1.00
Methanol	39.00		Effluent water	874.00
Activated carbon	6.00		(Water-825,Water from ammonia-18.6,Acetic acid-5, Ammonium actetae-24.4, Methanol-1)	
Water	825.00		Spent carbon	6.00
			Organic Residue	7.70
			(Organic Impurities-6.7, Methanol-1)	
Total	1024.70		Total	1024.70

6. FLUCONAZOLE

Process Description:

Stage-1

1, 3-Difluorobenzene reacts with Chloroacetyl Chloride in the presence of Aluminum chloride to get 2-Chloro-1-(2, 4-difluorophenyl) ethanone.

Stage-2

2-Chloro-1-(2,4-difluorophenyl) ethanone reacts with 1,2,4-triazole in the presence of Triethyl amine and Ethyl Acetate as a Solvent media to get 1-(2,4-difluorophenyl)-2-(1,2,4-triazol-1-yl) ethanone.

Stage-3

1-(2, 4-difluorophenyl)-2-(1, 2, 4-triazol-1-yl) ethanone reacts with Tri methyl sulfoxonium iodide in the presence of potassium hydroxide to get 1-[2-(2, 4-difluorophenyl)-2, 3-epoxypropyl]-1H-1, 2, 4-Triazole

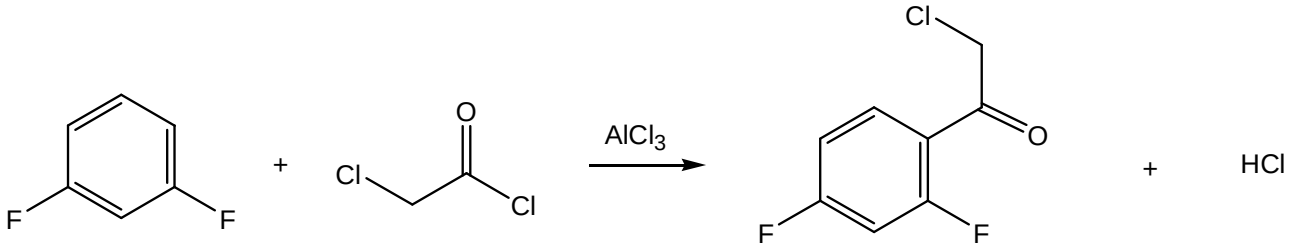
Stage-4

1-[2-(2, 4-difluorophenyl)-2,3-epoxypropyl]-1H-1,2,4-Triazole reacts with 1,2,4-triazole in the presence of Potassium carbonate and Toluene solvent media to get Fluconazole Tech. Finally Purified with Isopropyl Alcohol in the presence of Magnesium sulfate to get pure Fluconazole

FLUCONAZOLE

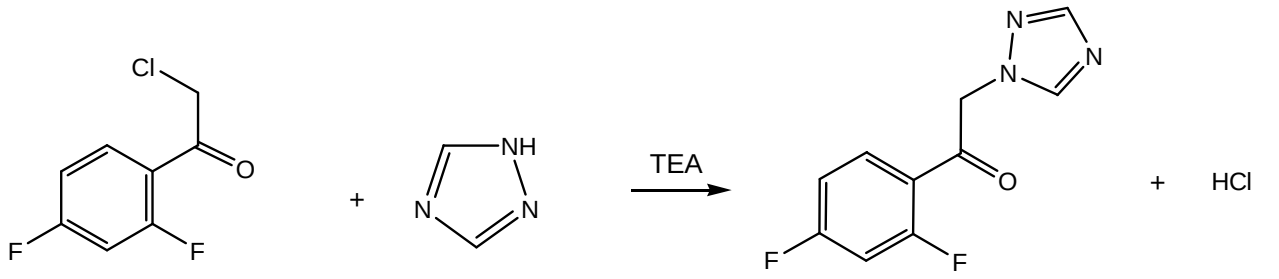
Route of Synthesis:

Stage-1



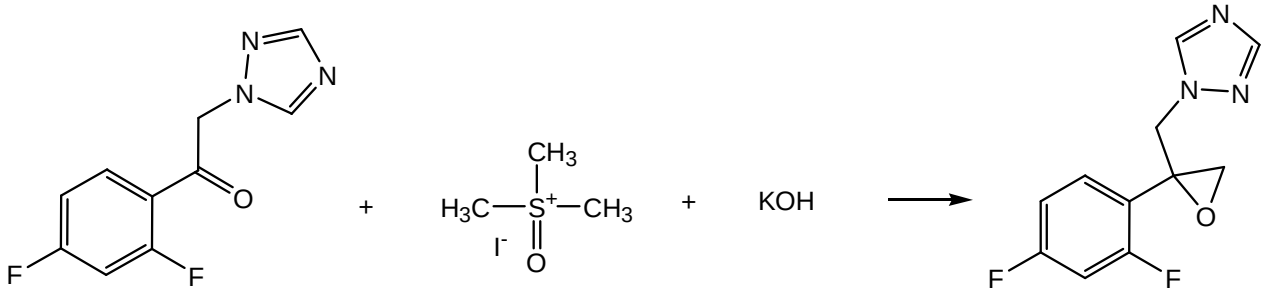
1,3-Difluorobenzene	Chloroacetyl chloride	2-Chloro-1-(2,4-difluorophenyl)ethanone	36.5
$C_6H_4F_2$	$C_2H_2Cl_2O$	$C_8H_5ClF_2O$	
114.09	112.94	190.57	

Stage-2



2-Chloro-1-(2,4-difluoro phenyl)ethanone	1,2,4-triazole	1-(2,4-difluorophenyl)-2-(1,2,4-triazol-1-yl)ethanone	36.46
$C_8H_5ClF_2O$	$C_2H_3N_3$	$C_{10}H_7F_2N_3O$	
190.57	69.07	223.18	

Stage-3

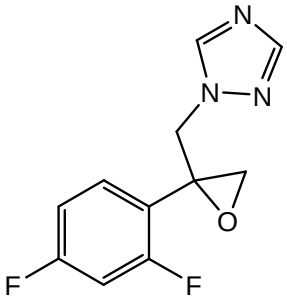


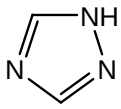
1-(2,4-difluorophenyl)-2-(1,2,4-triazol-1-yl)ethanone	Trimethyl sulfoxonium iodide	56.11	1-[2-(2,4-di fluorophenyl)-2,3-epoxypropyl]-1H-1,2,4-Triazole
$C_{10}H_7F_2N_3O$	C_3H_9IOS		$C_{11}H_9F_2N_3O$
223.18	220.07		237.21

+ $(CH_3)_2SO$ + KI + H_2O

Dimethyl Sulfoxide	Potassium Iodide	Water
78.13	166.0	18.0

Stage-4



+  + K_2CO_3 + 2 HCl ⟶

1-[2-(2,4-di fluorophenyl)-2,3-epoxypropyl]-1H-1,2,4-Triazole

$C_{11}H_9F_2N_3O$

237.21

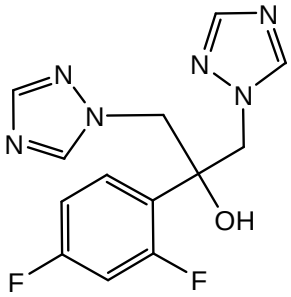
1,2,4-Triazole

$C_2H_3N_3$

69.07

138.21

2X36.5=73.0



+ 2 KCl + H_2O + CO_2 ↑

Fluconazole

$C_{13}H_{12}F_2N_6O$

306.27

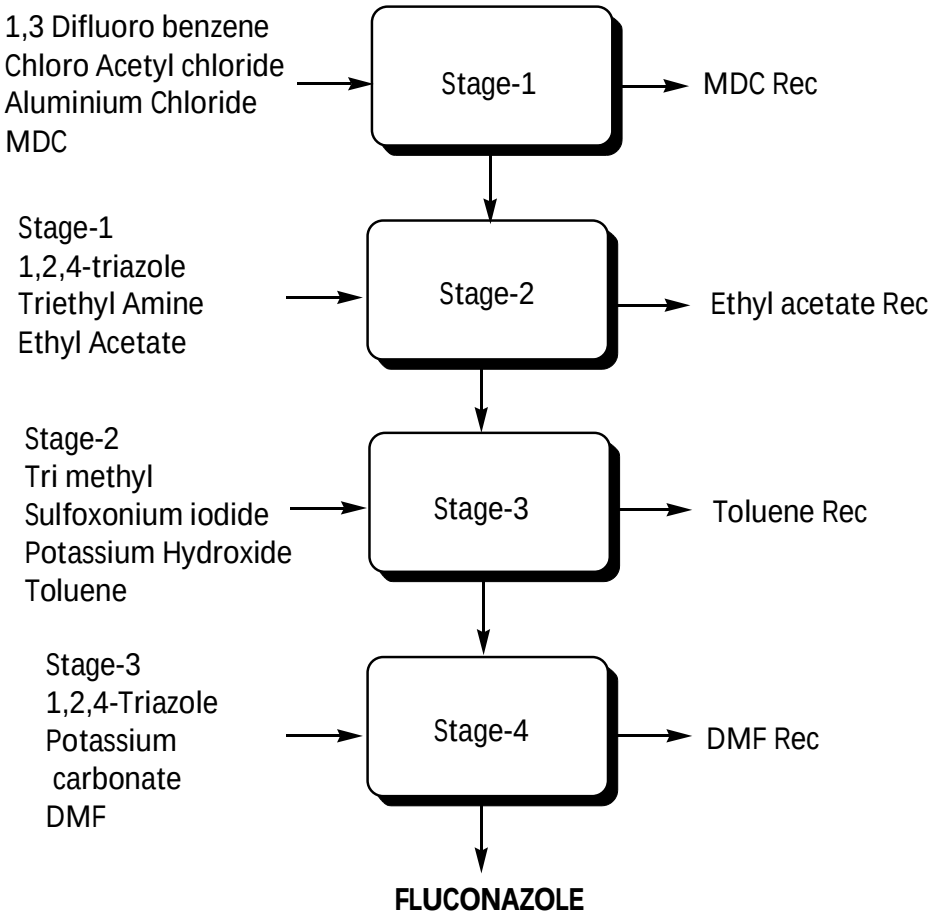
2X74.55=149.1

18.0

44.0

FLUCONAZOLE

Flow Chart:



FLUCONAZOLE

Material Balance:

Material Balance of Fluconazole Stage-1 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
1,3 Difluoro benzene	50.00		Stage-1	70.00
Chloro Acetyl chloride	49.50		MDC Recovery	760.00
Aluminium Chloride	15.00		MDC Loss	40.00
MDC	800.00		Effluent Water	531.00
DM Water	500.00		(Water-500,Hydrochloric Acid-16, Aluminium chloride-15)	
			Organic Residue	13.50
Total	1414.50		Total	1414.50

Material Balance of Fluconazole Stage-2 Batch Size: 250Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	70.00		Stage-2	78.00
1,2,4-triazole	26.00		Ethyl Acetate Recovery	664.00
Triethyl Amine	37.00		Ethyl Acetate Loss	35.00
Ethyl Acetate	700.00		Effluent Water	551.40
Water	500.00		(Water-500,Triethyl Amine hydrochloride-50.4,Ethyl Acetate-1.0)	
			Organic Residue	4.60
Total	1333.00		Total	1333.00

Material Balance of Fluconazole Stage-3 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	78.00		Stage-3	80.00
Tri methyl Sulfoxonium iodide	78.00		Toluene Recovery	758.00
Potassium Hydroxide	20.00		Toluene Loss	40.00
Toluene	800.00		Effluent Water	942.08
Water	850.00		(Water-850,generated water-6.28, Potassium iodide-58,DMSO-27.3, Toluene-0.5)	
			Organic Residue	5.92
Total	1826.00		Total	1826.00

Material Balance of Fluconazole Stage-4 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-3	80.00		Fluconazole	100.00
1,2,4-Triazole	24.00		DMF Recovery	616.00
Cetyl tri methyl Ammonium Bromide	10.00		DMF Loss	32.50
Potassium carbonate	47.00		IPA Recovery	427.50
DMF	650.00		IPA Loss	22.50
Hydrochloric Acid	25.00		Effluent Water	813.36
Magnesium Sulfate	5.00		(Water-750,generated water-6.16, Potassium chloride-50.7, Magnesium sulfate-5,DMF-1.5)	
IPA	450.00		Spent Carbon	10.00
Activated Carbon	10.00		Organic Residue	14.18
DM Water	750.00		Process Emission	14.96
			(Carbon dioxide)	
Total	2051.00		Total	2036.82

7. LAMIVUDINE

Process Description:

Stage-1

Menthol reacts with glyoxalic acid in the presence of cyclohexane as solvent media to give stage-1 as product.

Stage-2

Stage-1 reacts with 2, 5 di hydroxy diethane in the presence of toluene as solvent media to give stage-2 as product.

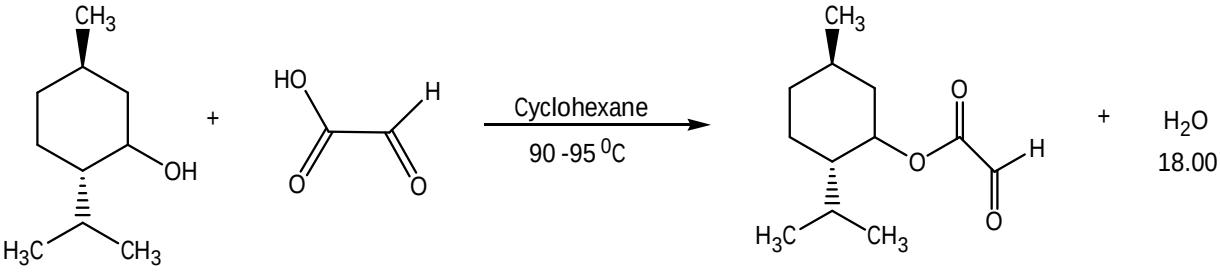
Stage-3

Stage -2 reacts with Thionyl chloride and cytosine in the presence of toluene as solvent media to give Lamivudine as product.

LAMIVUDINE

Route of Synthesis:

Stage -1

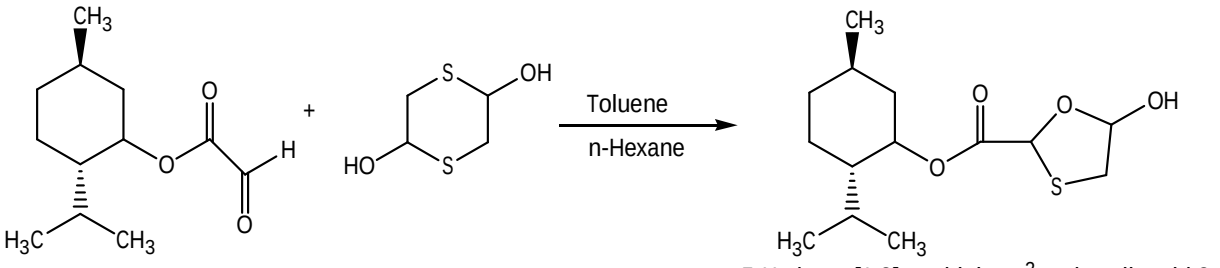


L(+)Menthol
$C_{10}H_{20}O$
156.26

Glyoxalic acid
$C_2H_2O_3$
74.03

Oxo-acetic acid 2-isopropyl-5-methyl-cyclohexyl ester
$C_{12}H_{20}O_3$
212.28

Stage -2



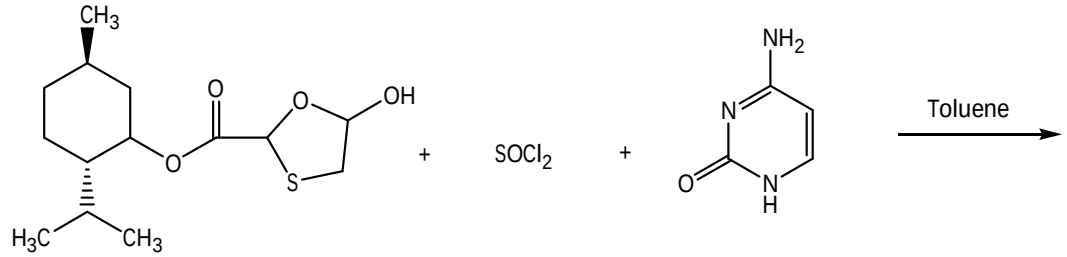
Oxo-acetic acid 2-isopropyl^{-} 5-methyl-cyclohexyl ester
$C_{12}H_{20}O_3$
212.28

2,5-Dihydroxy di ethane
$C_4H_8O_2S_2$
152.23

5-Hydroxy-[1,3]oxathiolane^{-2}-carboxylic acid 2-isopropyl^{-5}-methyl-cyclohexyl ester
$C_{14}H_{24}O_4S$
288.40

+ SCH_2CH_2OH
C_2H_5OS
77.12

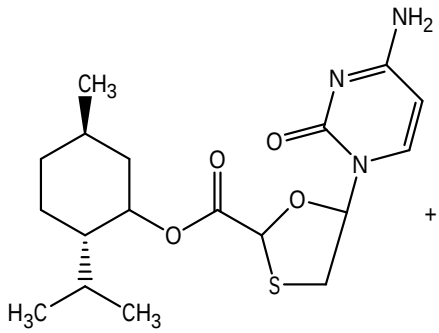
Stage -3



5-Hydroxy-[1,3]oxathiolane^{-2}-carboxylic acid 2-isopropyl^{-5}-methyl-cyclohexyl ester
$C_{14}H_{24}O_4S$
288.40

Thionyl chloride
118.97

Cytosine
$C_4H_5N_3O$
111.10

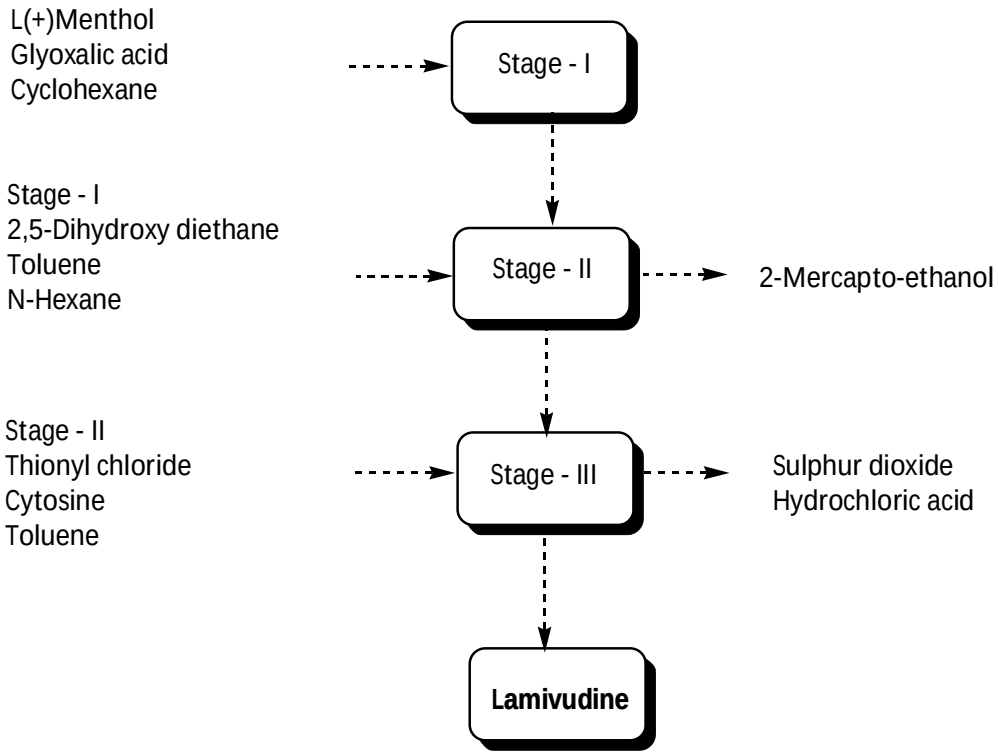


+ SO_2 Sulphur dioxide 64.06 + 2 HCl Hydrochloric acid 73.00

Lamivudine
$C_{18}H_{27}N_3O_4S$
381.48

LAMIVUDINE

Flow Chart:



LAMIVUIDNE

Material Balance:

Material Balance of Lamivudine Stage-1 Batch Size: 200Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
L(+)Menthol	82.60		Stage-1	112.00
Glyoxalic Acid (35%)	112.00		Cyclohexane Recovery	1055.00
Sodium Bisulfate	63.00		Cyclohexane Loss	45.00
Sodium Carbonate	15.00		Effluent Water	2416.60
Formaldehyde	16.00		(Water-2300,gen.water-9.8, water From Glyoxalic Acid-72.8,Sodium Carbonate-15, Sulphuric Acid-3, Formaldehyde-16)	
Sulphuric Acid	3.00		Inorganic Solid Waste	63.00
Cyclohexane	1100.00		(Sodium Bisulfate)	
DM Water	2300.00			
Total	3691.60		Total	3691.60

Material Balance of Lamivudine Stage-2 Batch Size: 200Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	112.00		Stage-2	152.00
2,5 Diethane	80.00		Toluene Recovery	665.00
Acetic Acid	43.00		Toluene Loss	35.00
Triethyl Amine	3.00		n-Hexane Recovery	220.00
Toluene	700.00		n-Hexane Loss	10.00
n-Hexane	230.00		Effluent Water	2046.00
Activated Carbon	5.00		(Water-2000,Acetic Acid-43, Triethyl Amine-3)	
Hyflo	5.00		Spent Carbon	10.00
DM Water	2000.00		By-Product	40.00
			(Thio acetic Acid)	
Total	3178.00		Total	3178.00

Material Balance of Lamivudine Stage-3 Batch Size: 200Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	152.00		Lamivudine	200.00
Cytosine	58.55		Methylene Dichloride Recovery	1050.00
HMDS	15.00		Methylene Loss	50.00
Thionyl Chloride	63.00		Toluene Recovery	300.00
Dimethylformamide	54.00		Toluene Loss	10.00
Triethyl amine	102.00		n-Hexane Recovery	190.00
MSA	1.00		n-Hexane Loss	10.00
Methylene Dichloride	1100.00		Ethyl Acetate Recovery	140.00
Toluene	310.00		Ethyl Acetate Loss	10.00
n-Hexane	200.00		DMF Recovery	40.00
Ethyl Acetate	150.00		DMF Loss	10.00
Water	2500.00		Triethyl Amine Reuse	102.00
			HMDS Reuse	15.00
			Effluent Water	2542.52
			(Water-2500,Hydrochloric acid-38.52,DMF-4)	
			Process Emission	33.88
			(Sulphur dioxide)	
			Organic Residue	2.15
Total	4705.55		Total	4705.55

8. LEVO SULPRIDE

Process Description:

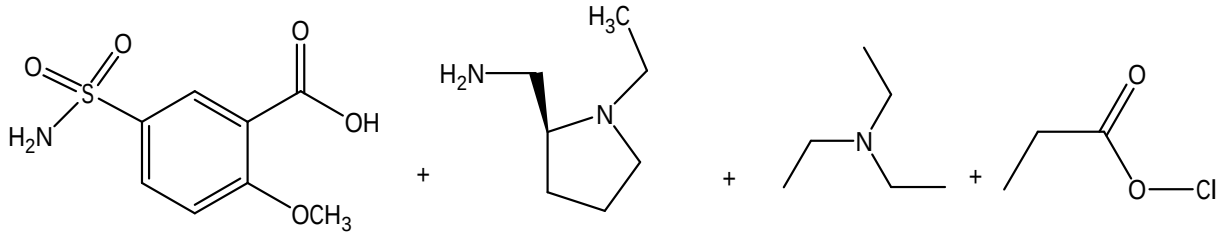
Stage-1

2-Methoxy-5-sulfmayl benzoic acid reacts with (S) - 1-(ethyl-pyrrolidin-2-yl)-methylamine, Triethylamine and ethyl chloro formate in the Presence of MDC as solvent media to give Levosulpride as product.

LEVO SULPRIDE

Route of Synthesis:

Stage-1



2-Methoxy-5-sulfamoyl-benzoic acid
$C_8H_9NO_5S$
231.23

+

S-(1-Ethyl-pyrrolidin-2-yl)-methylamine
$C_7H_{16}N_2$
128.22

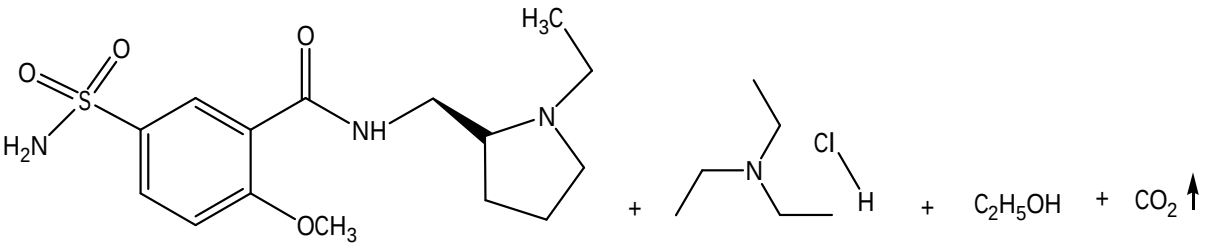
+

Triethyl amine
$C_6H_{15}N$
101.19

+

Ethyl chloro formate
$C_3H_5ClO_2$
108.52

MDC



Levosulpride
$C_{15}H_{23}N_3O_4S$
341.43

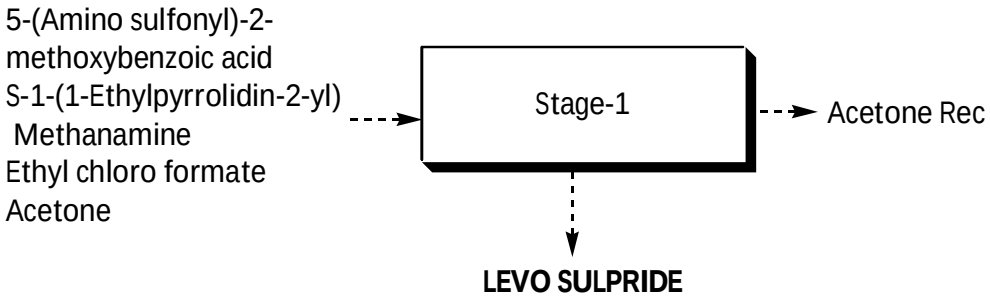
+

Triethyl amine hydrochloride
$C_6H_{16}ClN$
137.65

+ C_2H_5OH 46.07 + CO_2 44.0

LEVO SULPRIDE

Flow Chart:



LEVO SULPRIDE

Material Balance:

Material Balance of Levosulpride Stage-1 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
5-(Amino sulfonyl)-2-methoxybenzoic acid	70.00		Levosulpride	100.00
S-1-(1-Ethylpyrrolidin-2-yl) Methanamine	38.81		Acetone Recovery	282.00
Triethyl amine	30.60		Acetone Loss	15.00
Ethyl chloro formate	32.90		Ethyl acetate Recovery	380.00
Acetone	300.00		Ethyl acetate Loss	20.00
Ethyl acetate	400.00		MDC Recovery	215.00
MDC	225.00		MDC Loss	10.00
Water	1000.00		Effluent water	1056.50
			(Water-1000,TEA HCl-41.6, Ethanol-12.9,Acetone-2)	
			Organic Residue	5.50
			(Organic Impurities-3.5,Acetone-1,Ethanol-1)	
			Process Emission	13.31
			(Carbon dioxide)	
Total	2097.31		Total	2097.31

9. LOPINAVIR

Process Description

Stage-1

Step-A

(R)-2-amino-3-phenyl propanoic acid reacts with benzyl chloride ,Potassium carbonate in presence of Ethanol as solvent media to give Stage-A as product.

Step-B

Stage-A Product reacts with Acetonitrile, Sodium amide and citric acid monohydrate in presence of MTBE as solvent media to give Stage-1 product.

Stage-2

Satge-1 reacts with Benzyl magnesium chloride in presence of THF, MTBE as solvent media to give Stage-2 as product.

Stage-3

Step-A

Stage-2 product reacts with sodium borohydride in presence of Methane sulphonic acid, TEA and 1, 2-DME to give step-A as product.

Step-B

(2S)- (1-Tetra hydro pyramid-2-one)-3-methyl butanoic acid reacts with Imidazole in presence of THF as solvent media to give Step-B as product.

Step-C

Step-A reacts with Ste-B in presence of Ethyl acetate as solvent media to give Step-C as product.

Step-D

Step-C reacts with Ammonium formate in presence of Palladium carbon and Methanol as solvent media to give Step-D as product.

Step-E

Step-D product reacts with L-Pyro glutamic acid in presence of DMF, Ethyl acetate as solvent media to give (2S, 3S, 5S)-2-Amino-3-hydroxy-5-(1-tetra hydro pyrmid-2-onyl)-3-methyl butanoyl) amino-1, 6-diphenyl hexane-S-pyro glutamate (THP).

Stage-4

N-(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydropyrimidin-1-yl)-butyramide (S)-5-oxo-pyrrolidine-2-carboxylate reacts with 2,6-Dimethyl phenoxy acetyl chloride and sodium bicarbonate in the presence of Ethyl acetate as a solvent media to give stage-4 as product.

Stage-5

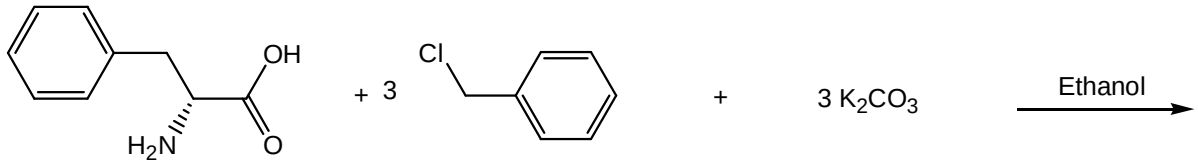
Stage-4 undergoes purification with ethanol to give Lopinavir (pure) as product.

LOPINAVIR

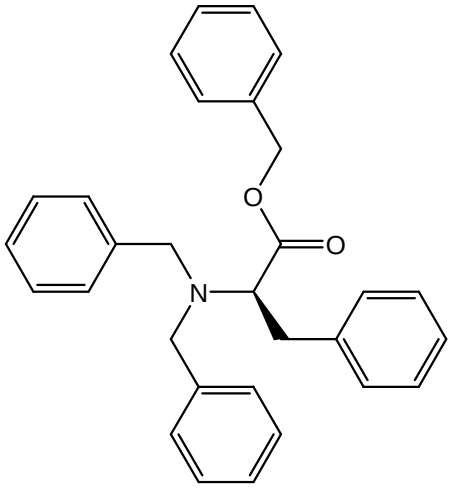
Route of Synthesis:

Stage-1

Step-A



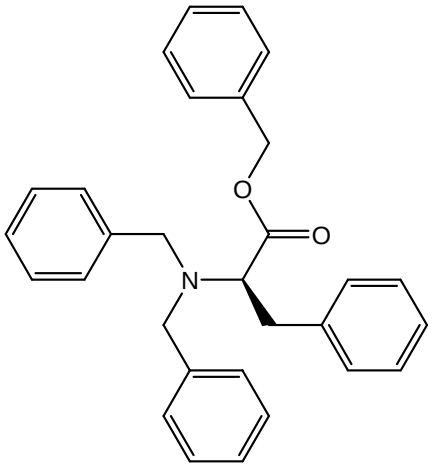
(R)-2-amino-3-phenyl propanoic acid	Benzyl Chloride	Potassium Carbonate
$C_9H_{11}NO_2$	C_7H_7Cl	3X138.21=414.63
165.19	3X126.58=379.74	



+ 3 KCl + 3 KOH + 3 CO_2 ↑

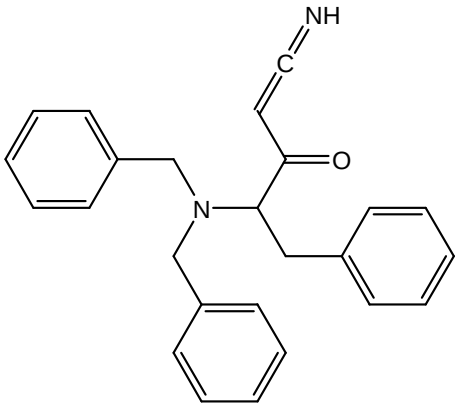
(R) -benzyl 2-(dibenzyl amino) -3-phenyl propanoate	3X74.55=223.61	3X56.11=168.32	3X44=132
$C_{30}H_{29}NO_2$			
435.56			

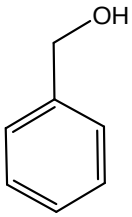
Step-B



+ CH_3CN + $NaNH_2$ + $C_6H_{10}O_8$ —MTBE→

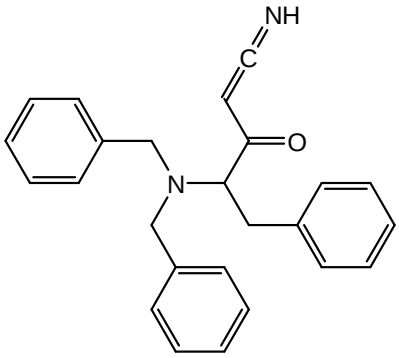
(R) -benzyl 2-(dibenzyl amino) -3-phenyl propanoate	Acetonitrile	Sodium Amide	Citric Acid Monohydrate
$C_{30}H_{29}NO_2$	41.05	39.01	210.14
435.56			

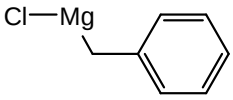


+  + $C_6H_7O_7Na$ + NH_4OH

1-Imino-4-(N,N-dibenzylamino) 5-phenyl-3-oxo-pent-1-ene	Benzyl Alcohol	Sodium Citrate	Ammonium Hydroxide
$C_{25}H_{24}N_2O$	C_7H_8O	258.06	35.05
368.47	108.14		

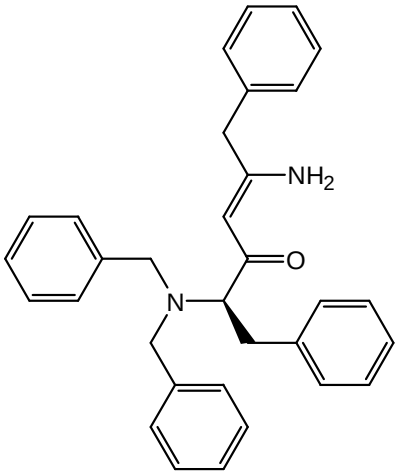
Stage-2



+  + $C_6H_8O_7\ H_2O$ + NaCl

1-Imino-4-(N,N dibenzylamino) -5-phenyl-3-oxo-pent-1-ene	Benzyl Magnesium Chloride	Citric Acid monohydrate	58.5
$C_{25}H_{24}N_2O$	C_7H_7MgCl	210.14	
368.47	150.89		

THF/MTBE

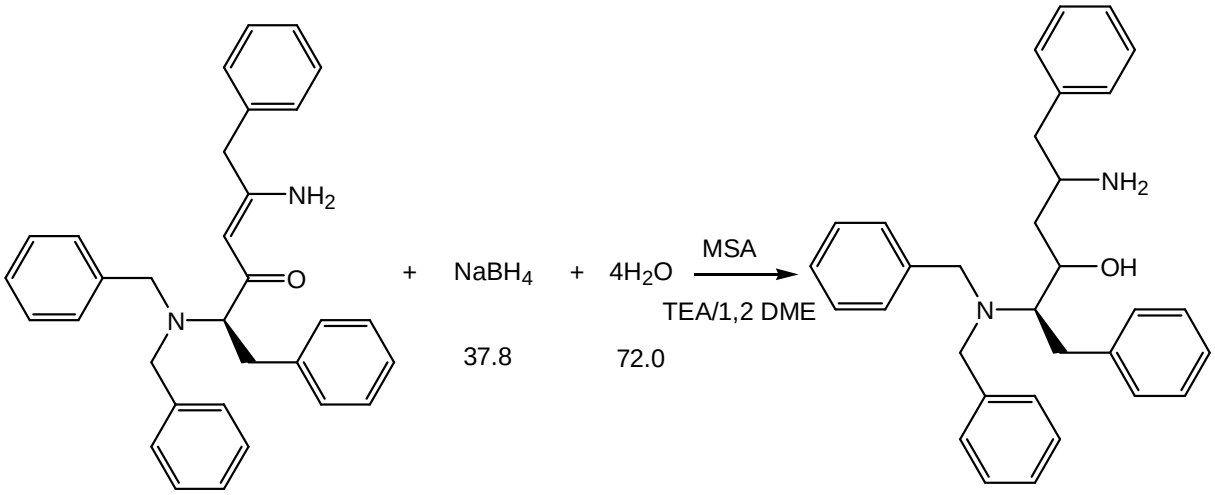


+ $MgCl_2$ + $C_6H_7O_7Na$ + H_2O

(R,Z)-5-amino-2-(dibenzyl amino) -1,6-diphenyl hex-4-en-3-one	Magnesium Chloride	Monosodium Citrate	Water
$C_{32}H_{32}N_2O$	95.21	214.11	18.0
460.61			

Stage-3

Step-A



(R,Z)-5-amino-2-(dibenzyl amino)
-1,6-diphenyl hex-4-en-3-one

$C_{32}H_{32}N_2O$

460.61

(2R)-5-amino-2-(dibenzyl amino)
-1,6-diphenyl hexane-3-ol

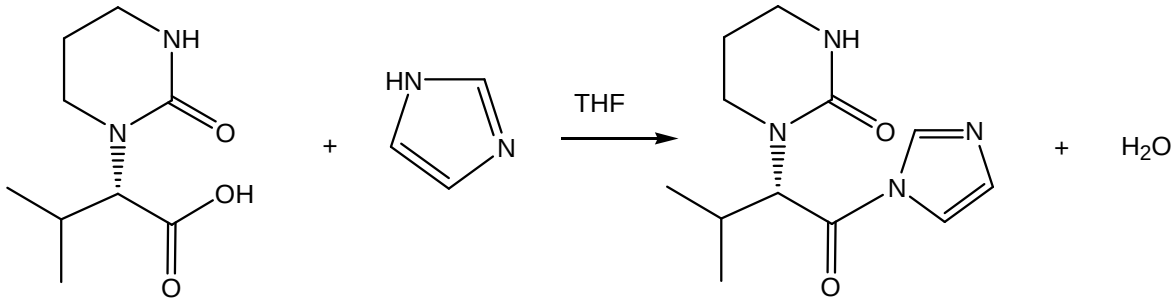
$C_{32}H_{36}N_2O$

464.64

+ H_3BO_3 + NaOH + 2 H_2↑

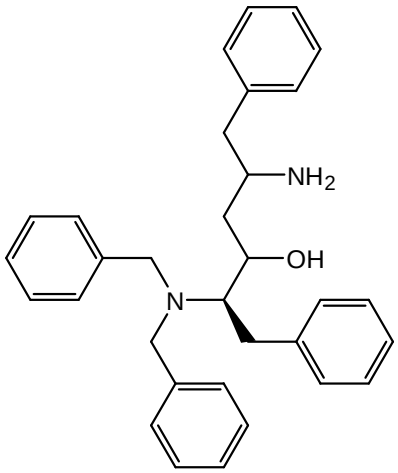
61.83 40.0 4.0

Step-B

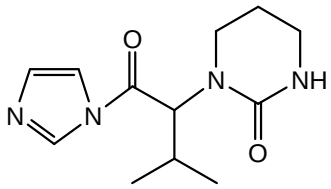


(2S)-(1-Tetrahydropyramid-2-one) -3-methylbutanoic acid	Imidazole	1-[1-(Imidazole-1-carbonyl)-2-methyl -propyl]-tetrahydro-pyrimidin-2-one	18.0
$C_9H_{16}N_2O_3$	$C_3H_4N_2$	$C_{12}H_{18}N_4O_2$	
200.23	68.07	250.30	

Step-C



+



Ethyl acetate

Water

5-Amino-2-dibenzylamino-1,6-diphenyl-hexan-3-ol

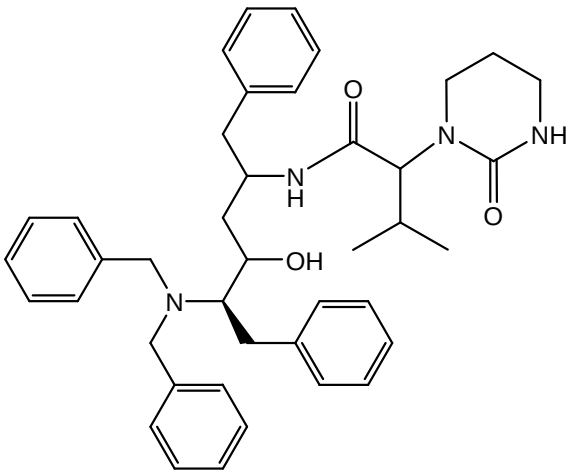
$C_{32}H_{36}N_2O$

464.64

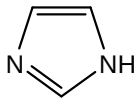
1-[1-(4,5-Dihydro-imidazole-1-carbonyl)
-2-methyl-propyl]-tetrahydro-pyrimidin-2-one

$C_{12}H_{18}N_4O_2$

250.30



+



N-(1-Benzyl-4-dibenzylamino-3-hydroxy
-5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydro
-pyrimidin-1-yl)-butyramide

$C_{41}H_{50}N_4O_3$

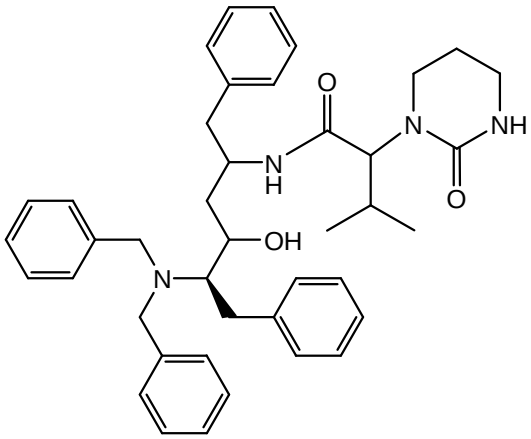
646.86

Imidazole

$C_3H_4N_2$

68.08

Step-D



+ $2CH_5NO_2$ $\xrightarrow[MeoH]{Pd/C}$

N-(1-Benzyl-4-dibenzylamino-3-hydroxy -5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydro -pyrimidin-1-yl)-butyramide

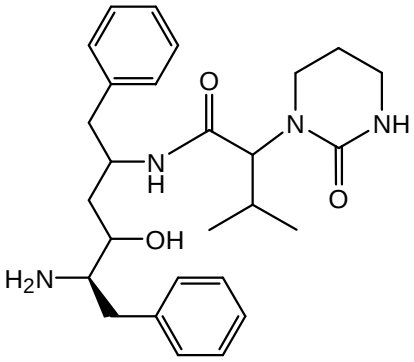
$C_{41}H_{50}N_4O_3$

646.86

Ammonium formate

CH_5NO_2

2X63.06=126.12



+ $2\ C_7H_8$ + $2\ NH_3$ + $2CO_2$ ↑

N-(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide

$C_{27}H_{38}N_4O_3$

466.62

Toluene

C_7H_8

2X92.14=184.28

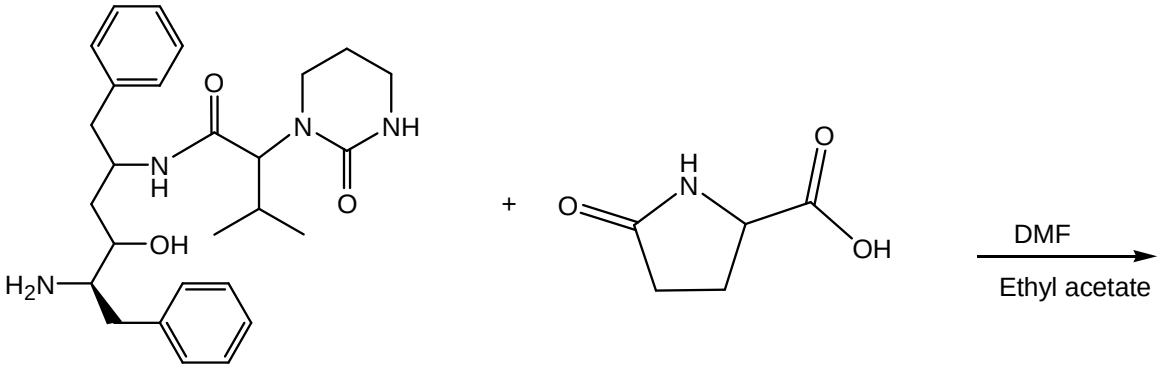
Ammonia

2x17=34

Carbondioxide

2x44=88

Step-E



N-(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide

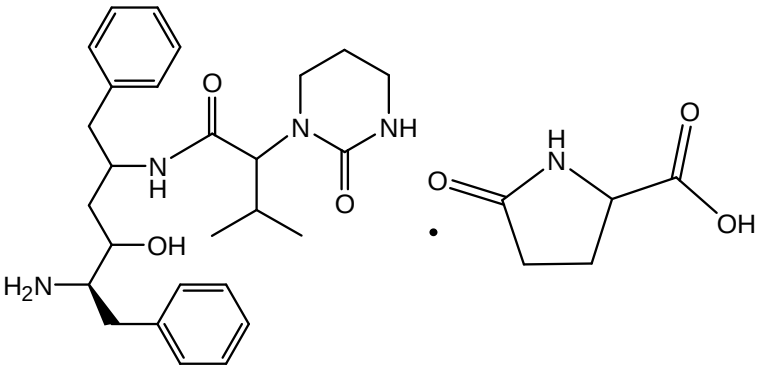
$C_{27}H_{38}N_4O_3$

466.62

L-Pyroglutamic acid

$C_5H_7NO_3$

129.11

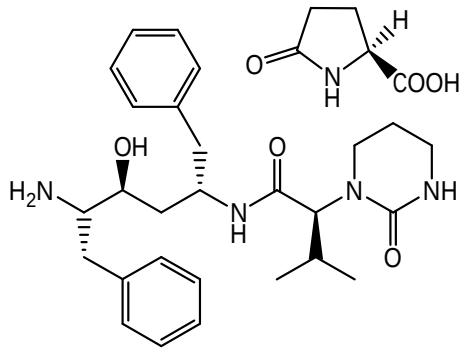


(2S, 3S, 5S)-2-Amino-3-hydroxy-5-(1-tetra hydro pyrmid-2-onyl) -3-methyl butanoyl) amino-1, 6-diphenyl hexane-S-pyro glutamate (THP)

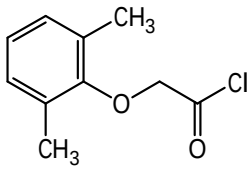
$C_{32}H_{45}N_5O_6$

595.73

Stage-4



+



+ $NaHCO_3$

N-(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl)-3-methyl -2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide; compound with 5-oxo-pyrrolidine-2-carboxylic acid

$C_{32}H_{45}N_5O_6$

595.72

2,6-Dimethyl phenoxy acetyl chloride

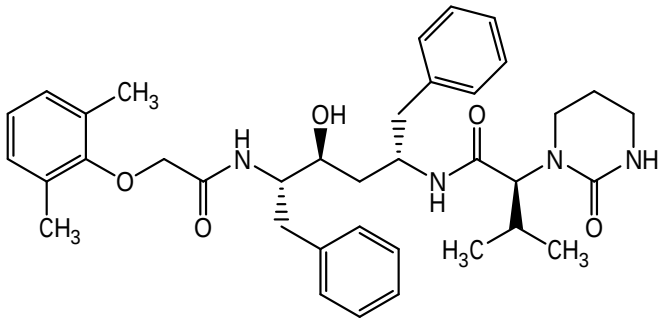
$C_{10}H_{11}ClO_2$

198.64

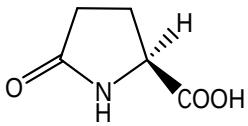
Sodium bicarbonate

84.00

Ethyl acetate



+



+ NaCl

N-{1-Benzyl-4-[2-(2,6-dimethyl-phenoxy)-acetylamino]-3-hydroxy-5-phenyl-pentyl}-3-methyl-2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide (Lopinavir Crude)

$C_{37}H_{48}N_4O_5$

628.80

5-Oxo-pyrrolidine-2-carboxylic acid

$C_5H_7NO_3$

129.11

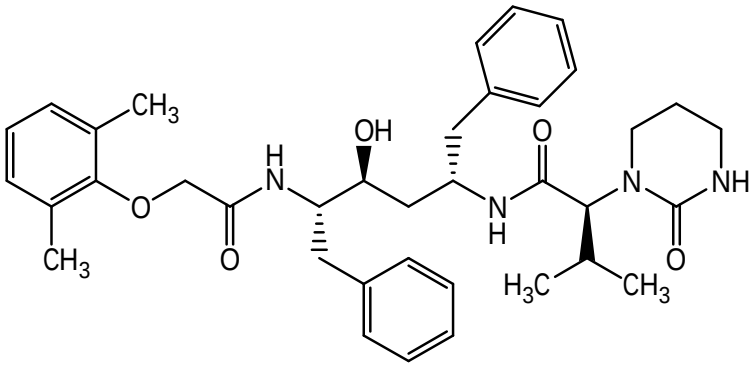
Sodium chloride

58.44

+ CO_2 ↑ + H_2O

44.00 18.00

Stage-5



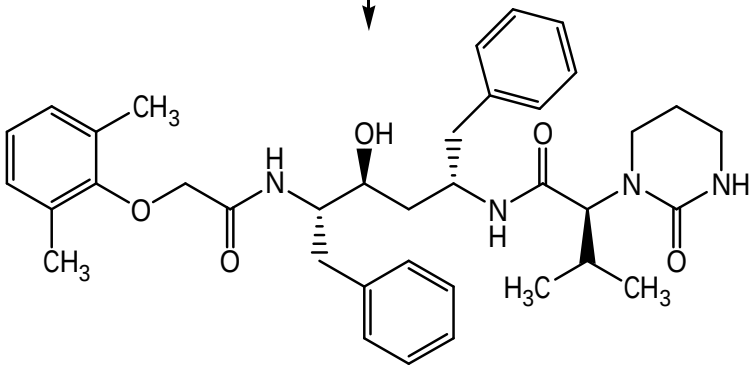
N-{1-Benzyl-4-[2-(2,6-dimethyl-phenoxy)-acetylamino]-3-hydroxy-5-phenyl-pentyl}-3-methyl-2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide

(Lopinavir Crude)

$C_{37}H_{48}N_4O_5$

628.80

Ethanol



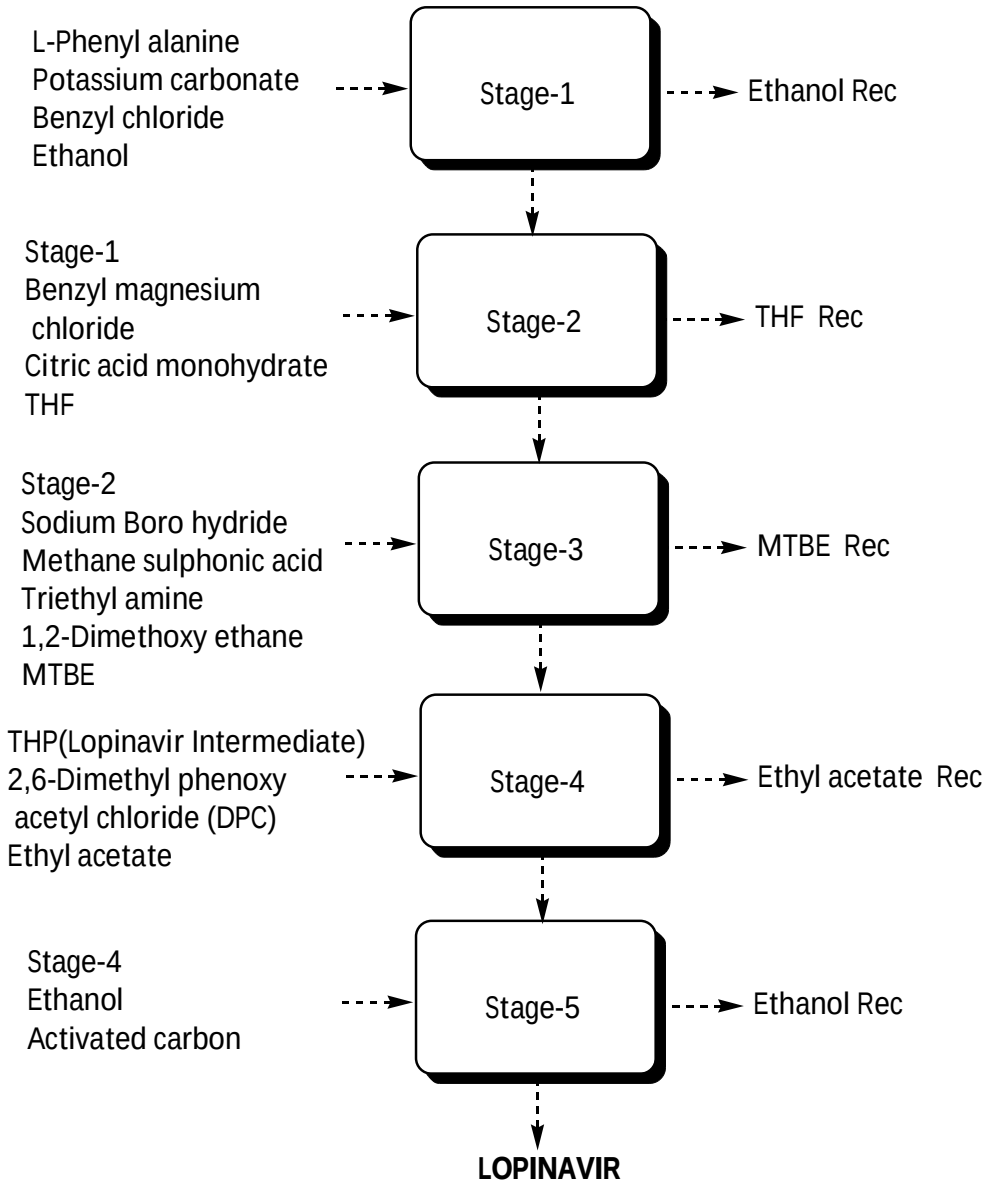
Lopinavir (pure)

$C_{37}H_{48}N_4O_5$

628.80

LOPINAVIR

Flow Chart:



LOPINAVIR

Material Balance:

Material Balance of Lopinavir Stage-1 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
L-Phenyl alanine	75.00		Stage-1	114.00
Potassium carbonate	207.00		n-Heptane Recovery	266.00
Benzyl chloride	173.50		n-Heptane Loss	14.00
Ethanol	865.00		MTBE Recovery	873.00
n-Heptane	280.00		MTBE Loss	45.00
Methanol	434.00		Methanol Recovery	408.00
Sodamide	43.00		Methanol Loss	21.00
Acetonitrile	18.75		Ethanol Recovery	822.00
Citric acid monohydrate	232.00		Ethanol Loss	43.00
MTBE	918.00		Effluent water	2537.80
Sodium chloride	90.00		(Water-2355,Ammonium hydroxide-38.7, Benzyl Alcohol-49.1,Methanol-5, Sodium chloride-90)	
Water	2355.00		Inorganic solid waste	111.65
			(Potassium chloride-111.65)	
			Potassium Hydroxide Reuse	84.00
			Process Emissions	66.00
			(Carbon dioxide)	
			Organic Residue	49.42
			By-Product	236.38
			(Sodium citrate)	
Total	5691.25		Total	5691.25

Material Balance of Lopinavir Stage-2 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	114.00		Stage-2	114.00
Benzyl magnesium chloride	46.00		Ethanol Recovery	770.00
Citric acid monohydrate	103.00		Ethanol Loss	40.00
THF	537.00		MTBE Recovery	689.00
Sodium chloride	29.00		MTBE Loss	36.00
Ethanol	810.00		THF Recovery	506.00
MTBE	725.00		THF Loss	26.00
Water	700.00		Effluent water	743.20
			(Water-700,Magnesium chloride-29.4,Generated water-8.8,THF-5)	
			By-Product	106.00
			(sodium citrate)	
			Organic Residue	33.80
Total	3064.00		Total	3064.00

Material Balance of Lopinavir Stage-3 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	114.00		(2S, 3S, 5S)-2-Amino-3-hydroxy-5-(1-tetra hydro pyrmid-2-onyl)-3-methyl butanoyl) amino-1,6-diphenyl hexane-S-pyro glutamate (THP)	100.00
Sodium Boro hydride	10.00		1,2-Dimethoxy ethane Recovery	1005.00
Methane sulphonic acid	156.00		1,2-Dimethoxy ethane Loss	53.00
Triethyl amine	106.00		MTBE Recovery	234.00
1,2-Dimethoxy ethane	1058.00		MTBE Loss	12.00
MTBE	246.00		THF Recovery	532.00

Ammonium chloride	200.00		THF Loss	28.00
Imidazole	18.90		IPA Recovery	119.00
TPA	55.00		IPA Loss	6.00
THF	560.00		Ethyl acetate Recovery	1777.00
Ethyl acetate	1870.00		Ethyl acetate Loss	93.00
Ammonium formate	31.00		Methanol Recovery	751.00
Methanol	790.00		Methanol Loss	39.00
Palladium carbon	20.60		DMF Recovery	376.00
L-Pyro glutamic acid	31.54		DMF Loss	19.00
DMF	395.00		MDC Recovery	1112.00
HCl	8.00		MDC Loss	58.00
IPA	125.00		Dimethyl Acetamide recovery	152.00
Dimethyl acetamide	160.00		Dimethyl Acetamide Loss	8.00
MDC	1170.00		Methane sulphonic acid Recovery	149.00
Water	1500.00		Triethyl amine Reuse	96.00
			Effluent water	1539.03
			(Water-1482.2,Boric acid-16.35, Sodium hydroxide-10.58, Generated water-4.9,HCl-8, Methane sulphonic acid-7,Triethyl amine-10)	
			Imidazole Reuse	18.90
			Palladium carbon Reuse	20.60
			Toluene Recovery	45.20
			Process Emissions	30.91
			(Hydrogen-1.05,Carbondioxide-21.56,Ammonia-8.3)	
			Inorganic Solid Waste	200.00
			(Ammonium Chloride)	
			Organic Residue	51.40
Total	8625.04		Total	8625.04

Material Balance of Lopinavir Stage-4 Batch Size: 100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
THP(Lopinavir Intermediate)	100.00		Stage-4	103.00
2,6-Dimethyl phenoxy acetyl chloride (DPC)	35.00		Ethyl acetate Recovery	760.00
Ethyl acetate	800.00		Ethyl acetate Loss	40.00
Sodium bicarbonate (10%)	170.00		Acetone Recovery	473.00
Sodium chloride (10%)	100.00		Acetone Loss	25.00
Sodium sulphate	20.00		Effluent Water	790.46
Acetone	500.00		(Water-500,generated water-3.64,Sodium chloride-21.82, water from Sodium bicarbonate-153,water from Sodium chloride-90, Pyroglutamic acid-22)	
Activated carbon	10.00		Spent Carbon	10.00
Water	500.00		Inorganic Solid Waste	20.00
			(Sodium Sulfate)	
			Organic Residue	4.64
			(Organic Impurities-2.64, Acetone-2)	
			Process Emissions	8.90
			(Carbon dioxide)	
Total	2235.00		Total	2235.00

Material Balance of Lopinavir Stage-5 Batch Size: 100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-4	103.00		Lopinavir(pure)	100.00
Ethanol	920.00		Ethanol Recovery	870.00
Activated carbon	10.00		Ethanol Loss	45.00
Hyflow	5.00		Spent carbon & Hyflow	15.00
Water	500.00		Effluent Water	505.00
			(Water-500,Ethanol-5)	
			Organic Residue	3.00
Total	1538.00		Total	1538.00

10. N-BUTYL LITHIUM

Process Description

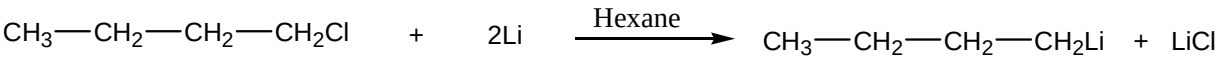
Stage-1

N-Butyl chloride reacts with Lithium in presence of Hexane to give N-Butyl Lithium and Lithium chloride as a by-product.

N-BUTYL LITHIUM

Route of Synthesis:

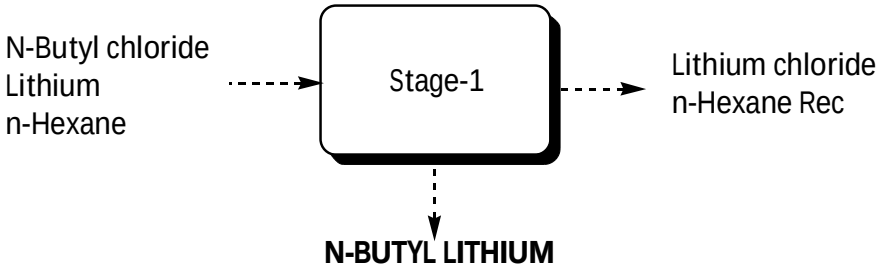
Stage-1



n-Butyl chloride	Lithium	n-Buytl lithium	Lithium chloirde
C_4H_9Cl		C_4H_9Li	
92.57	2x6.94=13.88	64.06	42.39

N-BUTYL LITHIUM

Flow-Chart:



N-BUTYL LITHIUM

Material Balance:

Material Balance of N-Butyl Lithium Stage-1 Batch Size: 50.0Kg (100% basis)				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
N-Butyl chloride	80.00		N-Butyl Lithium In Hexane (20%)	250.00
Lithium	12.00		Hexane Loss	3.00
Hexane	203.00		**By-Product**	36.70
			(Lithium Chloride)	
			Organic Impurities	5.30
Total	295.00		Total	295.00

11. PANTOPRAZOLE SODIUM

Process Description

Stage-1

Maltol and Dimethyl sulphate condense in Acetone solvent medium. Excess Dimethyl sulphate is removed by treating the reaction mass with Potassium Carbonate. Reaction takes place as per the below equation.

Stage-2

Stage-1 compound on treating with Liquor Ammonia solution stage-2 compound is formed. Reaction proceeds as per the below equation

Stage-3

Stage-2 compound on reaction with Phosphorous oxy chloride produces stage-3 compound. Further reaction is stopped by treating the reaction mass with water. Final product is extracted with MDC and after distilling out MDC compound is obtained. Below is the reaction scheme.

Stage-4

Stage-3 compound when reacts with Hydrogen peroxide in presence of Acetic acid, stage-4 compound is obtained. Methanol is the solvent employed.

Stage-5

Stage-4 compound on reaction with Methanol in sodium hydroxide presence produces stage-5 compound. Execs Methanol is used. Below is the reaction

Stage-6

Above stage compound on reaction with Acetic anhydride produces an intermediate.MDC used as solvent. Product is precipitated with C.S. Flakes. Below is the reaction scheme.

Stage-7

Stage-6 compound when reacts with Thionyl chloride an intermediate is formed.MDC is used as solvent. Product is crystallized in Methanol. Finally product is purified with Acetone.

Stage-8

When 2-Chloromethyl-3, 4-dimethoxy-pyridine Hydrochloride reacts with 5-diFluoro methoxy-2-mercapto-benzimidazole, in presence of Sodium hydroxide, product is formed. Mythylene dichloride is the solvent.

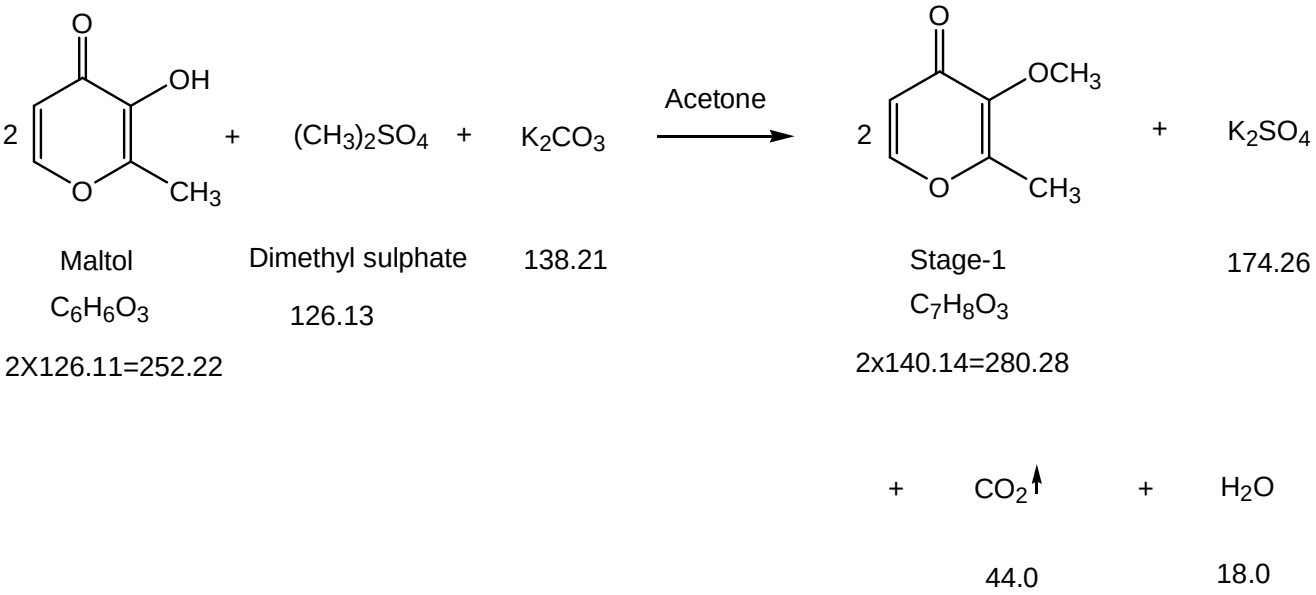
Stage-9

Stage-8 is treated with Sodium hypochlorite in presence of Sodium hydroxide, to produce the Pantoprazole sodium .This is purified in Acetone. Methylene dichloride is used as solvent.

PANTOPRAZOLE SODIUM

Route of Synthesis:

Stage-1



Maltol
$C_6H_6O_3$
2X126.11=252.22

Dimethyl sulphate
126.13

138.21

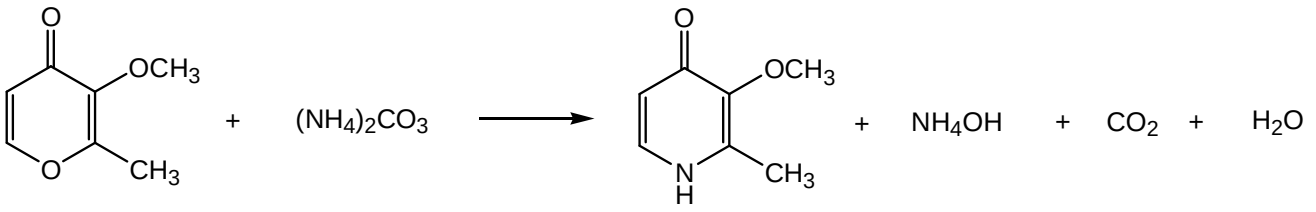
Stage-1
$C_7H_8O_3$
2x140.14=280.28

174.26

44.0

18.0

Stage-2



Stage-1
$C_7H_8O_3$
140.14

Ammonium carbonate
96.0

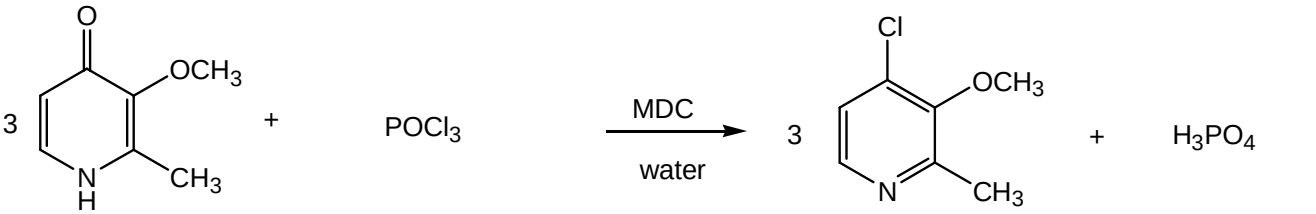
Stage-2
139.15
$C_7H_9NO_2$

35.0

44.0

18.0

Stage-3



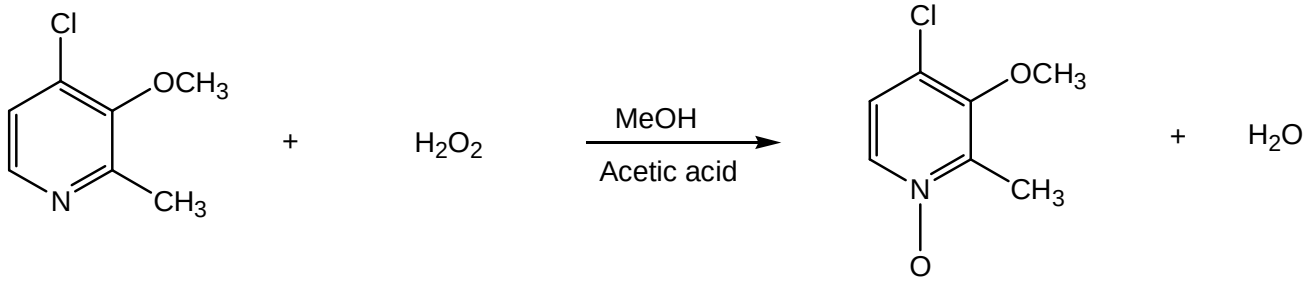
Stage-2
$C_7H_9NO_2$
3X139.15=417.45

Phosphorous oxychloride
153.33

Stage-3
C_7H_8ClNO
3X157.60=472.8

Phosphoric Acid
98.0

Stage-4



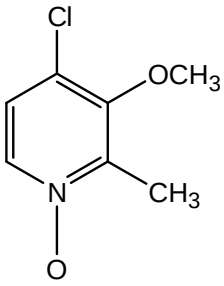
Stage-3
C_7H_8ClNO
157.60

Hydrogen peroxide
34.01

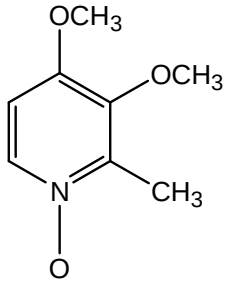
Stage-4
C_7H_8ClNO
173.60

18.0

Stage-5



+ CH_3OH + NaOH $\xrightarrow{MeOH}$

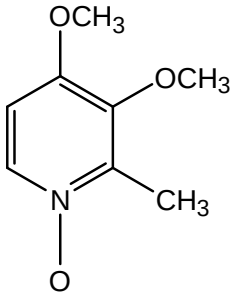


+ NaCl + H_2O

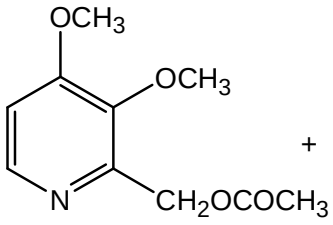
Stage-4			Stage-5		
C_7H_8ClNO	32.0	40.0	$C_8H_{11}NO_3$	58.5	18.0
173.60			169.18		

Stage-6

Step-A



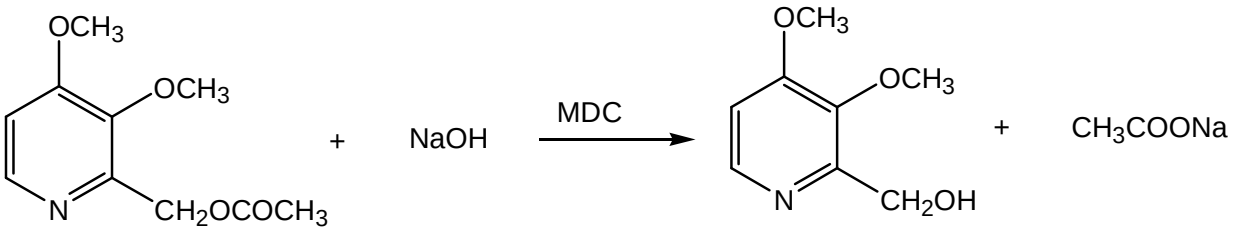
+ $(CH_3CO)_2O$ $\xrightarrow{MDC}$



+ CH_3COOH

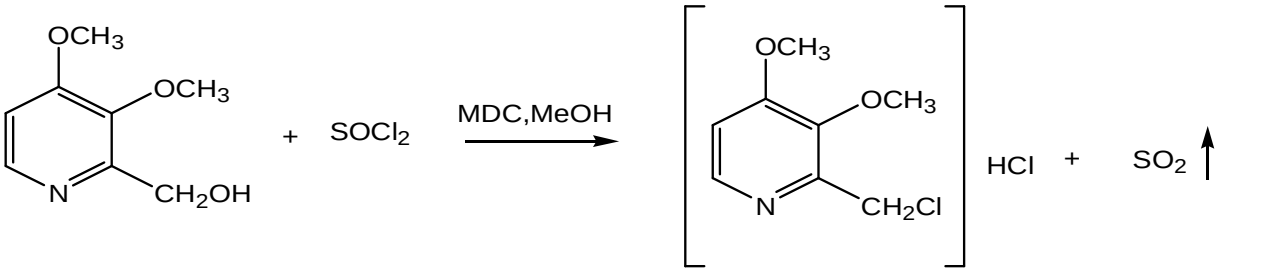
Stage-5		Stage-6	
$C_8H_{11}NO_3$	Acetic anhydride	$C_{10}H_{13}NO_4$	Acetic acid
169.18	102.09	211.21	60.0

Step-B



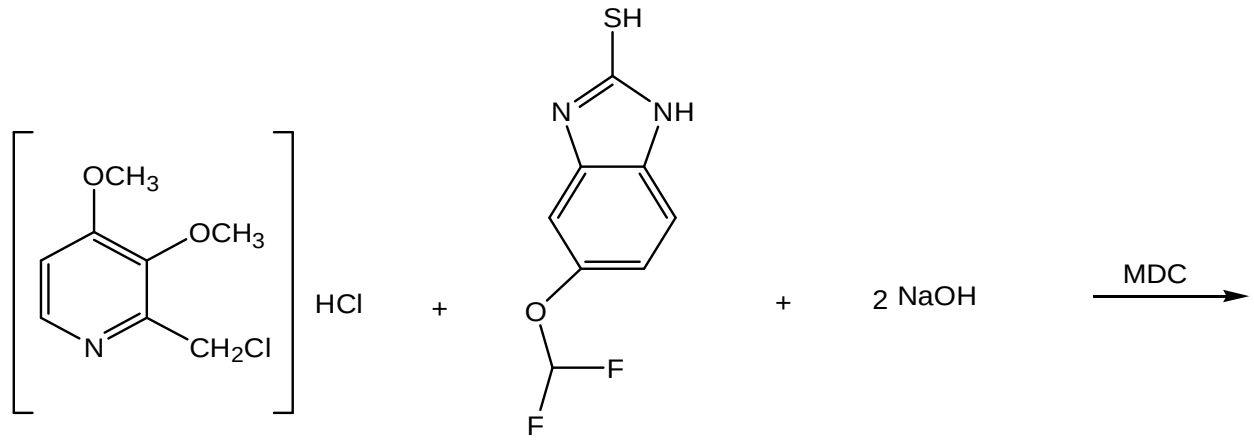
Stage-6A	Sodium hydroxide	Stage-6B	Sodium acetate
$C_{10}H_{13}NO_4$		$C_8H_{11}NO_3$	
211.21	40.0	169.18	82.03

Stage-7



Stage-6B	Thionyl chloride	Stage-7	Sulphur dioxide
$C_8H_{11}NO_3$		$C_8H_{10}ClNO_2.HCl$	
169.18	118.97	224.12	64.0

Stage-8



Stage-7

$C_8H_{10}ClNO_2.HCl$

224.12

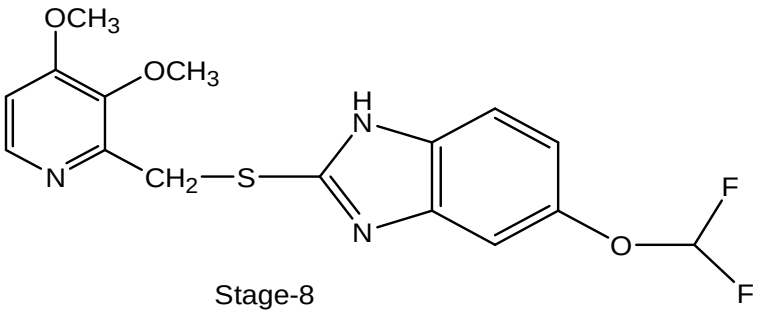
5-Difluoromethoxy
-2-mercaptobenzimidazole

$C_8H_6F_2N_2OS$

216.21

Sodium
hydroxide

2x40.0=80



Stage-8

$C_{16}H_{15}F_2N_3O_3S$

367.37

+ 2 NaCl + $2\,H_2O$

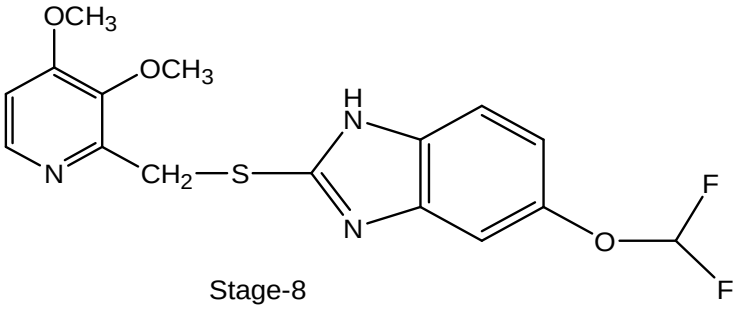
Sodium chloride

2x58.5=117

Water

2x18.0=36

Stage-9



Stage-8

$C_{16}H_{15}F_2N_3O_3S$

367.37

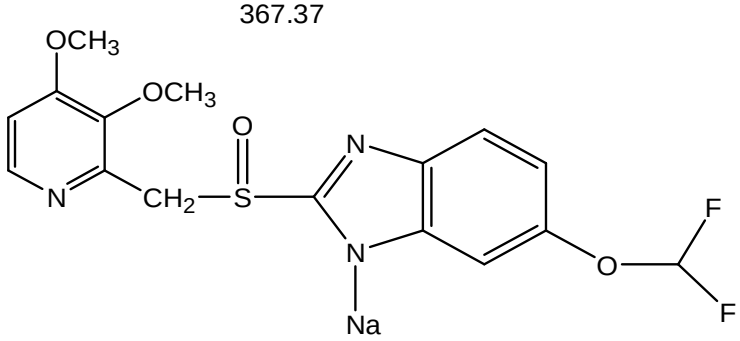
+ NaOCl + NaOH $\xrightarrow[\text{Acetone}]{\text{MDC}}$

Sodium hypochlorite

74.44

Sodium hydroxide

40.0



Pantoprazole sodium

$C_{16}H_{14}F_2N_3NaO_4S$

405.35

+ NaCl + H_2O

Sodium chloride

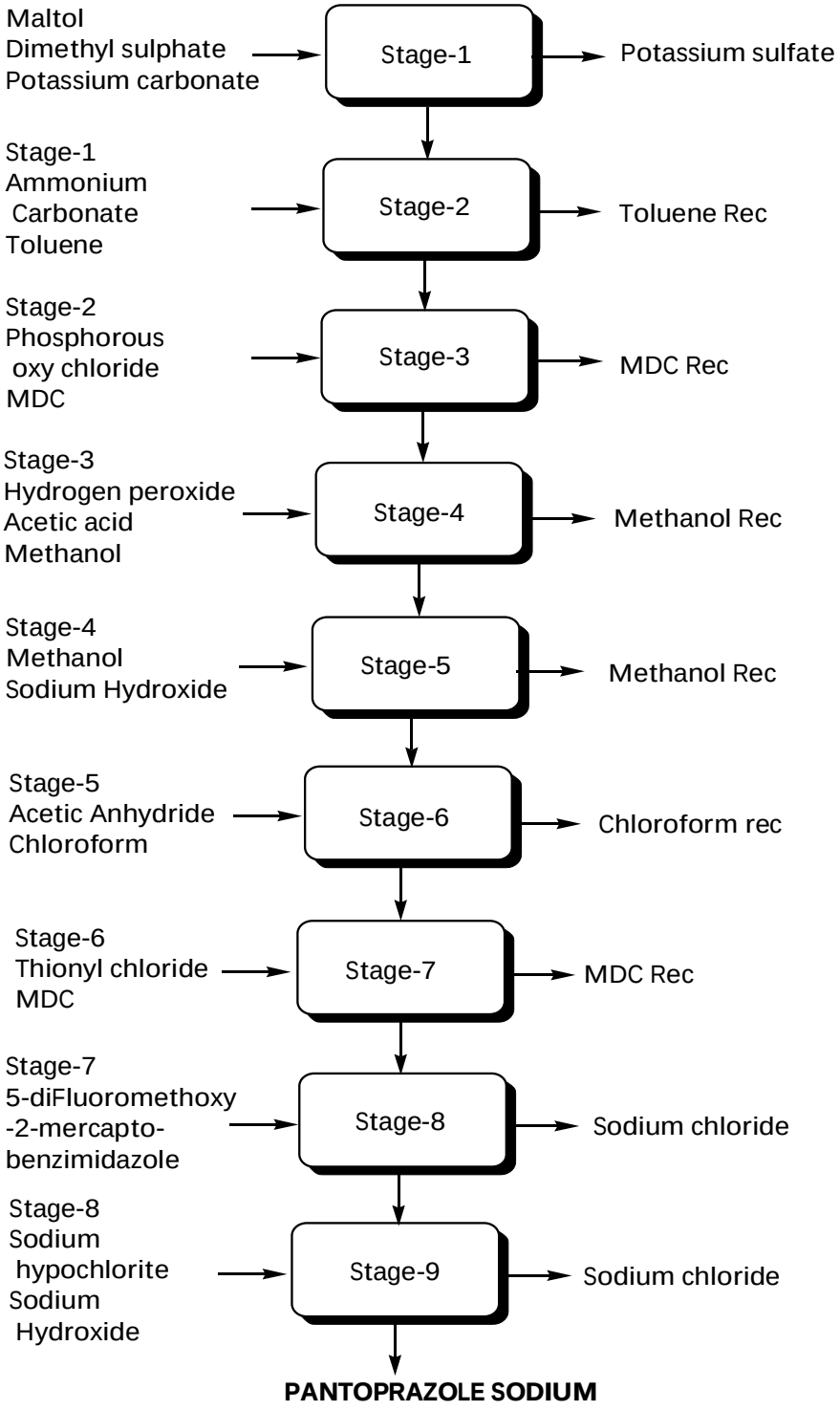
58.5

Water

18.0

PANTOPRAZOLE SODIUM

Flow Chart:



PANTOPRAZOLE SODIUM

Material Balance:

Material Balance of Pantoprazole Sodium Stage-1 Batch Size: 100 Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Maltol	85.00		Stage-1	85.00
Dimethyl sulphate	45.00		Acetone Recovery	378.00
Potassium carbonate	55.00		Acetone Loss	20.00
Acetone	400.00		Generated water	6.00
			Inorganic Solid Waste	67.30
			(Potassium Sulphate-58.8, Potassium carbonate-8.5)	
			Organic Residue	13.70
			(Organic Impurities-11.7, Acetone-2)	
			Process Emission	15.00
			(Carbon dioxide)	
Total	585.00		Total	585.00

Material Balance of Pantoprazole Sodium Stage-2 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-1	85.00		Stage-2	75.00
Ammonium Carbonate	65.00		Toluene Recovery	280.00
Toluene	300.00		Toluene Loss	15.00
Water	700.00		Effluent Water	740.80
			(Water-700,Ammonium hydroxide-21.2,Ammonium carbonate-6.7,generated water-10.9,Toluene-2)	
			Organic Residue	12.48
			(Organic Impurities-9.48, Toluene-3)	
			Process Emission	26.72
			(Carbon dioxide)	
Total	1150.00		Total	1150.00

Material Balance of Pantoprazole Sodium Stage-3 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-2	75.00		Stage-3	70.00
Phosphorous oxy chloride	35.00		MDC Recovery	280.00
Sodium Hydroxide	30.00		MDC Loss	15.00
Methylenedichloride	300.00		Effluent Water	780.00
Water	725.00		(Water-725,Phosphoric acid-18,Phosphorus oxychloride-7, Sodium hydroxide-30)	
			Organic Residue	20.00
			(Organic Impurities-15,MDC-5)	
Total	1165.00		Total	1165.00

Material Balance of Pantoprazole Sodium Stage-4 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-3	70.00		Stage-4	65.00
Hydrogen peroxide (30%)	50.00		MDC Recovery	668.00
Acetic acid	35.00		MDC Loss	30.00
Methanol	250.00		Methanol Recovery	233.00
Sodium Hydroxide	20.00		Methanol Loss	12.50
MDC	700.00		Effluent Water	801.10
Water	700.00		(Water-700,Sodium Acetate-41,Acetic Acid-5,generated water-17.6,water from hydrogen peroxide-35, Methanol-2.5)	
			Organic Solid Waste	15.40
			(Organic Impurities-11.4,MDC-2,Methanol-2)	
Total	1825.00		Total	1825.00

Material Balance of Pantoprazole Sodium Stage-5 Batch Size: 100 Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-4	65.00		Stage-5	60.00
Methanol	500.00		Methanol Recovery	465.00
Sodium Hydroxide	22.00		Methanol Loss	20.00
Acetic Acid	10.00		Effluent Water	748.45
Water	700.00		(Water-700,gen.water-9.85, Sodium Chloride-22,Sodium Acetate-13.6,Methanol-3)	
			Organic Residue	0.55
Total	1294.00		Total	1294.00

Material Balance of Pantoprazole Sodium Stage-6 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-5	60.00		Stage-6	55.00
Acetic Anhydride	45.00		Chloroform + Acetic Anhydride Recovery	198.80
Chloroform	200.00		Chloroform Loss	10.00
Sodium hydroxide	20.00		Effluent Water	555.00
Water	500.00		(Water-500,Acetic Acid-21.3, Sodium hydroxide-7,Sodium Acetate-26.7)	
			Organic Residue	6.20
Total	825.00		Total	825.00

Material Balance of Pantoprazole Sodium Stage-7 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-6	55.00		Stage-7	65.00
Thionyl chloride	39.00		MDC Recovery	810.00
Methylenedichloride	850.00		MDC Loss	40.00
Methanol	125.00		Methanol Recovery	99.00
Acetone	200.00		Methanol Loss	25.00
			Acetone Recovery	189.00
			Acetone Loss	10.00
			Process Emission	21.00
			(Sulphur Dioxide)	
			Organic Residue	10.00
			(Organic Impurities-8, Methanol-1,Acetone-1)	
Total	1269.00		Total	1269.00

Material Balance of Pantoprazole Sodium Stage-8 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-7	65.00		Stage-8	95.00
5-diFluoromethoxy-2-mercapto-benzimidazole	70.00		Toluene Recovery	472.00
Sodium Hydroxide flakes	25.00		Toluene Loss	25.00
Toluene	500.00		Effluent Water	747.70
Water	700.00		(Water-700,Sodium Chloride-34,gen.Water-10.4, Sodium hydroxide-1.8, Toluene-1.5)	
			Organic Residue	20.30
			(Organic Impurities-18.8, Toluene-1.5)	
Total	1360.00		Total	1360.00

Material Balance of Pantoprazole Sodium Stage-9:Pharma Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the output	Quantity in Kg
Stage-8	95.00		Pantoprazole Sodium	100.00
Sodium hypochlorite (4%)	500.00		MDC Recovery	950.00
Sodium Hydroxide flakes	12.00		MDC Loss	50.00
Ammonium Chloride	25.00		Acetone Recovery	378.00
Methylene dichloride	1000.00		Acetone Loss	20.00
Activated Carbon	10.00		Effluent Water	1726.85
Acetone	400.00		(Water-1200,gen.water-4.65, Sodium chloride-15.2,water from sodium hypochlorite-480, Aluminum chloride-25, Acetone-2)	
Water	1200.00		Spent carbon	10.00
			Organic Residue	7.15
Total	3242.00		Total	3242.00

12. RITANAVIR

Process Description:

Stage-1

Step-A

Stage-2 react with sodium boro hydride in presence of MSA, TEA and 1, 2-DME as solvent media to give Step-A as a product.

Step-B

Step-A reacts with Di tert.butyl oxy di formate, potassium carbonate in presence of MTBE as a solvent media to give Step-B as a product.

Step-C

Step-B product reacts with ammonium formate in presence of palladium carbon and methanol as a solvent media to give Step-C as a product.

Step-D

Step-c reacts with succinic acid, acetic acid and sodium hydroxide by using IPA,DMA as solvent media to give (2s, 3s, 5s)-2-amino-3-hydroxy-5-(tert.butyloxy carbonyl) amino-1, 6-diphenyl hemi succinic acid salt (BDH succinic acid salt)

Stage-2

5-hydroxy methyl thiazole reacts with 4-nitro phenyl chloro formate in presence of pyridine as a catalyst and ethyl acetate as a solvent media to give carbonic acid-4-nitro phenyl-5-thiazolyl methyl ester.

Stage-3

(2s, 3s, 5s)-2-amino-3-hydroxy-5-(tert.butyloxy carbonyl) amino-1, 6-diphenyl hemi succinic acid salt (BDH succinic acid salt) reacts with carbonic acid-4-nitro phenyl-5-thiazolyl methyl ester in the presence of Ethyl acetate as solvnet media to give Stage-4 as product.

Stage-4

Isobutyamide reacts with Phosphorous penta sulphide undergoes sulphonation to give Isothio butyramide

Stage-5

Isothiobutyramide reacts with 1, 3-Dichloroacetone in presence of mono methyl amine undergoes cyclization to give (S)-methyl-3-methyl-2-((4-Nitrophenoxy) carbonyl amino butanoic acid.

Stage-6

(S)-methyl-3-methyl-2-((4-Notrophenoxy) carbonyl amino) butanoic acid reacts with Phenoxy carbonyl L-valine undergoes condensation to give (2S)-3-Methyl-2-((methyl-((2-(1-methylethyl) thiazole-4-yl) methyl) amino butanoic acid

Stage-7

N-(N-methyl-N-(2-Isopropyl-4-thiazolyl)methyl)amino)carbonyl)_L-Valine reacts with Thiazol-5-yl-methyl-N-(1S,2S,4S)-4-amino-1-benzyl-2-hydroxy-5-phenyl-pentyl)carbamate in the presence of THF as solvent media to give Stage-1 as product.

Stage-8

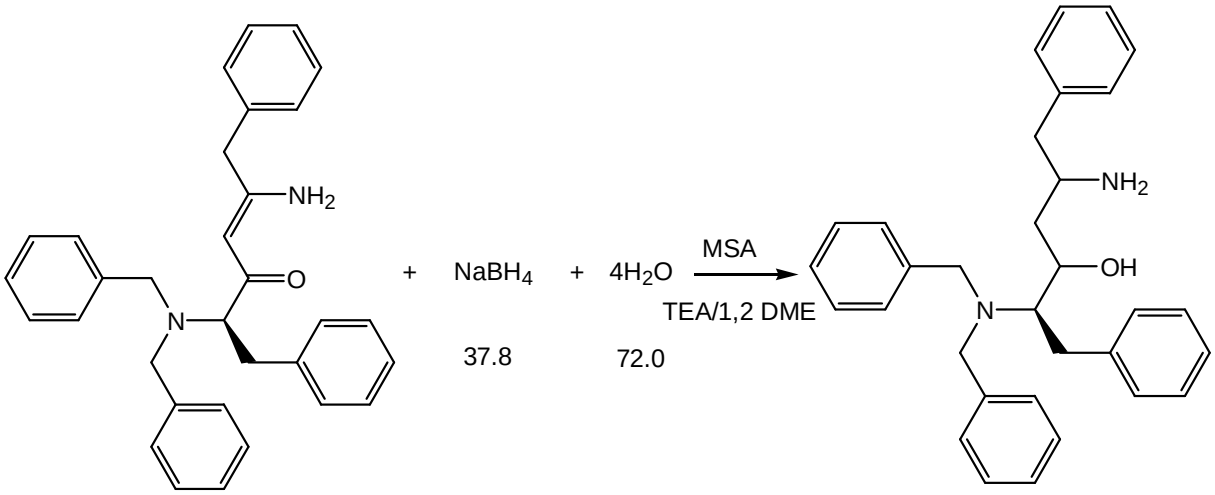
Stage-1 product undergoes purification with N-Heptane as solvent media to give Pure Ritonovir as product.

RITANAVIR

Route of Synthesis:

Stage-1

Step-A



(R,Z)-5-amino-2-(dibenzyl amino) -1,6-diphenyl hex-4-en-3-one

$C_{32}H_{32}N_2O$

460.61

37.8

72.0

(2R)-5-amino-2-(dibenzyl amino) -1,6-diphenyl hexane-3-ol

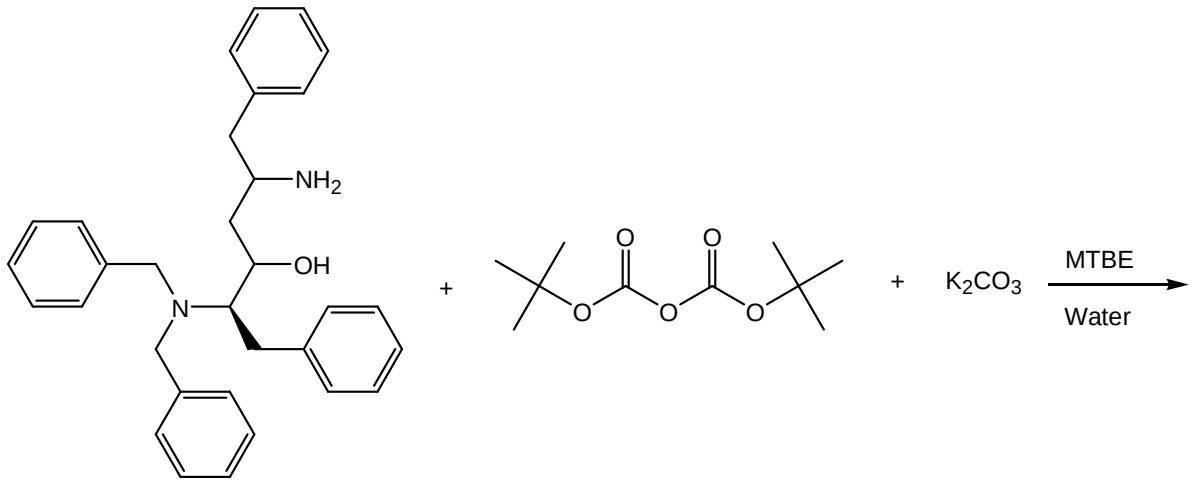
$C_{32}H_{36}N_2O$

464.64

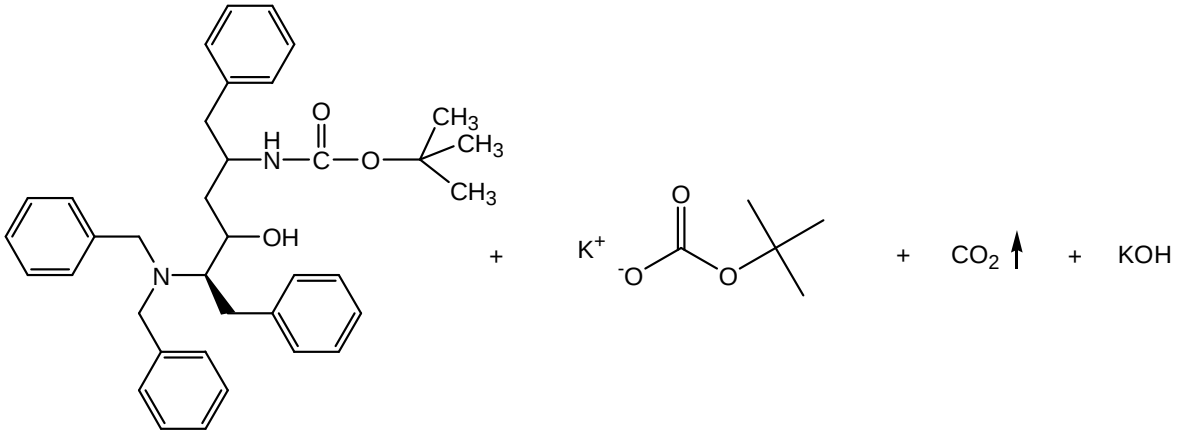
+ H_3BO_3 + NaOH + 2 H_2↑

61.83 40.0 4.0

Step-B

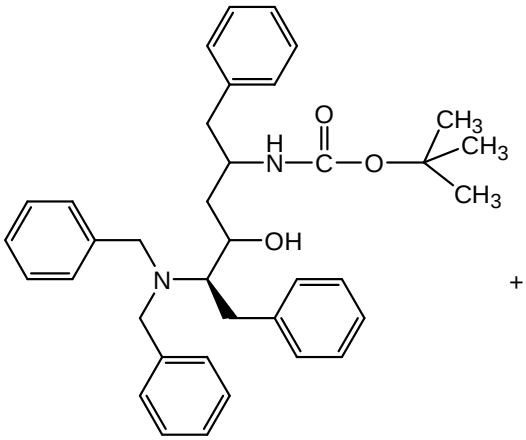


(2R)-5-amino-2-(dibenzyl amino) -1,6-diphenyl hexane-3-ol	Di-tert-butyl oxydiformate	Potassium Carbonate
$C_{32}H_{36}N_2O$	$C_{10}H_{18}O_5$	138.21
464.64	218.25	



(1-Benzyl-4-dibenzylamino-3-hydroxy-5 -phenyl-pentyl)-carbamic acid *tert*-butyl ester	Di Potassium tert-butylcarbonate	Carbon dioxide	Potassium Hydroxide
$C_{37}H_{44}N_2O_3$	$C_5H_9KO_3$	44.0	56.11
564.76	156.22		

Step-C



+ $2\ CH_5NO_2$ —(5% Pd/C, Methanol)→

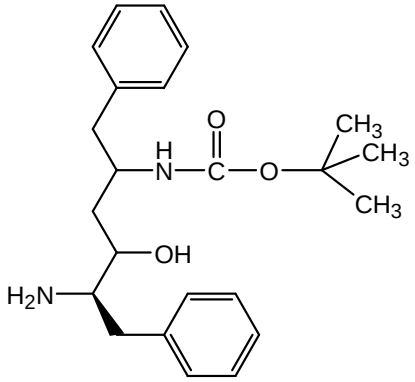
(1-Benzyl-4-dibenzylamino-3-hydroxy-5 -phenyl-pentyl)-carbamic acid *tert*-butyl ester

$C_{37}H_{44}N_2O_3$

564.76

Ammonium formate

2X63.06=126.12



+ $2\ C_7H_8$ + $2\ CO_2$ ↑ + $2NH_3$

(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl) -carbamic acid *tert*-butyl ester

$C_{23}H_{35}N_2O_5$

384.51

Toluene

2X92.14=184.28

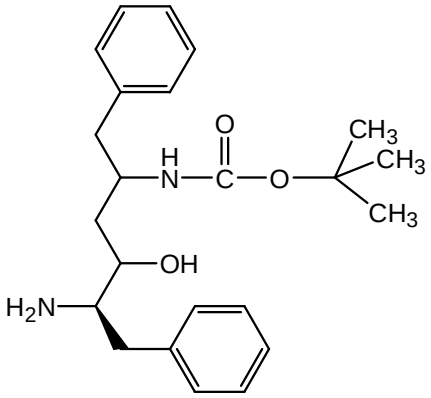
Carbondioxide

2x44=88

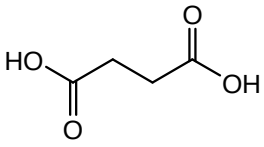
Ammonia

2x17.0=34

Step-D



+ 1/2



+ CH_3COOH + NaOH

(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl) -carbamic acid *tert*-butyl ester

Succinic Acid

60.0

40.0

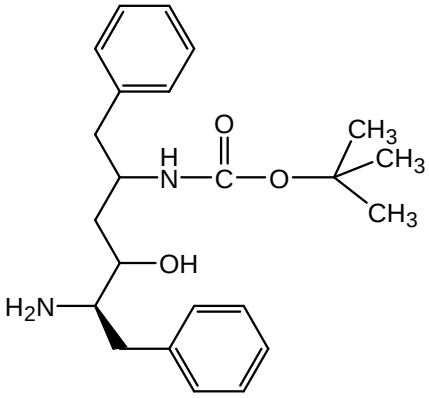
$C_{23}H_{35}N_2O_5$

384.51

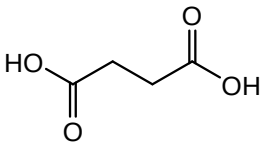
$C_4H_6O_4$

1/2X118.09=59.04

IPA/DMA



1/2



+ CH_3COONa + H_2O

(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl) -carbamic acid *tert*-butyl ester hemi succinic acid

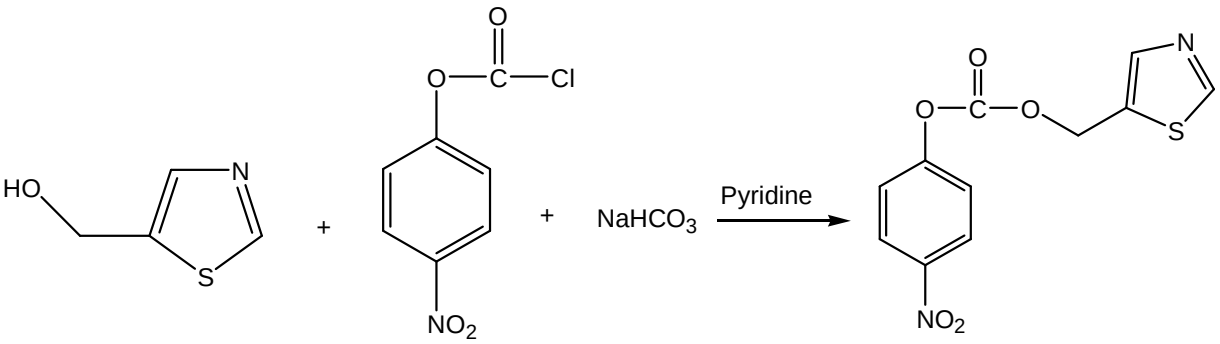
82.03

18.0

$C_{25}H_{35}N_2O_5$

443.56

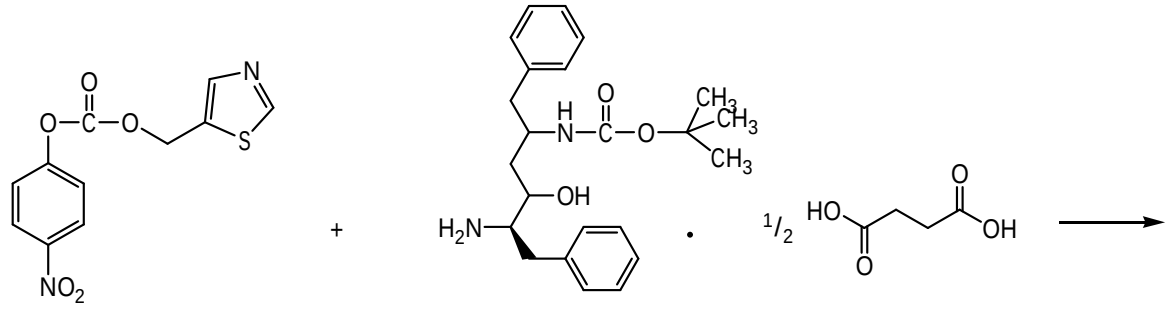
Stage-2



5-Hydroxymethyl thiazole	4-Nitro phenyl chloro formate	Sodium bicarbonate	Carbonic acid,4-Nitrophenyl-5-thiazolyl methyl ester
C_4H_5NOS	$C_7H_4O_4ClN$		$C_{11}H_8O_5N_2S$
115.15	201.56	84.0	280.26

+ NaCl	+ H_2O	+ CO_2 ↑
Sodium chloride	Water	Carbon dioxide
58.5	18.0	44.0

Stage-3:



Carbonic acid,4-Nitrophenyl-5-thiazolyl methyl ester

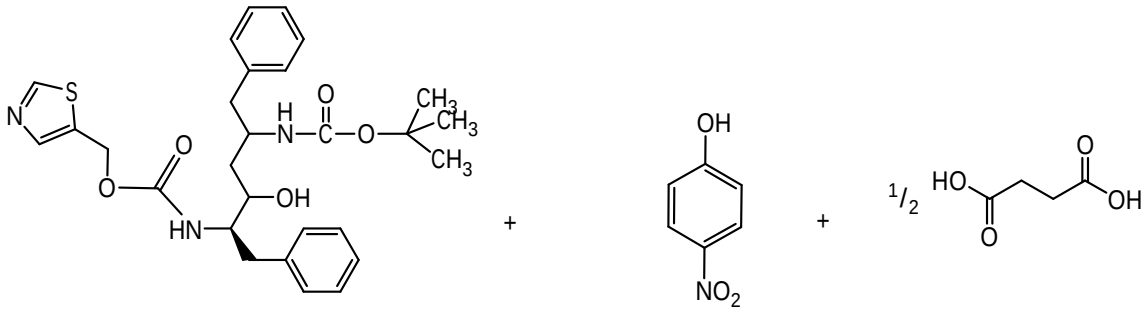
$C_{11}H_8O_5N_2S$

280.26

(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl) -carbamic acid *tert*-butyl ester hemi succinic acid

$C_{25}H_{35}N_2O_5$

443.55



(1-Benzyl-4-*tert*-butoxycarbonylamino-2-hydroxy-5-phenyl-pentyl)-carbamic acid thiazol-5-ylmethyl ester

$C_{28}H_{35}N_3O_5S$

525.66

4-Nitro-phenol

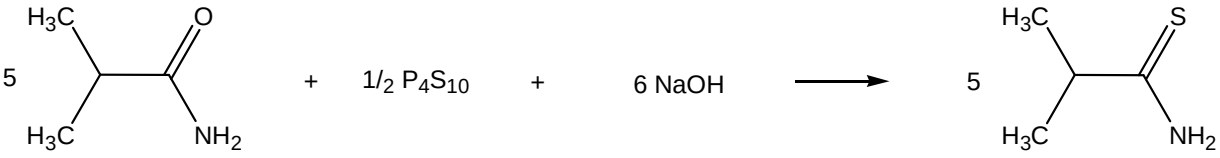
$C_6H_5NO_3$

139.11

Hemisuccinic acid

59.04

Stage-4



Isobutyramide

C_4H_9O

5 X 87.12 = 435.6

Phosphorus penta sulphide

1/2 X 444.55 = 222.27

6X40=240

Thioisobutyramide

C_4H_9NS

5X103.19=515.95

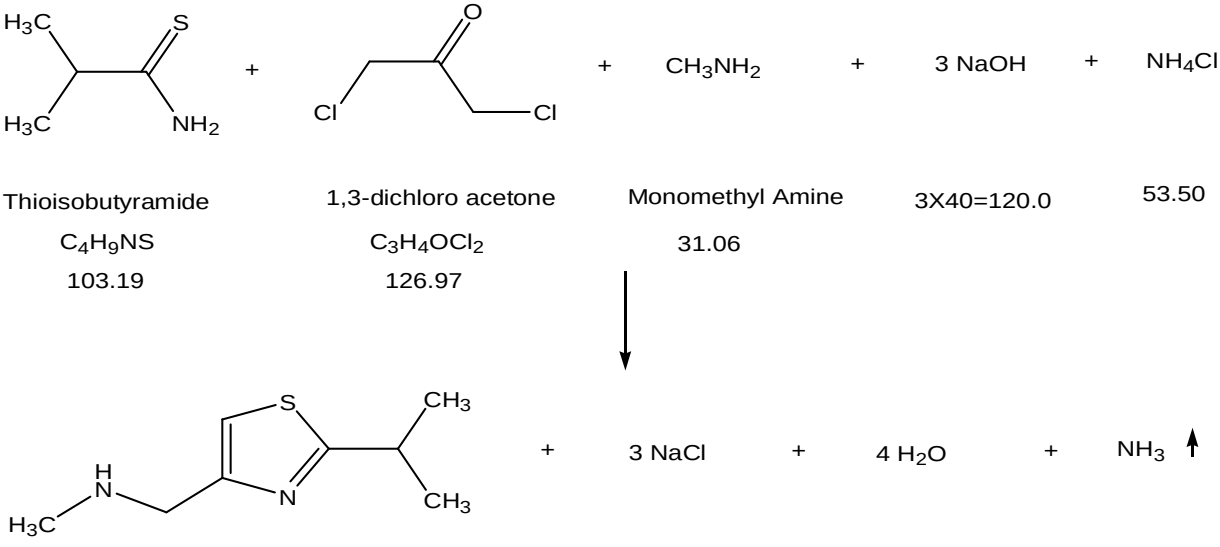
+ $2\ Na_3PO_4$ + $3\ H_2O$

Sodium Phosphate

2X163.94 = 327.88

3X18=54

Stage-5



Thioisobutyramide

C_4H_9NS

103.19

1,3-dichloro acetone

$C_3H_4OCl_2$

126.97

Monomethyl Amine

31.06

3X40=120.0

53.50

1-(2-Isopropylthiazol-4-yl)-N-methyl methanamine

$C_8H_{14}N_2S$

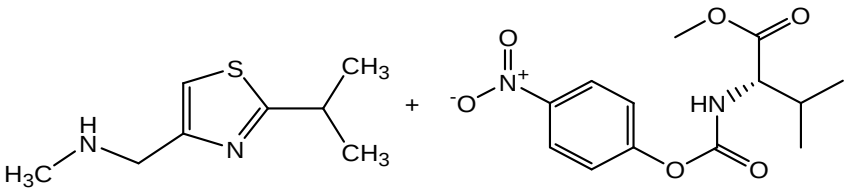
170.28

3X58.5=175.5

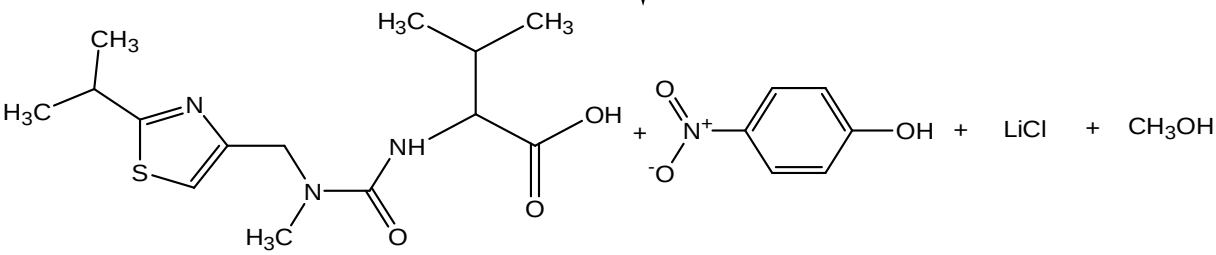
4X18=72.0

17.0

Stage-6

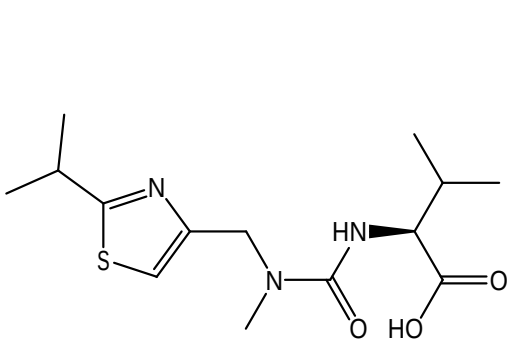


1-(2-Isopropylthiazol-4-yl)-N-methyl methanamine $C_8H_{14}N_2S$ 170.28	(S)- methyl-3-methyl-2-((4-Nitrophenoxy) carbonyl amino)butanoate $C_{13}H_{16}N_2O_6$ 296.28	23.95	36.5



(S)-2-(3-((2-Isopropylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanoic acid $C_{14}H_{23}N_3O_3S$ 313.42	4-Nitro-phenol $C_6H_5NO_3$ 139.1	42.39	32.0

Stage-7

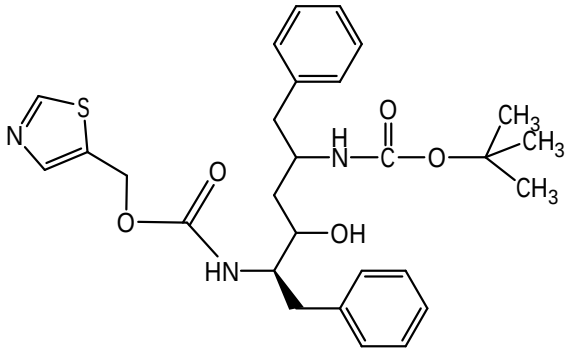


N-((N-methyl-N-((2-isopropyl-4-thiazolyl)methyl) amino)carbonyl)-L-valine

$C_{14}H_{23}N_3O_3S$

313.42

+

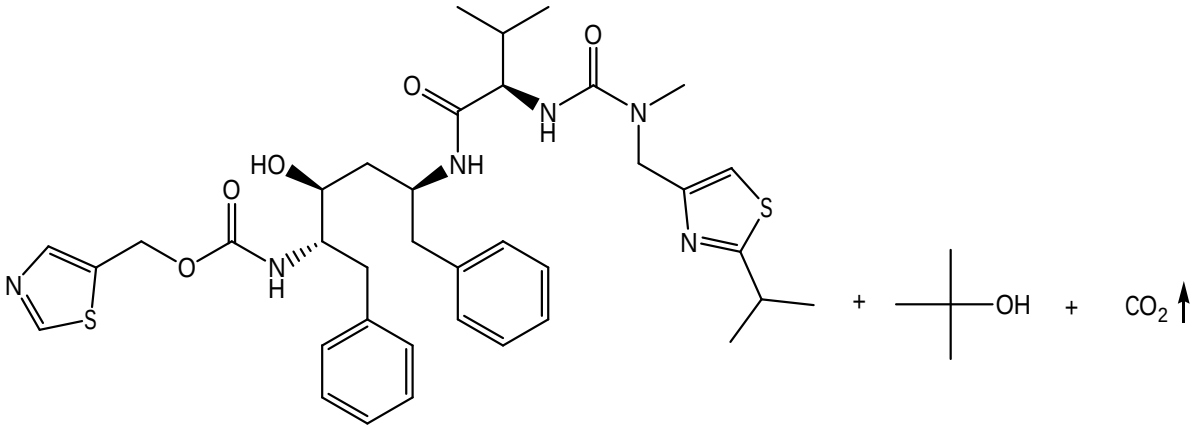


(1-Benzyl-4-*tert*-butoxycarbonylamino-2-hydroxy-5-phenyl-pentyl)-carbamic acid thiazol-5-ylmethyl ester

$C_{28}H_{35}N_3O_5S$

525.66

THF



Ritanovir

$C_{37}H_{48}N_6O_5S_2$

720.94

+ OH + CO_2

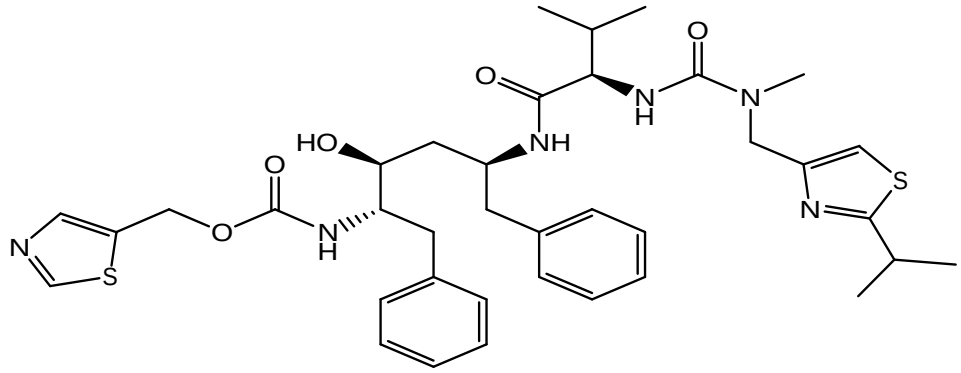
Tert butanol

$C_4H_{10}O$

74.12

44.0

Stage-8

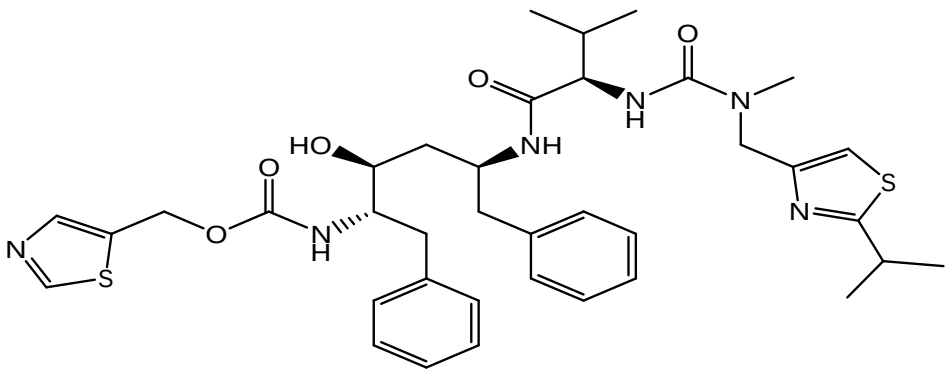


Ritanovir crude

$C_{37}H_{48}N_6O_5S_2$

720.94

n-Heptane



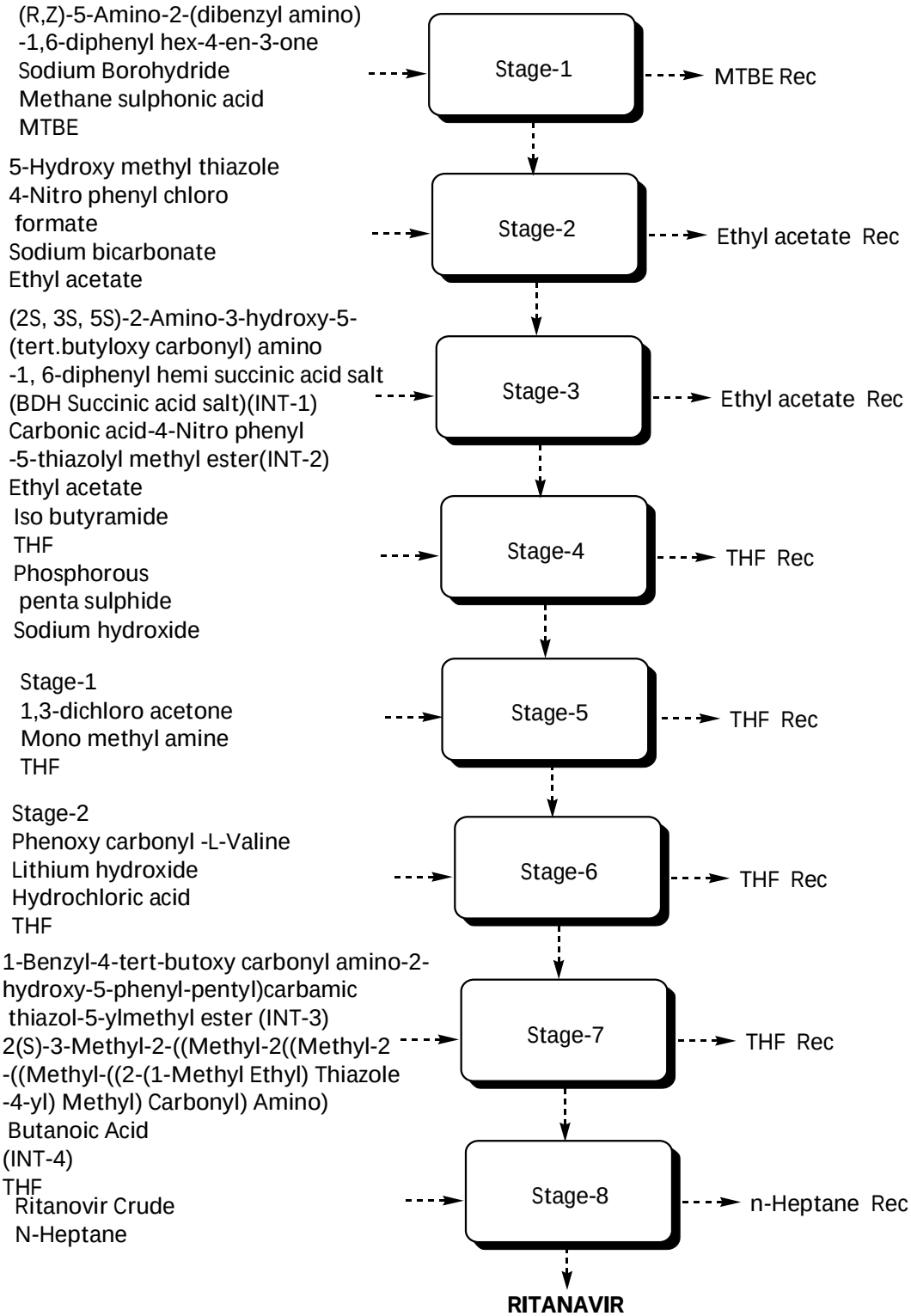
Ritanovir Pure

$C_{37}H_{48}N_6O_5S_2$

720.94

RITANAVIR

Flow Chart:



RITANAVIR

Material Balance:

Material Balance of Ritonovir Stage-1 Batch Size: 100.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
(R,Z)-5-Amino-2-(dibenzyl amino)-1,6-diphenyl hex-4-en-3-one	114.00		(2S, 3S, 5S)-2-Amino-3-hydroxy-5-(tert.butyloxy carbonyl) amino-1, 6-diphenyl hemi succinic acid salt (BDH Succinic acid salt) (**INT-1)**	70.00
Sodium Borohydride	10.00		1,2-Dimethoxy ethane Recovery	1330.00
Methane sulphonic acid	156.00		1,2-Dimethoxy ethane Loss	70.00
Triethyl amine	106.00		MTBE Recovery	891.00
Potassium carbonate	34.00		MTBE Loss	46.00
1,2-Dimethoxy ethane	1400.00		Methanol Recovery	1615.00
Di-tert butyl oxy diformate	60.00		Methanol Loss	85.00
MTBE	937.00		IPA Recovery	1589.00
Ammonium chloride	200.00		IPA Loss	83.00
Sodium chloride	33.00		Di methyl Acetamide Recovery	152.00
Methanol	1700.00		Di methyl Acetamide Loss	8.00
Acetic acid	14.70		Palladium carbon Reuse	22.00
Succinic acid	15.37		Methane sulphonic acid Recovery	151.00
Palladium carbon	22.00		Tri ethyl amine Recovery	100.00
Ammonium formate	31.00		Effluent water	2286.30
Sodium hydroxide	9.80		(Water-2129.2,Boric acid-16.4, Sodium hydroxide-10.5, Di potassium tert-butyl carbonate -43,Potassium hydroxide-13.8, Sodium acetate-20,generated water-4.4,IPA-5,MSA-5,TEA-6, Sodium chloride-33)	
IPA	1677.00		Toluene Recovery	45.12
Di methyl acetamide	160.00		Inorganic Solid Waste	200.00
Water	2147.00		(Ammonium chloride)	
			Process Emissions	27.27
			(Carbon dioxide-22.10,Hydrogen-1.0,Ammonia-4.17)	
			Organic Residue	56.18
Total	8826.87		Total	8826.87

Material Balance of Ritonovir Stage-2 Batch Size: 100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
5-Hydroxy methyl thiazole (5-HMT)	50.00		Carbonic acid-4-Nitro phenyl -5-thiazolyl methyl ester **(INT-2)**	100.00
4-Nitro phenyl chloro formate	88.00		Ethyl acetate Recovery	845.00
Sodium bicarbonate	36.50		Ethyl acetate Loss	44.00
Pyridine	2.00		Ethanol Recovery	335.50
Ethyl acetate	889.00		Ethanol Loss	17.00
Ethanol	355.00		Pyridine Reuse	2.00
Water	500.00		Effluent Water	535.23
			(Water-500,Sodium chloride-25.41,Generated water-7.82,n Ethanol-2.0)	
			Process Emission	19.10
			(Carbon dioxide)	
			Organic Residue	22.67
			(Organic Impurities-22.17, Ethanol-0.5)	
Total	1920.50		Total	1920.50

Material Balance of Ritonovir Stage-3 Batch Size: 100.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
(2S, 3S, 5S)-2-Amino-3-hydroxy-5-(tert.butyloxy carbonyl) amino-1, 6-diphenyl hemi succinic acid salt (BDH Succinic acid salt)(**INT-1)**	70.00		1-Benzyl-4-tert-butoxy carbonyl amino-2-hydroxy-5-phenyl-pentyl)carbamic acid thiazol-5-ylmethyl ester **(INT-3)**	83.00
Carbonic acid-4-Nitro phenyl -5-thiazolyl methyl ester **(INT-2)**	100.00		Ethyl acetate Recovery	1330.00
Sodium bicarbonate	24.00		Ethyl acetate Loss	70.00
Aq.Ammonia solution (25%)	10.00		Effluent water	1203.84
Sodium hydroxide	22.00		(Water-1130,Ammonia-2.5,Water from ammonia-7.5,Generated water-5.14,Sodium chloride-16.7, Sodium hydroxide-22,Sodium chloride-20)	
Sodium chloride	20.00		Spent Hyflow	5.00
Hydrochloric acid	11.00		Hemisuccinic acid Reuse	9.31
Ethyl acetate	1400.00		Process Emissions	12.57
Hyflow	5.00		(Carbon dioxide)	
Water	1130.00		By-Product	49.60
			(4-Nitro phenol)	
			Organic Residue	28.68
Total	2792.00		Total	2792.00

Material Balance of Ritonovir Stage-4 Batch Size: 100.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Iso butyramide	30.00		Stage-4	25.50
THF	210.00		THF Recovery	198.00
Phosphorous penta sulphide	15.50		THF Loss	10.00
Sodium hydroxide	16.50		Ethyl acetate Recovery	342.00
Ethyl acetate	360.00		Ethyl acetate Loss	18.00
Water	100.00		Effluent water	127.20
			(Water-100,gen water-3.7,Sodium phosphate-22.5,THF-1)	
			Organic Residue	11.30
			(Organic Impurities-10.3,THF-1)	
Total	732.00		Total	732.00

Material Balance of Ritonovir Stage-5 Batch Size:100.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-4	25.50		Stage-5	23.00
1,3-dichloro acetone	31.30		THF Recovery	94.00
Mono methyl amine	7.70		THF Loss	5.00
Sodium hydroxide	30.00		MDC Recovery	474.50
Hydrochloric acid	2.00		MDC Loss	25.00
THF	100.00		Effluent water	339.30
MDC	500.00		(Water-275,gen water-18,Sodium chloride-43.3,THF-1,Hydrochloric acid-2)	
Ammonium chloride	13.00		Process Emission	4.20
Water	275.00		(Ammonia)	
			Organic Residue	19.50
			(Organic Impurities-19,MDC-0.5)	
Total	984.50		Total	986.5

Material Balance of Ritonovir Stage-6 Batch Size: 100.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-5	23.00		2(S)-3-Methyl-2-((Methyl-2((Methyl-2-((Methyl-((2-(1-Methyl Ethyl) Thiazole-4-yl) Methyl) Carbonyl) Amino) Butanoic Acid **(INT-4)**	40.00
Phenoxy carbonyl –L-Valine	40.00		THF Recovery	496.50
Lithium hydroxide	3.25		THF Loss	26.00
Hydrochloric acid	5.00		Toluene Recovery	262.50
THF	523.00		Toluene Loss	13.00
MTBE	610.00		MTBE Recovery	580.00
Toluene	276.00		MTBE Loss	30.00
Water	250.00		Effluent water	261.15
			(Water-250,Methanol-4.4,Lithium chloride-5.75,Toluene-0.5,THF-0.5)	
			By-Product	18.88
			(4-nitro phenol)	
			Organic Residue	2.22
Total	1730.25		Total	1730.25

Material Balance of Ritonavir Stage-7 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
1-Benzyl-4-tert-butoxy carbonyl amino-2-hydroxy-5-phenyl-pentyl)carbamic acid thiazol-5-ylmethyl ester **(INT-3)**	83.00		Ritanovir Crude	110.00
2(S)-3-Methyl-2-((Methyl-2((Methyl-2-((Methyl-((2-(1-Methyl Ethyl) Thiazole-4-yl) Methyl) Carbonyl) Amino) Butanoic Acid **(INT-4)**	40.00		THF Recovery	475.00
1-hydroxybenzotriazole hydrate	15.00		THF Loss	25.00
N-ethyl-N'-dimethylaminopropyl-carbodiimide	12.00		Effluent Water	1525.70
Tetrahydrofuran	500.00		(Water-1500, N-ethyl-N'-dimethylaminopropyl-carbodiimide-12, THF-2,Tert butanol-11.7,)	
Water	1500.00		Organic Residue	4.36
			(1-hydroxybenzotriazole hydrate-4.36)	
			Process Emission	6.94
			(Carbon dioxide)	
Total	2147.00		Total	2147.00

Material Balance of Ritonovir Stage-8 Batch Size: 100.0Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Ritanovir Crude	110.00		Ritonavir	100.00
N-Heptane	1178.00		N-Heptane Recovery	1138.00
Sodium Chloride	42.50		n-Heptane Loss	40.00
Water	1200.00		Effluent Water	1242.50
Activated Carbon	10.00		(Water-1200,Sodium Chloride-42.5)	
Hyflow	5.00		Spent Carbon	15.00
			Organic Residue	10.00
Total	2545.50		Total	2545.50

13. TRICLABENDAZOLE

Process Description:

Stage-1

5-(2,3-dichlorophenoxy)-6-chloro-1H-benzo[d]imidazole-2-thiol reacts with Dimethyl Sulphate in the presence of Sodium hydroxide with Methanol solvent media to gives Triclabendazole Tech compound.

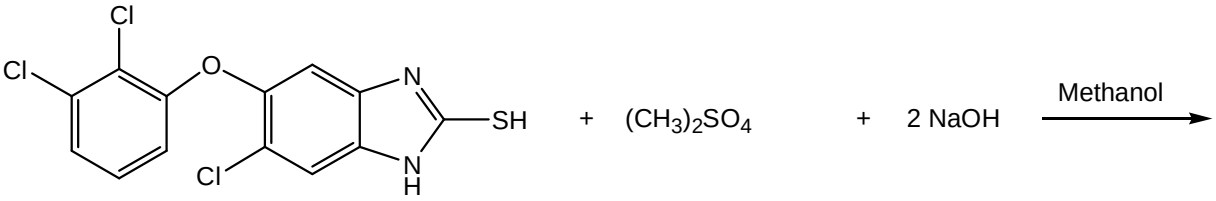
Stage-2

Triclabendazole Tech Purification with Activated carbon in Methanol Solvent to give 6-Chloro-5-(2, 3-dichloro-phenoxy)-2-methylsulfanyl-1H-benzimidazole.

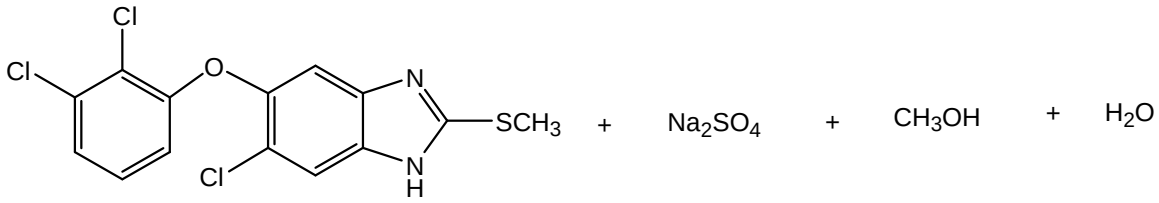
TRICLABENDAZOLE

Route of Synthesis:

Stage-1

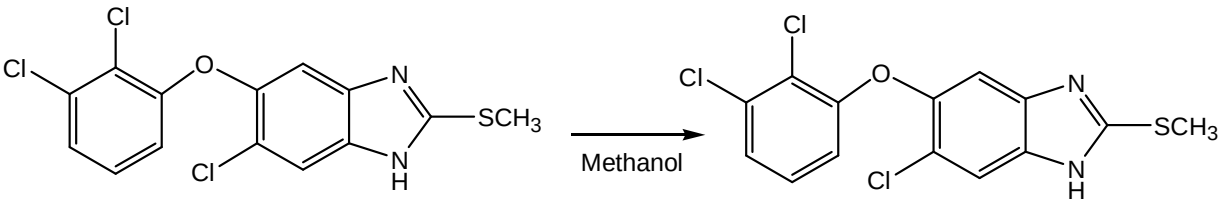


5-(2,3-dichlorophenoxy)-6-chloro-1H-benzo[d]imidazole-2-thiol	Dimethyl Sulphate	2X40=80
$C_{13}H_7Cl_3N_2OS$	126.13	
345.63		



6-Chloro-5-(2,3-dichloro-phenoxy)-2-methylsulfanyl-1*H*-benzimidazole	142.04	32.0	18.0
$C_{14}H_9Cl_3N_2OS$			
359.66			

Stage-2



Triclabendazole

6-Chloro-5-(2,3-dichloro-phenoxy)-2 -methylsulfanyl-1*H*-benzimidazole

$C_{14}H_9Cl_3N_2OS$

359.66

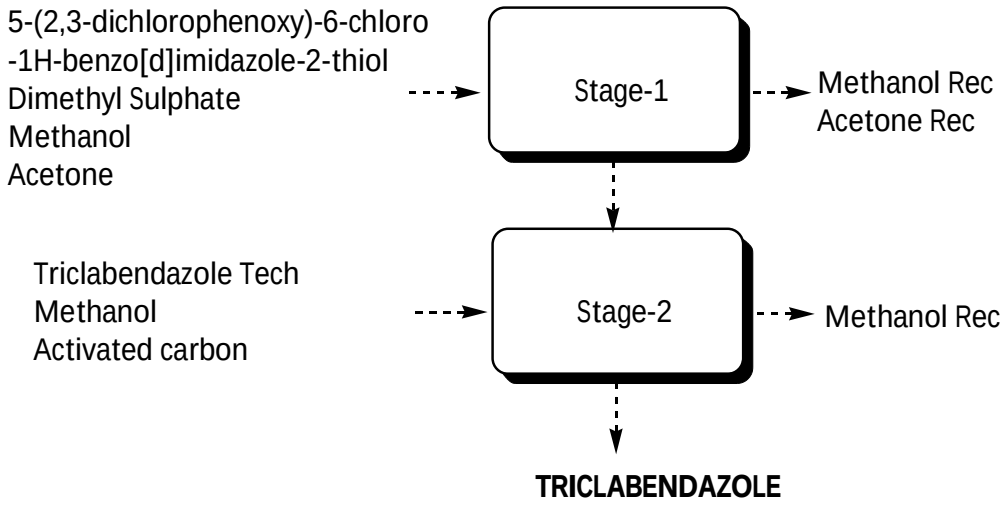
6-Chloro-5-(2,3-dichloro-phenoxy)-2 -methylsulfanyl-1*H*-benzimidazole

$C_{14}H_9Cl_3N_2OS$

359.66

TRICLABENDAZOLE

Flow Chart:



TRICLABENDAZOLE

Material Balance:

Material Balance of Triclabendazole Stage-1 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
5-(2,3-dichlorophenoxy)-6-chloro-1H-benzo[d]imidazole-2-thiol	110.00		Triclabendazole Tech	105.00
Dimethyl Sulphate	42.00		Methanol Recovery	428.00
Methanol	450.00		Methanol Loss	20.00
Acetone	300.00		Acetone Recovery	285.00
Liq.Ammonia	10.00		Acetone Loss	15.00
CS.Flakes	26.00		Effluent water	1286.30
Water	1260.00		(Water-1260,generated water-5.7,Ammonium hydroxide-10,Methanol-10.6)	
			Inorganic solid waste	46.16
			(Sodium sulphate)	
			Organic Residue	12.54
			(Organic Impurities-10.54, Methanol-2)	
Total	2198.00		Total	2198.00

Material Balance of Triclabendazole Stage-2 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Triclabendazole Tech	105.00		Triclabendazole	100.00
Methanol	745.00		Methanol Recovery	706.00
Activated carbon	10.00		Methanol Loss	37.00
Liq.Ammonia	10.00		Effluent water	314.60
EDTA	1.30		(Water-300,Ammonium hydroxide-10,EDTA-1.3, Hydrose-1.3, Methanol-2)	
Hydrose	1.30		Spent Carbon	10.00
Water	300.00		Organic Residue	5.00
Total	1172.60		Total	1172.60

14. VALSARTAN

Process Description

Stage-1

L-Valine reacts with Methanol in presence of Methanol as solvent media to give Stage-1 as product.

Stage-2

Stage-1 product reacts with 4-Bromomethyl-biphenyl-2-carbonitrile in presence of Methanol as solvent media to give Stage-2 as product.

Stage-3

Stage-2 product reacts with Valeryl chloride in presence of Methanol as solvent media to give Stage-3 as product.

Stage-4

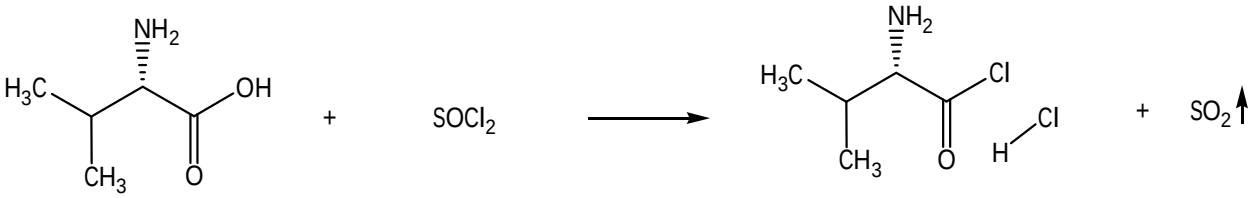
Stage-3 product reacts with Sodium azide; Tri butyl tin chloride undergoes Hydrogenation in presence of Methanol as solvent media t give Valsartan as product.

VALSARTAN

Route of Synthesis:

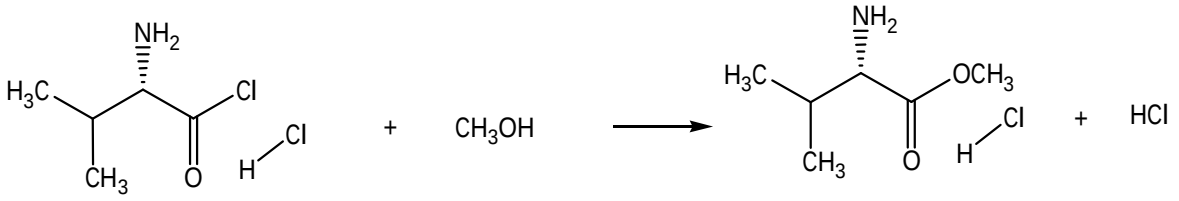
Stage-1

Step-A



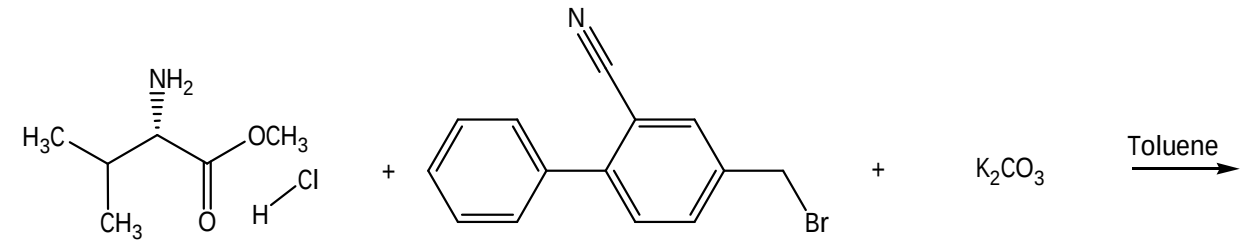
L-Valine	Thionyl Chloride	2-Amino-3-methyl-butyryl chloride hydrochloride	64.06
$C_5H_{11}NO_2$	118.97	$C_5H_{11}Cl_2NO$	
117.15		172.05	

Step-B

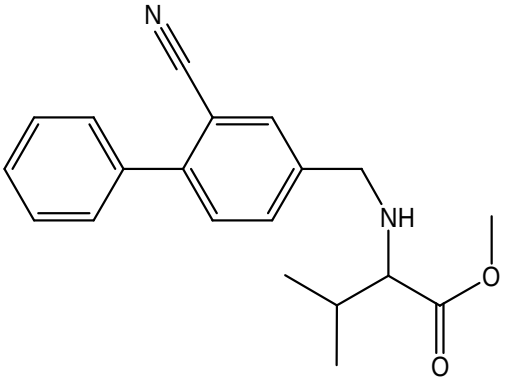


2-Amino-3-methyl-butyryl chloride hydrochloride	32.04	2-Amino-3-methyl-butyric Acid methyl ester hydrochloride	36.46
$C_5H_{11}Cl_2NO$		$C_6H_{14}NO_2Cl$	
172.05		167.63	

Stage-2



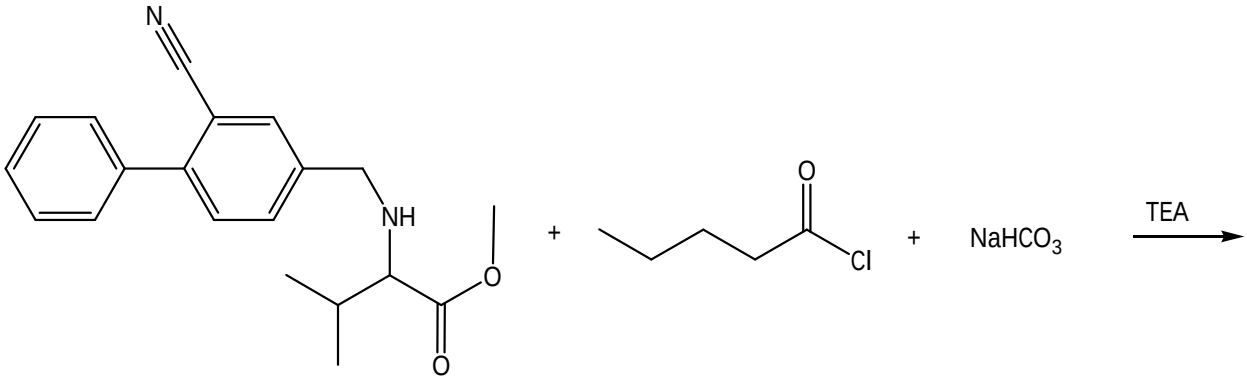
2-Amino-3-methyl-butyric Acid methyl ester hydrochloride	4-Bromomethyl-biphenyl-2-carbonitrile	Potassium Carbonate
$C_6H_{14}NO_2Cl$	$C_{14}H_{10}BrN$	138.21
167.63	272.14	



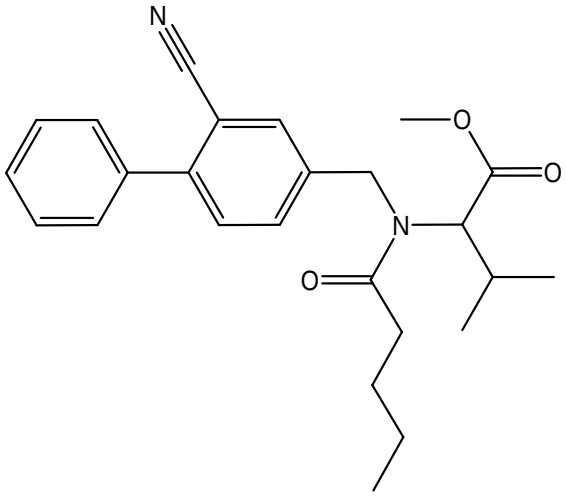
+ KBr + KCl + CO_2 + H_2O

2-[(2-Cyano-biphenyl-4-ylmethyl)-amino]-3-methyl-butyric acid methyl ester	119.0	74.55	44.0	18.0
$C_{20}H_{22}N_2O_2$				
322.40				

Stage-3



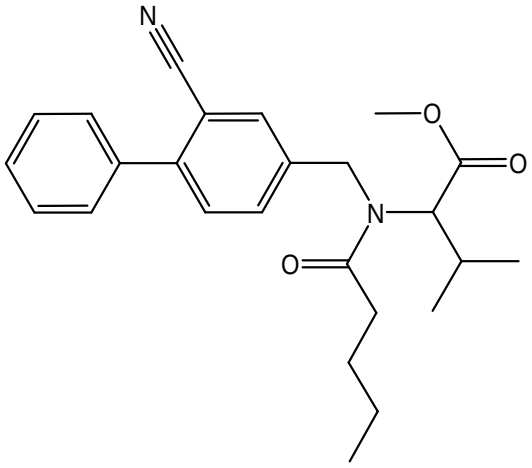
2-[(2-Cyano-biphenyl-4-ylmethyl)-amino]-3-methyl-butyric acid methyl ester	Valeryl Chloride	Sodium bicarbonate
$C_{20}H_{22}N_2O_2$	C_5H_9ClO	84.0
322.40	120.58	



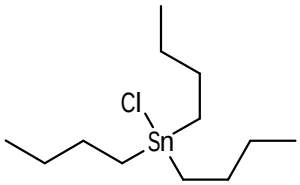
+ NaCl + CO_2 + H_2O

2-[(2-Cyano-biphenyl-4-ylmethyl)-pentanoyl-amino]-3-methyl-butyric acid methyl ester	58.44	44.0	18.0
$C_{25}H_{30}N_2O_3$			
406.52			

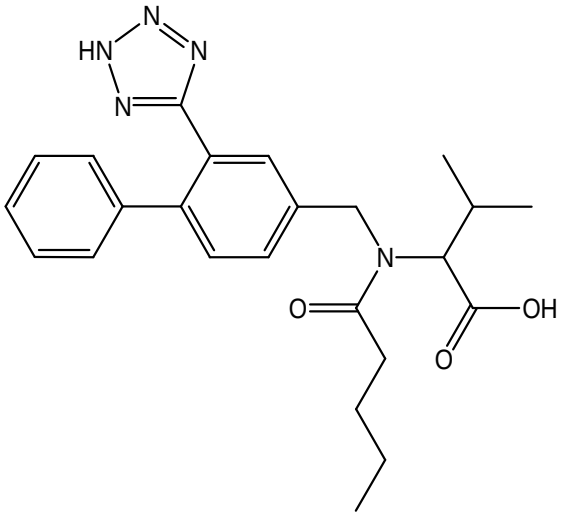
Stage-4



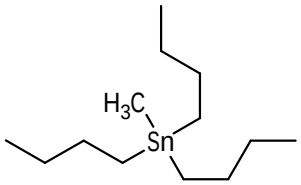
+ H_2 + NaN_3 +



2-[(2-Cyano-biphenyl-4-ylmethyl)-pentanoyl-amino]-3-methyl-butyric acid methyl ester	Hydrogen	Sodium Azide	Tributyl tin chloride
$C_{25}H_{30}N_2O_3$	2.0	65.0	$C_{12}H_{27}ClSn$
406.52			325.5



+

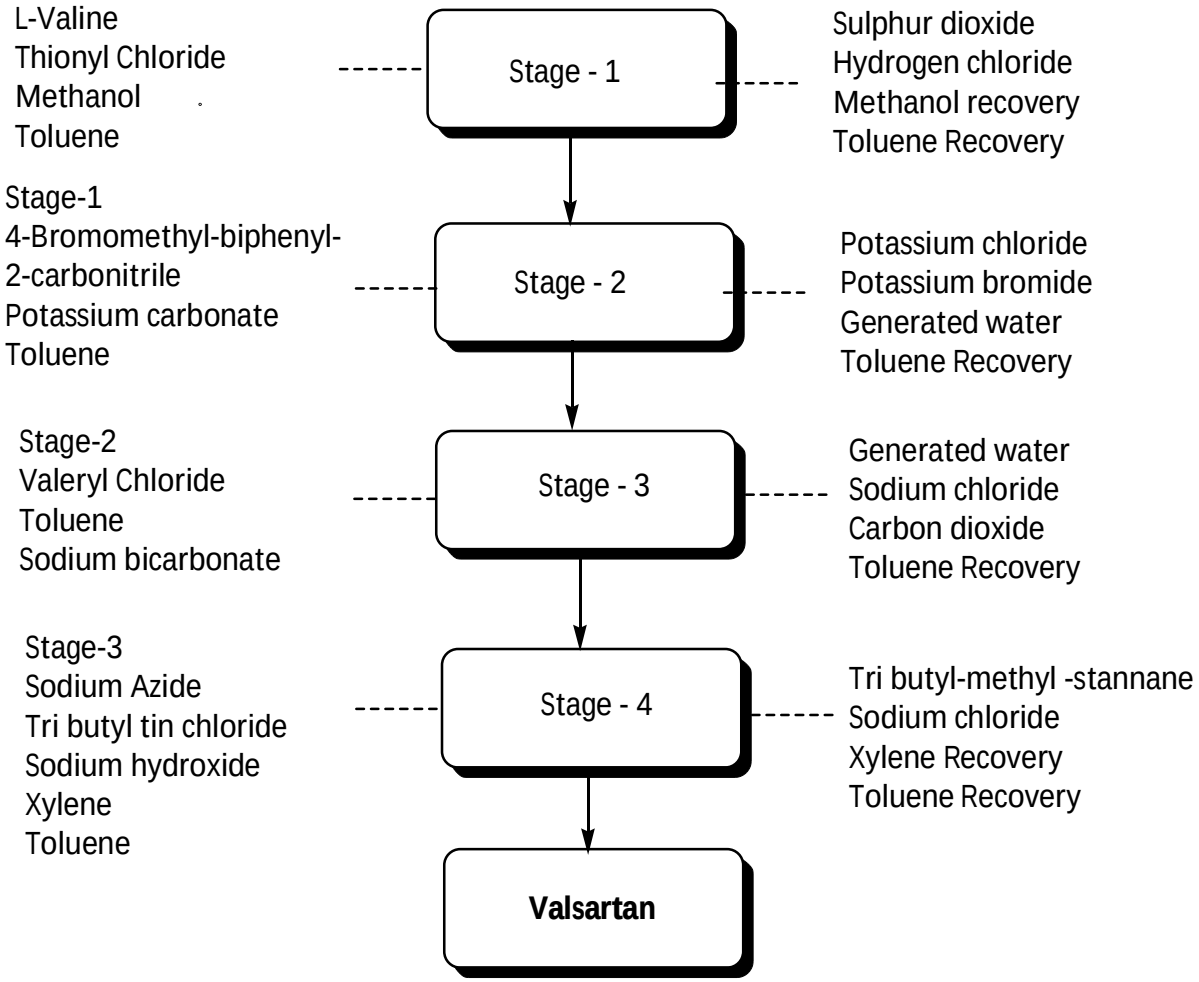


+ NaCl

Valsartan	Tributyl methyl stannane	58.46
$C_{24}H_{29}N_5O_3$	$C_{13}H_{30}Sn$	
435.5	305.0	

VALSARTAN

Flow Chart:



VALSARTAN

Material Balance:

Material Balance of Valsartan Stage-1 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
L-Valine	45.00		Stage-1	50.00
Thionyl Chloride	45.70		Methanol Recovery	758.00
Methanol	800.00		Methanol Loss	40.00
Toluene	500.00		Toluene Recovery	474.00
			Toluene Loss	25.00
			Organic Residue	8.33
			(Organic Impurities-5.33, Methanol-2, Toluene-1)	
			Process Emission	35.37
			(Hydrogen chloride-10.8, Sulfur dioxide-24.57)	
Total	1390.70		Total	1390.70

Material Balance of Valsartan Stage-2 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-1	50.00		Stage-2	90.00
4-Bromomethyl-biphenyl-2-carbonitrile	82.00		Toluene Recovery	565.00
Potassium carbonate	45.00		Toluene Loss	30.00
Toluene	600.00		Effluent Water	869.78
Water	800.00		(Water-800,generated water-5.3,Potassium chloride-22.2,Potassium Bromide-35.5,Potassium carbonate-3.78,Toluene-3)	
			Organic Residue	9.22
			(Organic Impurities-7.22, Toluene-2	
			Process Emission	13.00
			(Carbon dioxide)	
Total	1577.00		Total	1577.00

Material Balance of Valsartan Stage-3 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-2	90.00		Stage-3	100.00
Valeryl Chloride	34.00		Toluene Recovery	660.00
Toluene	700.00		Toluene Loss	35.00
TEA	20.00		Effluent Water	744.80
Sodium bicarbonate	25.00		(Water-700,generated water-5, Sodium chloride-16.3, Sodium bicarbonate-1.5,TEA-20,Toluene-2)	
Sodium Sulphate	10.00		Inorganic Solid Waste	10.00
Water	700.00		(Sodium Sulphate)	
			Organic Residue	16.93
			(Organic Impurities-13.93, Toluene-3)	
			Process Emission	12.27
			(Carbon dioxide)	
Total	1579.00		Total	1579.00

Material Balance of Valsartan Stage-4 Batch Size: 100Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity in Kg
Stage-3	100.00		Valsartan	100.00
Sodium Azide	16.00		Toluene Recovery	660.00
Tri butyl tin chloride	80.00		Toluene Loss	35.00
Hydrogen	0.50		MDC Recovery	475.00
Sodium hydroxide	20.00		MDC Loss	25.00
Xylene	240.00		Xylene Recovery	228.00
Toluene	700.00		Xylene Loss	12.00
MDC	500.00		N-Hexane Recovery	190.00
Acetic Acid	40.00		N-Hexane Loss	10.00
N-Hexane	200.00		Effluent Water	877.30
Activated Carbon	10.00		(Water-800,generated water-9,Sodium Chloride-14.3,Toluene-3, Sodium Acetate-41,Acetic Acid-10)	
Water	800.00		Spent Carbon	10.00
			Tri butyl-methyl –stannane for sale	74.98
			Organic Residue	9.22
			(Organic Impurities-7.22, Toluene-2)	
Total	2706.50		Total	2706.50

15. ZIDOVUDINE

Process Description

Stage – 1

β-Thymidine is reacted with Trityl chloride and Tri ethyl amine in the presence of 1, 4-dioxane to give 5'-O-Trityl Thymidine.

Stage –2

5'-O-Trityl Thymidine is reacted with methane sulphonyl chloride and tri ethylamine in the presence of Toluene to give mesyl thymidine intermediate, which is reacted with tri ethylamine in the presence of methanol to give 5'-O- Trityl -2,3'-Anhydro Thymidine.

Stage – 3

5'-O-Trityl -2, 3'-Anhydro Thymidine is reacted with sodium azide and ammonium chloride in the presence of di methyl sulphoxide to give 5'-O-Trityl -Zidovudine.

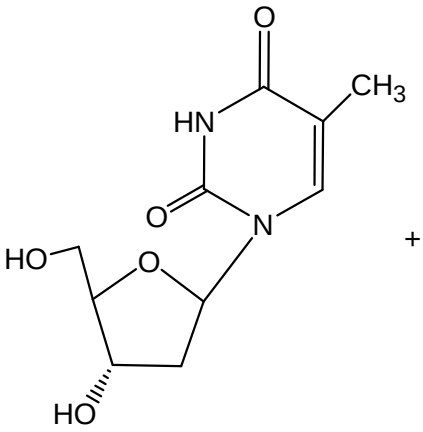
Stage – 4

5'-O-Trityl –Zidovudine is reacted with p-Toluene sulphonic acid monohydrate in the presence of Methanol to give Zidovudine.

ZIDOVUDINE

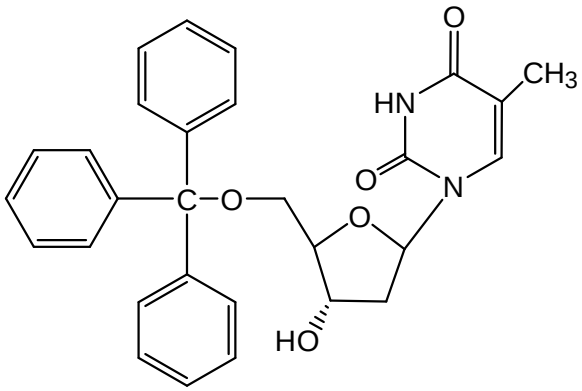
Route of Synthesis:

Stage-1



+ $(C_6H_5)_3CCl$ + $C_6H_{15}N$ —(1,4-Dioxane)→

Thymidine	Trityl chloride	Triethyl amine
$C_{10}H_{14}N_2O_5$	278.78	101.19
242.23		

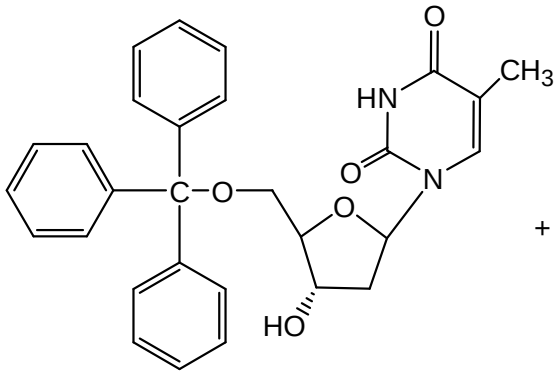


+ $C_6H_{15}N.HCl$

Trityl thymidine	Triethyl amine hydrochloride
$C_{29}H_{28}N_2O_5$	137.69
484.54	

Stage-2

Step-A



+ CH_3SO_2Cl + $C_6H_{15}N$ —Toluene→

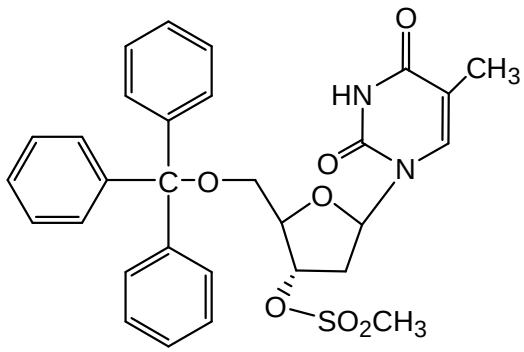
Trityl thymidine

$C_{29}H_{28}N_2O_5$

484.54

114.55

101.19



+ $C_6H_{15}N.HCl$

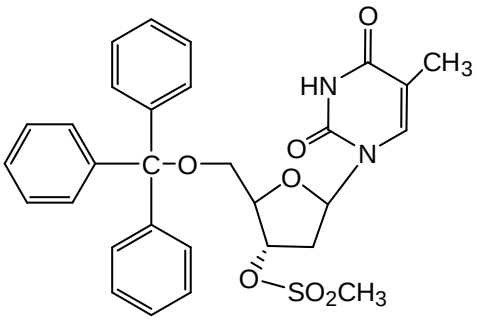
Methanesulfonic acid 5-(5-methyl-2,4-dioxo-3,4-dihydro-2*H*-pyrimidin-1-yl)-2-trityloxymethyl-tetrahydro-furan-3-yl ester

$C_{30}H_{30}N_2O_7S$

562.63

137.69

Step-B



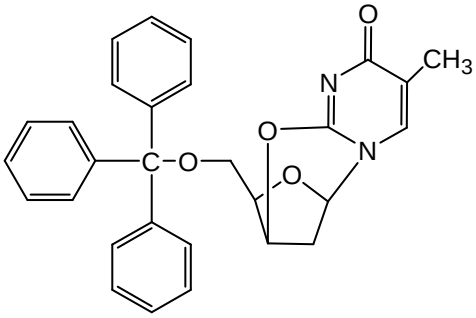
+ $C_6H_{15}N$ —Methanol→

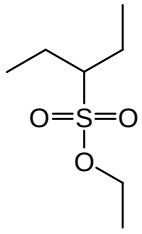
Methanesulfonic acid 5-(5-methyl-2,4-dioxo-3,4-dihydro-2*H*-pyrimidin-1-yl)-2-trityloxymethyl-tetrahydro-furan-3-yl ester

101.19

$C_{30}H_{30}N_2O_7S$

562.63



+  + NH_3 ↑

5-O-Trityl-2,3-anhydro thymidin

$C_{29}H_{26}N_2O_4$

466.53

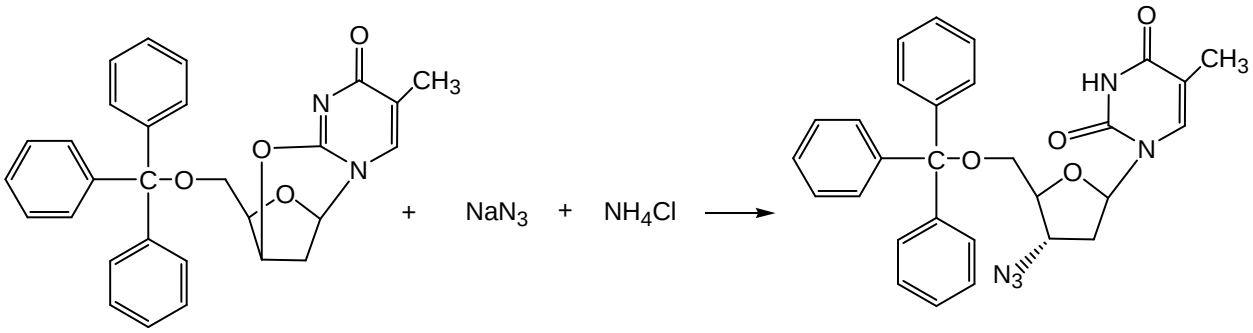
Triethyl methane sulfonate

$C_7H_{16}O_3S$

180.27

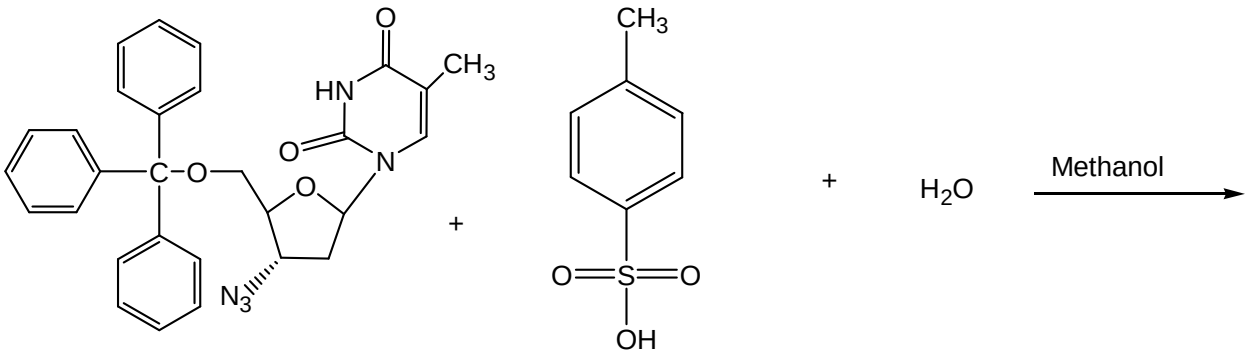
17.0

Stage-3



5-O-Trityl-2,3-anhydro thymidin	Sodium azide	53.49	5-O-Trityl-Zidovudine
$C_{29}H_{26}N_2O_4$	65.01		$C_{29}H_{27}N_5O_4$
466.53			509.56
			+ NaCl + NH_3
			58.5 17.0

Stage-4



5-O-Trityl-Zidovudine

$C_{29}H_{27}N_5O_4$

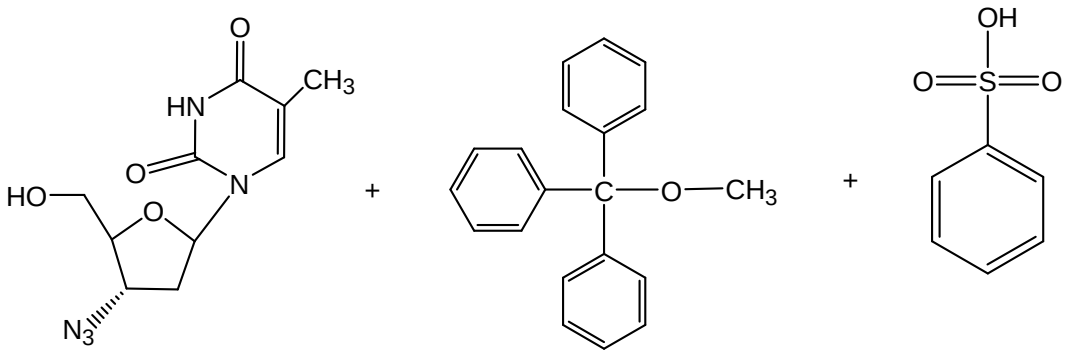
509.56

p-Toulenesulfonic Acid

$C_7H_8SO_3$

172.2

18.0



Zidovudine

$C_{10}H_{13}N_5O_4$

267.24

Trityl methyl Ether

$C_{20}H_{18}O$

274.36

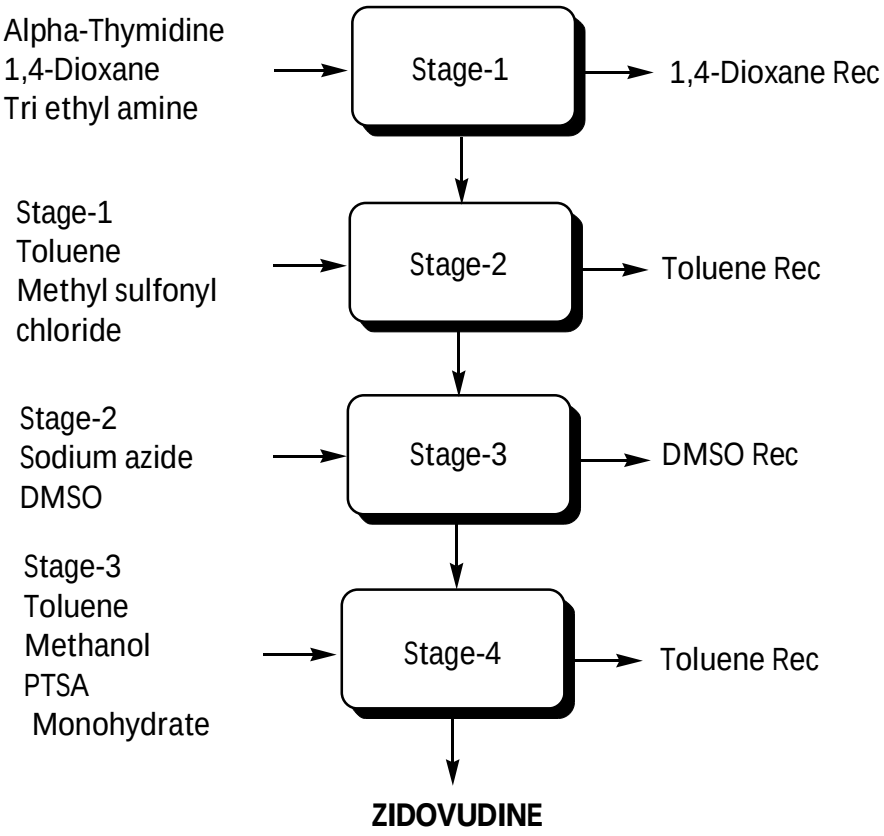
Sulfonic Acid

$C_6H_6O_3S$

158.18

ZIDOVUDINE

Flow Chart:



ZIDOVUDINE

Material Balance:

Material balance of Zidovudine Stage-1 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
β-Thymidine	70.00		Stage-1	110.00
1,4-Dioxane	700.00		1,4-Dioxane Recovery	665.00
Tri ethyl amine	23.00		1,4-Dioxane Loss	35.00
Trityl chloride	64.00		Toluene Recovery	472.00
Toluene	500.00		Toluene Loss	25.00
Water	950.00		Effluent water	984.30
			(Water-950,Triethyl Amine Hydrochloride-31.3,Toluene-3)	
			Organic Residue	15.70
Total	2307.00		Total	2307.00

Material balance of Zidovudine Stage-2 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-1	110.00		Stage-2	100.00
Toluene	1200.00		Toluene Recovery	1138.00
Methyl sulfonyl chloride	26.00		Toluene Loss	60.00
Tri ethyl amine	50.00		Methanol Recovery	663.00
Methanol	700.00		Methanol Loss	35.00
Water	1000.00		Effluent water	1039.80
			(Water-1000,Triethyl Amine Hydrochloride-31.3,TEA-4.5,Toluene-2,Methanol-2)	
			Organic solid waste	46.40
			(Tri ethyl methane sulfonate-40,Organic Impurities-6.40)	
			Process Emission	3.80
			(Ammonia)	
Total	3086.00		Total	3086.00

Material balance of Zidovudine Stage-3 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-2	100.00		Stage-3	100.00
Sodium azide	14.00		DMSO Recovery	565.00
Ammonium chloride	12.00		DMSO Loss	30.00
DMSO	600.00		Effluent water	1417.60
Water	1400.00		(Water-1400,Sodium Chloride-12.6,DMSO-5)	
			Organic Residue	9.75
			Process Emission	3.65
			(Ammonia)	
Total	2126.00		Total	2126.00

Material balance of Zidovudine Stage-4 Batch Size:50.0 Kg				
Name of the input	Quantity in Kg		Name of the out put	Quantity In Kg
Stage-3	100.00		Zidovudine	50.00
Toluene	1920.00		Toluene Recovery	1824.00
Methanol	800.00		Toluene Loss	94.00
PTSA Monohydrate	34.00		Ethyl Acetate Recovery	1235.00
Sodium carbonate	10.00		Ethyl Acetate Loss	65.00
Ethyl Acetate	1300.00		Methanol Recovery	758.00
Activated Carbon	5.00		Methanol Loss	40.00
Water	1200.00		Effluent water	1241.70
			(Water-1196.5,Sulfonic Acid-31.2,Sodium carbonate-10, Methanol-2,Toluene-2)	
			Spent Carbon	5.00
			Organic solid waste	56.30
			(Trityl methyl Ether-53.84, Organic Impurities-2.46)	
Total	5369.00		Total	5369.00

WATER CONSUMPTION DETAILS

WATER CONSUMPTION DETAILS

S. No	Purpose	Water Consumption In KLD
1	Process	32.78
2	Washings	2.00
3	Daily Boiler Make up	29.00
4	Daily Cooling towers Make up	38.00
5	DM Plant	2.00
6	Scrubbing system	2.00
7	Domestic Usage	2.00
8	Gardening	5.00
	Total	**112.78**

SOLID WASTE DETAILS

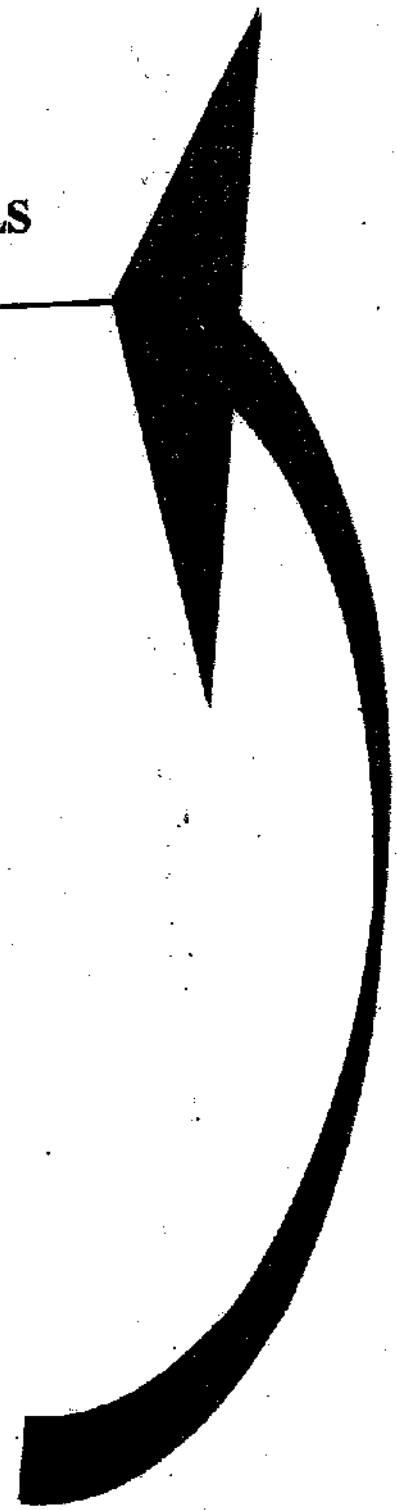
SOLID WASTE DETAILS

S. No	Name of the Solid Waste	Quantity Kg/Day	Disposal Method
1	Inorganic Solid Waste	764.47	Sent to TSDF
2	Organic solid waste	977.45	Sent to Cement Industries
3	MEE Salts	1402.18	Sent to TSDF
4	Spent Carbon	110.39	Sent to Cement Industries
5	ETP Sludge	50.00	Sent to TSDF
6	Coal ash from Boiler	5875.00	Sent to Brick Manufacturers
7	Solvent Distillation Bottom Residue	1503.00	Sent to Cement Industries

HAZARDOUS WASTE DETAILS

S. No	Description	Quantity	Mode of Disposal
1	Waste Oils & Grease	2 KL/Annum	APPCB Authorized Agencies for Reprocessing/Recycling
2	Detoxified Containers	300 No's / Month	After Detoxification sent back to suppliers/APPCB Authorized Parties
3	Used Lead Acid Batteries	4 No's/ Annum	Send back to suppliers for buyback of New Batteries

STACK EMISSION DETAILS



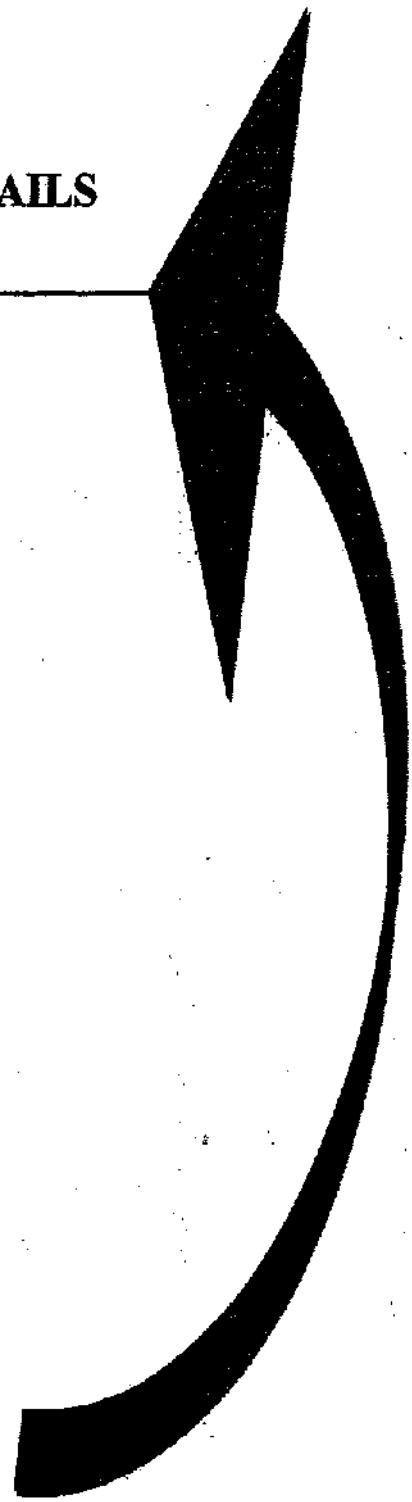
STACK EMISSION DETAILS FOR BOILER

Particulars	Units	2.0 TPH Coal fired Boiler	3.0 TPH Coal fired Boiler
Type of Fuel	--	Indian Coal	Indian Coal
Coal Consumption	TPD	5.0	7.5
Ash Content	%	47	47
Sulphur Content	%	0.8	0.8
Nitrogen Content	%	1.07	1.07
No. of Stacks	No	1	1
Height of stack	M	30	30
Diameter of Stack	M	0.60	0.60
Temperature of Flue Gas	^{o}C	95	100
Velocity of Flue Gas	m/s	6.5	7.5
Particulate Matter at outlet of Bag filter (Based on 115 mg/Nm3 at outlet)	gm/sec	0.21	0.24
Sulphur dioxide emission	gm/sec	0.46	0.69
Oxides of Nitrogen emission	gm/sec	0.57	0.93

STACK EMISSION DETAILS FOR 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.
380KVA	74.0	150.0	185.0	0.20	185	10	21.0
250KVA	58.0	24.0	30.0	0.30	250	10	18.24

PROCESS EMISSION DETAILS



PROCESS EMISSION DETAILS

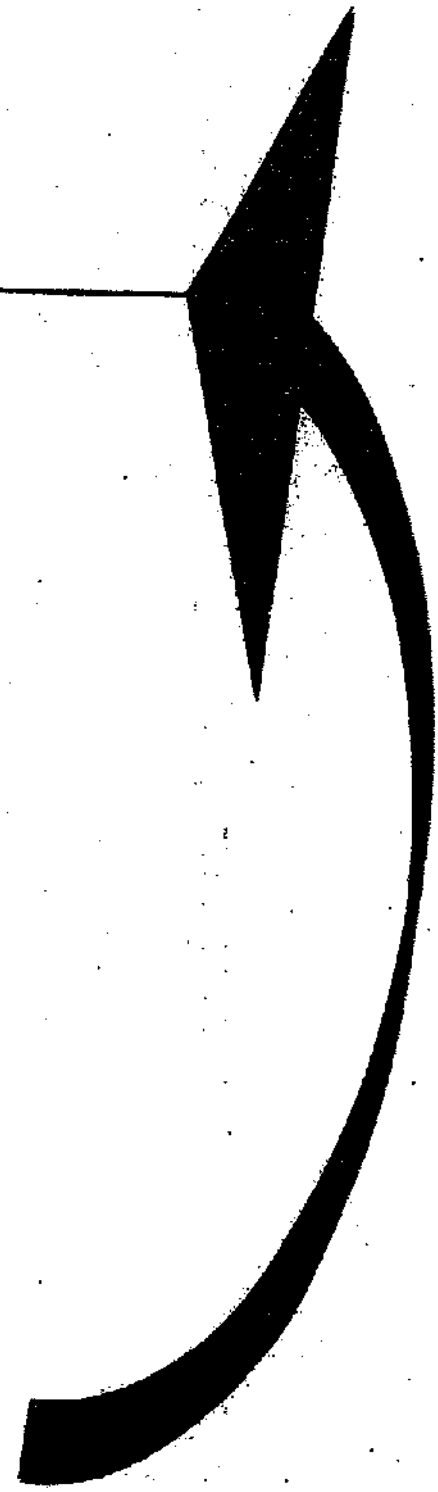
➢ POLLUTING PROCESS EMISSION DETAILS:

S. No	Name of the Gas	Quantity In Kg/Day	Treatment Method
1	Ammonia	18.72	Scrubbed by using chilled water media
2	Sulphur dioxide	27.16	Scrubbed by using C. S. Lye solution
3	Hydrogen chloride	43.42	Scrubbed by using Chilled water media
4	Nitrogen dioxide	28.90	Scrubbed with Urea solution

➢ NON- POLLUTING PROCESS EMISSION DETAILS:

S. No	Name of the Gas	Quantity In Kg/Day	Treatment Method
1	Carbon dioxide	135.40	Dispersed into atmosphere
2	Hydrogen	9.59	Diffused by using Nitrogen through Flame arrestor

DRAFT TOR



Proposed Draft Terms of Reference for Preparation of EIA & EMP For M/s. Vineet Life Sciences Pvt. Ltd.

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

PRE-FEASIBILITY REPORT

PRE FEASIBILITY REPORT

OF

M/S. VINEET LIFE SCIENCES PRIVATE LIMITED.

Flat No.202, Sridevi Residency, Siva Ganga Colony

L.B Nagar, Hyderabad, Andhra Pradesh

MANUFACTURING OF

BULK DRUGS & INTERMEDIATES FACILITY

At

SURVEY NO: 1019, 1020/A-2, 1020/B& 1021,

JANGAMAHESWARA PADU VILLAGE, DURGI MANDAL,

GUNTUR (DT), ANDHRA PRADESH.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF FLOW CHART

1.0 EXECUTIVE SUMMARY

M/s. Vineet Life Sciences Pvt Ltd. is incorporated to produce bulk drugs and bulk drug intermediates with registered address at Flat No.202, Sridevi Residency, Siva Ganga Colony, L.B Nagar, Hyderabad, Andhra Pradesh.

The company proposes to establish its bulk drug and intermediate manufacturing facility at Jangamaheswara Padu Village, Durgi Mandal, Guntur (Dt), Andhra Pradesh.

S. No	Parameter	Description
1	Project Location	Survey No's: 1019,1020/A-2,1020/B & 1021, Jangamaheswara Padu Village, Durgi Mandal, Guntur (Dt), Andhra Pradesh.
2	Category of Project as per EIA Notification & Amendments	5(f) "A"
3	Project cost	12.31 Crores
4	Plot area	3.40 Acres
5	Proposed Products	50.0 MT of Bulk Drugs and Intermediate products & the details products and Quantities are mentioned in Section 3.1
6	Resources	
	(I)Electricity Requirement	800 KVA
	Source of electricity	APSPDCL
	D. G. Sets	380 & 250 KVA D.G Sets will be installed to meet emergency power requirement during power failures.
	(II)Water consumption	112.78 KLD
	Source of water	Ground Water
	Waste water generation	53.34 KLD
	Mode of disposal	Zero Liquid Discharge System
	(III)Boiler	3.0 & 2.0 TPH Boilers
	(IV)Fuel	Coal - 12.5 MT / Day
7	Solid waste generation	Mentioned in Para 3.1 of report
8	Nearest Highway	State Highway No.89 - 5.8 KMs
9	Nearest Railway Station	Macherla Railway Station – 16 KMs
10	Nearest Air Port	Vijayawada Gannavram Air Port - 135 KMs

2.0 INTRODUCTION OF THE PROJECT

The objective of this pre- feasibility study is to provide information for the proposed green field Bulk Drugs and Intermediates manufacturing unit by **M/s. Vineet Life Sciences Pvt. Ltd** at Survey No's: 1019,1020/A-2,1020/B & 1021, Jangamaheswara Padu Village, Durgi Mandal, Guntur (Dt), Andhra Pradesh.

2.1 project proponent

M/s. Vineet Life Sciences Pvt. Ltd is incorporated by K. Murali Mohan is the Director of this Company having more than two decades of rich industrial experience in this line of activity. He supervises the overall affairs of the company.

2.2 brief description of nature of the project.

The **M/s. Vineet Life Sciences Pvt. Ltd** proposes to manufacture Bulk Drugs and intermediate, which are active ingredients with medicinal properties.

2.3 Need for the project and its importance to the country and or region

The project in general holds significance for an emerging country like India where health care costs are increasing by the day due to demand supply gap in affordable medicines. Moreover due to low cost and hi technology the bulk drugs manufactured in India has immense export potential with consequent possibility of foreign exchange earnings

Hyderabad has emerged as major drug manufacture city with a presence in global market. Pharma industry in the state contribute more than one third to the country's total production.

Most of the companies have set up their R&D facilities in the state, thus making the state the pharmaceutical capital of the country.

Hyderabad has developed as a major production center for bulk drugs due to the location if the many major Pharmaceutical Industries such as Dr. Reddy's Laboratories, Aurobindo Pharma, Neuland Laboratories, Siris, Hetaro Drugs, Divis

Labs, Natco Pharma Limited, Matrix Labs, Nicholas Piramal etc., besides a large number of medium and small industries manufacturing bulk drugs of all kinds.

In support of this growth in Hyderabad and Bangalore, many basic chemical units and drug intermediate units have also come up to meet the input requirements of Bulk Drug manufacturing Companies. Large numbers of these units are still dependent on supply of basic chemicals mainly from Mumbai, Gujarat and other parts of the country involving heavy expenditure on transport and transit risks.

2.4 Demand-Supply Gap.

The demand for APIs and API intermediates is a derived demand. It gets derived from the demand for various medicinal formulations (final administrable drugs) for the formulation industry.

- The APIs and API intermediates being manufactured by basic drug manufacturers are exported as such or used by domestic formulators in their production processes. The formulation firms further produce final medicines and export these as well as sell these in the domestic market.
- There is a wide gap in the demand and availability of cheap and quality medicines in India and the world over.
- Generic medicines and off patent drugs have significant potential to increase access to cheap and effective medicines to poor people and in general to bridge the demand supply gap.
- Indian basic drug manufacturers are playing a significant role in increasing access to affordable off patent drugs.
- The products envisaged include third generation antibiotics, anticancer, antipsychotic, etc drugs which address the problems associated with present day stressful lifestyles and demand for these outstrips their demand and is increasing by the day.

Pharmaceutical Industry – Domestic Scenario

The Indian Pharmaceutical Industry today is in the front rank of India's Science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. The Indian Pharmaceutical industry is estimated to be worth US $ 8.0 billions at present, growing at a CAGR of over 15 % annually. If India' s high Economic growth rate holds steady, the pharmaceuticals market will triple to $ 24 billion by 2015 and become one of the world` s top 10 markets according to a study by McKinsey and company ,a leading management consulting firm. At a compounded annual growth rate of 15.0 %, the absolute growth of $ 24 billion will be next to the growth potential of the US and China, and in the same league as the growth in Japan and Canada and the UK. Five factors will drive the growth of the Indian Pharmaceuticals market over the next decade; Doubling of disposable incomes and the increase in numbers of middle class households , significant expansion of medical infrastructure, greater penetration of health insurance, a gradual shift in disease profile and adoption of patented products, and finally population growth.

It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. Playing a key role in promoting and sustaining development in the vital field of medicines, the Indian Pharmaceutical Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK.

The Indian Pharmaceutical sector has more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical Companies control 70% of the market. The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drugs intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables. There are about 250 large units and about 8000 small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce the complete range of pharmaceutical formulations, i.e. medicines ready for consumption by patients and about 350 bulk drugs, i.e.

chemicals having therapeutic value and used for production of pharmaceutical formulations.

2.5 Employment Generation (Direct and Indirect) due to the project

The project will employ permanent as well as contractual and sub-contractual employees from surrounding areas. Apart from this there will be significant non estimated employment generation at the supplier firms and service industry providing services to the company. Company shall be giving preference to people from economically weaker sections for employment in various semi-skilled/unskilled jobs thereby contributing to their upliftment.

.

It is expected to direct or indirect employ about 32people of various skills will be required during construction as well as operation phase. The Details of employment shown in below Table.

Particulars	**No. of employees**	**Functional Area**
Key managerial staff	6	Finance, Marketing, Production, Quality control, R&D, Logistics etc.
Administration	8	Office work
Skilled and semi skilled	18	Production Process, Maintenance, stores, Safety.& Un skilled workers
Total	**32**	

3.0 Project Description

M/s. Vineet Life Sciences Pvt. Ltd. proposed for installation of bulk drug manufacturing unit at Survey Nos: 1019,1020/A-2,1020/B & 1021, Jangamaheswara Padu Village, Durgi Mandal, Guntur (Dt), Andhra Pradesh. The Location map is shown at **Figure** – 1.

The site coordinates are

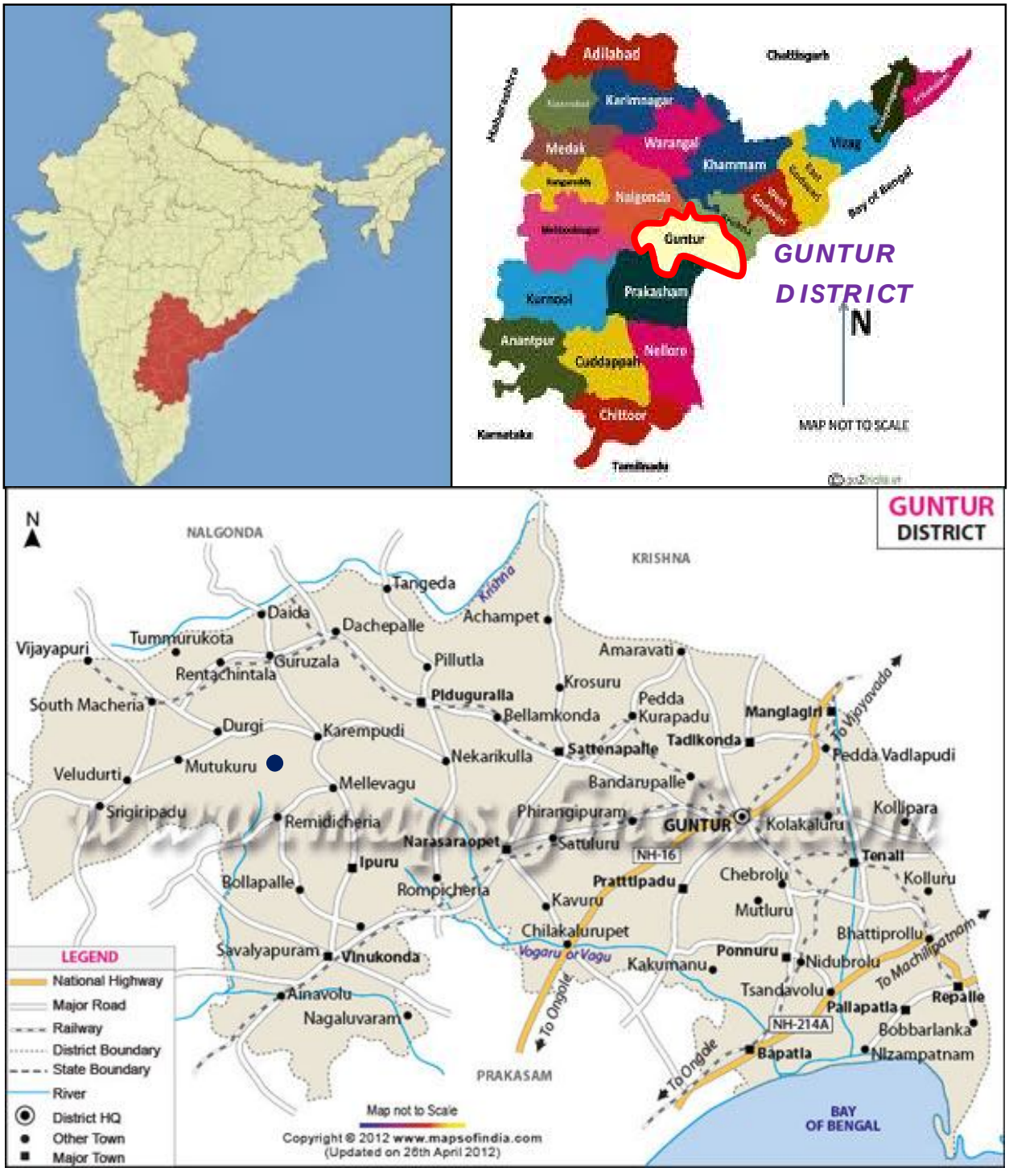
Latitude: 16°22'17.79"N

Longitude: 79°32'18.25"E

There are no major cities within 10 KMs radius and also no archaeological, historical sites located nearby. Therefore, the project site does not offer any negative impact on the local area, but rather has a positive impact on socio economic conditions of the habitants around it.

The proposed plant is well connected both to State Highway No– 9 and Railway line at Macherla Railway Station. A total of about 13759.21 SQMs of land is required for the project.

FIGURE 1.1: LOCATION MAP



- **M/s. Vineet Life Sciences Pvt. Ltd**

  Survey Nos: 1019, 1020/A-2, 1020/B & 1021,
  Jangamaheswara Padu Village, Durgi Mandal,
  Guntur (Dt), Andhra Pradesh

3.1 Products and Production Capacity

M/s. Vineet Life Sciences Pvt. Ltd. is proposes to produce the below mentioned shown in Table3.1.

Table3.1: Proposed Products and Quantities

S. No	Name of the Product	CAS No's	Quantity In Kg/Month	Quantity In Kg/Day
1	Albendazole	54965-21-8	5000.00	166.67
2	Amlodipine Besylate	111470-99-6	2000.00	66.67
3	Efavirenz	154598-52-4	3000.00	100.00
4	Emtricitabine	143491-57-0	3000.00	100.00
5	Famotidine	76824-35-6	6000.00	200.00
6	Fluconazole	86386-73-4	2000.00	66.67
7	Lamivudine	134678-17-4	1500.00	50.00
8	Levosulpride	23672-07-3	2000.00	66.67
9	Lopinavir	192725-17-0	1000.00	33.33
10	n-Butyl Lithium	109-72-8	15000.00	500.00
11	Pantoprazole sodium	138789-67-1	1500.00	50.00
12	Ritanovir	155213-67-5	1000.00	33.33
13	Triclabendazole	68786-66-3	5000.00	166.67
14	Valsartan	13786-2-53-4	1000.00	33.33
15	Zidovudine	30516-87-1	1000.00	33.33
	Total		**50000.00**	**1666.67**

3.2 Raw materials required and Quantities

All the raw materials required for manufacturing of above products will be sourced from local market. The products wise required raw materials and quantities are shown in below Tables 3.2-3.14.

TABLE 3.2: RAW MATERIALS FOR ALBENDAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	2-Nitro-4-Thiocyano aniline	74.00	123.33
2	n-Bromo propane	46.38	77.30
3	Sodium hydroxide	30.16	50.27
4	n-Propanol	2250.00	3750.00
5	Sulphuric acid	36.98	61.63
6	Sodium hydro sulphide	42.28	70.47
7	Cyanamide Solution	90.00	150.00
8	Methyl chloro formate	35.58	59.30
9	Sodium bicarbonate	31.63	52.72
10	Methanol	750.00	1250.00

TABLE 3.3: RAW MATERIALS FOR MLODIPINE BESYLATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Phthalic anhydride	100.50	55.84
2	Mono ethanolamine	42.00	23.34
3	Toluene	1516.00	842.39
5	Sodium Hydride	58.00	32.23
6	Ethyl-4-Chloroacetoacetate	115.00	63.90
7	Hydrochloric Acid (35%)	138.00	76.68
8	Acetic Acid	858.00	476.76
9	Sodium Chloride	115.00	63.90
10	Ortho chloro benzaldehyde	90.00	50.01
11	Hexane	240.00	133.36
12	Piperidine	6.00	3.33
13	Methyl-3-amino crotonate	160.00	88.91
14	Ethyl Acetate	1199.00	666.24
15	Mono methyl amine	700.00	388.97
16	Benzene Sulphonic Acid	50.00	27.78
17	Methanol	673.00	373.96
18	Activated Carbon	10.00	5.56

TABLE 3.4: RAW MATERIALS FOR EFAVIRENZ

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(S)-5-Chloro-a-(Cyclopropylethynyl)-2-(4'-methoxy enzylamino) (Trifluoromethyl) benzene methanol	110.00	220.00
2	Toluene	1755.00	3510.00
3	DDQ	63.00	126.00
4	Sodium Bicarbonate	20.00	40.00
5	Methanol	385.00	770.00
6	Sodium Borohydride	13.00	26.00
7	Acetic Acid	45.00	90.00
8	Sodium hydroxide (10%)	380.00	760.00
9	n-Hexane	275.00	550.00
10	Acetone	60.00	120.00
11	Triphosgene	27.00	54.00
12	Ethyl Acetate	65.00	130.00

TABLE 3.5: RAW MATERIALS FOR EMTRICITABINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)-[1,3]Oxa thiolane-2-carboxylic acid-2-isopropyl-5-methyl cyclo hexyl ester	200.00	200.00
2	IPA.HCl (25%)	73.20	73.20
3	Dipotassium hydrogen phosphate	25.00	25.00
4	Sodium Hydroxide flakes	5.00	5.00
5	Ethanol	950.00	950.00
6	Sodium borohydride	19.00	19.00
7	Toluene	1200.00	1200.00
8	Activated carbon	32.00	32.00
9	Isopropyl alcohol	1700.00	1700.00
10	Hydrochloric Acid	28.40	28.40
11	Tri ethylamine	47.00	47.00
13	Methanol	1200.00	1200.00
14	MDC	1500.00	1500.00
15	Hyflow	10.00	10.00

TABLE 3.6: RAW MATERIALS FOR FAMOTIDINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1,3-Dichloro acetone	53.00	106.00
2	Guanyl thiourea	50.00	100.00
3	Potassium Iodide	2.40	4.80
4	Acetone	170.00	340.00
5	Thiourea	25.13	50.26
6	Sodium hydroxide	40.00	80.00
7	N-Sulfamyl-3-chloro propionamidine HCl	74.00	148.00
8	Acetic acid	25.00	50.00
9	Methanol	3436.00	6872.00
10	Ammonia (23%)	24.00	48.00
11	Activated carbon	6.00	12.00

TABLE 3.7: RAW MATERIALS FOR FLUCONAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1,3 Difluoro benzene	50.00	33.33
2	Chloro Acetyl chloride	49.50	33.00
3	Aluminium Chloride	15.00	10.00
4	MDC	800.00	533.33
5	1,2,4-triazole	26.00	17.33
6	Triethyl Amine	37.00	24.67
7	Ethyl Acetate	700.00	466.67
8	Tri methyl Sulfoxonium iodide	78.00	52.00
9	Potassium Hydroxide	20.00	13.33
10	Toluene	800.00	533.33
11	1,2,4-Triazole	24.00	16.00
12	Cetyl tri methyl Ammonium Bromide	10.00	6.67
13	Potassium carbonate	47.00	31.33
14	DMF	650.00	433.33
15	Hydrochloric Acid	25.00	16.67
16	Magnesium Sulfate	5.00	3.33
17	IPA	450.00	300.00
18	Activated Carbon	10.00	6.67

TABLE 3.8: RAW MATERIALS FOR. LAMIVUDINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L(+)Menthol	82.60	20.650
2	Glyoxalic Acid (35%)	112.00	28.000
3	Sodium Bisulfate	63.00	15.750
4	Sodium Carbonate	15.00	3.750
5	Formaldehyde	16.00	4.000
6	Sulphuric Acid	3.00	0.750
7	Cyclohexane	1100.00	275.000
8	2,5 Diethane	80.00	20.000
9	Acetic Acid	43.00	10.750
10	Triethyl Amine	3.00	0.750
11	Toluene	1010.00	252.500
12	n-Hexane	430.00	107.500
13	Activated Carbon	5.00	1.250
14	Hyflo	5.00	1.250
15	Cytosine	58.55	14.638
16	HMDS	15.00	3.750
17	Thionyl Chloride	63.00	15.750
18	Dimethylformamide	54.00	13.500
19	Triethyl amine	102.00	25.500
20	MSA	1.00	0.250
21	Methylene Dichloride	1100.00	275.000
22	Ethyl Acetate	150.00	37.500

TABLE 3.9: RAW MATERIALS FOR LEVO SULPRIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(Amino sulfonyl)-2-methoxybenzoic acid	70.00	46.67
2	S-1-(1-Ethylpyrrolidin-2-yl) Methanamine	38.81	25.87
3	Triethyl amine	30.60	20.40
4	Ethyl chloro formate	32.90	21.93
5	Acetone	300.00	200.00
6	Ethyl acetate	400.00	266.67
7	MDC	225.00	150.00

TABLE 3.10: RAW MATERIALS FOR LOPINAVIR

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L-Phenyl alanine	75.00	25.00
2	Potassium carbonate	207.00	69.00
3	Benzyl chloride	173.50	57.83
4	Ethanol	2595.00	865.00
5	n-Heptane	280.00	93.33
6	Methanol	1224.00	408.00
7	Sodamide	43.00	14.33
8	Acetonitrile	18.75	6.25
9	Citric acid monohydrate	232.00	77.33
10	MTBE	1889.00	629.67
11	Sodium chloride	210.00	70.00
12	Benzyl magnesium chloride	46.00	15.33
13	Citric acid monohydrate	103.00	34.33
14	THF	1097.00	365.67
15	Sodium Boro hydride	10.00	3.33
16	Methane sulphonic acid	156.00	52.00
17	Triethyl amine	106.00	35.33
18	1,2-Dimethoxy ethane	1058.00	352.67
19	Ammonium chloride	200.00	66.67
20	Imidazole	18.90	6.30
21	TPA	55.00	18.33
22	Ethyl acetate	2670.00	890.00
23	Ammonium formate	31.00	10.33
24	Palladium carbon	20.60	6.87
25	L-Pyro glutamic acid	31.54	10.51
26	DMF	395.00	131.67
27	HCl	8.00	2.67
28	IPA	125.00	41.67
29	Dimethyl acetamide	160.00	53.33
30	MDC	1170.00	390.00
31	2,6-Dimethyl phenoxy acetyl chloride (DPC)	35.00	11.67
32	Sodium bicarbonate (10%)	170.00	56.67
33	Sodium sulphate	20.00	6.67
34	Acetone	500.00	166.67
35	Activated carbon	20.00	6.67
36	Hyflow	5.00	1.67

TABLE 3.11: RAW MATERIALS FOR N-BUTYL LITHIUM

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	N-Butyl chloride	80.00	800.00
2	Lithium	12.00	120.00
3	Hexane	203.00	2030.00

TABLE 3.12: RAW MATERIALS FOR PANTOPRAZOLE SODIUM

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Maltol	85.00	42.50
2	Dimethyl sulphate	45.00	22.50
3	Potassium carbonate	55.00	27.50
4	Acetone	1000.00	500.00
5	Ammonium Carbonate	65.00	32.50
6	Toluene	800.00	400.00
7	Phosphorous oxy chloride	35.00	17.50
8	Sodium Hydroxide	129.00	64.50
9	Methylenedichloride	2850.00	1425.00
10	Hydrogen peroxide (30%)	50.00	25.00
11	Methanol	875.00	437.50
12	Acetic Acid	10.00	5.00
13	Acetic Anhydride	45.00	22.50
14	Chloroform	200.00	100.00
15	Thionyl chloride	39.00	19.50
16	5-diFluoromethoxy-2-mercapto-benzimidazole	70.00	35.00
17	Sodium hypochlorite (4%)	500.00	250.00
18	Ammonium Chloride	25.00	12.50
19	Activated Carbon	10.00	5.00

TABLE 3.13: RAW MATERIALS FOR RITANAVIR

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(R,Z)-5-Amino-2-(dibenzyl amino)-1,6-diphenyl hex-4-en-3-one	114.00	38.00
2	Sodium Borohydride	10.00	3.33
3	Methane sulphonic acid	156.00	52.00
4	Triethyl amine	106.00	35.33
5	Potassium carbonate	34.00	11.33

6	1,2-Dimethoxy ethane	1400.00	466.67
7	Di-tert butyl oxy diformate	60.00	20.00
8	MTBE	937.00	312.33
9	Ammonium chloride	200.00	66.67
10	Sodium chloride	95.50	31.83
11	Methanol	1700.00	566.67
12	Acetic acid	14.70	4.90
13	Succinic acid	15.37	5.12
14	Palladium carbon	22.00	7.33
15	Ammonium formate	31.00	10.33
16	Sodium hydroxide	78.30	26.10
17	IPA	1677.00	559.00
18	Di methyl acetamide	160.00	53.33
19	5-Hydroxy methyl thiazole (5-HMT)	50.00	16.67
20	4-Nitro phenyl chloro formate	88.00	29.33
21	Sodium bicarbonate	36.50	12.17
22	Pyridine	2.00	0.67
23	Ethyl acetate	2289.00	763.00
24	Ethanol	355.00	118.33
27	Sodium bicarbonate	24.00	8.00
28	Aq.Ammonia solution (25%)	10.00	3.33
29	Hydrochloric acid	18.00	6.00
30	Hyflow	10.00	3.33
31	Iso butyramide	30.00	10.00
32	THF	1333.00	444.33
33	Phosphorous penta sulphide	15.50	5.17
34	Ethyl acetate	360.00	120.00
35	1,3-dichloro acetone	31.30	10.43
36	Mono methyl amine	7.70	2.57
37	MDC	500.00	166.67
38	Ammonium chloride	13.00	4.33
39	Phenoxy carbonyl –L-Valine	40.00	13.33
40	Lithium hydroxide	3.25	1.08
41	MTBE	610.00	203.33
42	Toluene	276.00	92.00
43	1-hydroxybenzotriazole hydrate	15.00	5.00
44	N-ethyl-N'-dimethylaminopropyl-carbodiimide	12.00	4.00
45	N-Heptane	1178.00	392.67
46	Activated Carbon	10.00	3.33

TABLE 3.14: RAW MATERIALS FOR TRICLABENDAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(2,3-dichlorophenoxy)-6-chloro-1H-benzo[d]imidazole-2-	110.00	183.33

	thiol		
2	Dimethyl Sulphate	42.00	70.00
3	Methanol	1195.00	1991.67
4	Acetone	300.00	500.00
5	Liq.Ammonia	10.00	16.67
6	CS.Flakes	26.00	43.33
7	Activated carbon	10.00	16.67
8	Liq.Ammonia	10.00	16.67
9	EDTA	1.30	2.17
10	Hydrose	1.30	2.17

TABLE 3.15: RAW MATERIALS FOR VALSARTAN

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L-Valine	45.00	15.00
2	Thionyl Chloride	45.70	15.23
3	Methanol	800.00	266.67
4	Toluene	2500.00	833.33
5	4-Bromomethyl-biphenyl-2-carbonitrile	82.00	27.33
6	Potassium carbonate	45.00	15.00
7	Valeryl Chloride	34.00	11.33
8	TEA	20.00	6.67
9	Sodium bicarbonate	25.00	8.33
10	Sodium Sulphate	10.00	3.33
11	Sodium Azide	16.00	5.33
12	Tri butyl tin chloride	80.00	26.67
13	Hydrogen	0.50	0.17
14	Sodium hydroxide	20.00	6.67
15	Xylene	240.00	80.00
16	MDC	500.00	166.67
17	Acetic Acid	40.00	13.33
18	N-Hexane	200.00	66.67
19	Activated Carbon	10.00	3.33

TABLE 3.16: RAW MATERIALS FOR ZIDOVUDINE

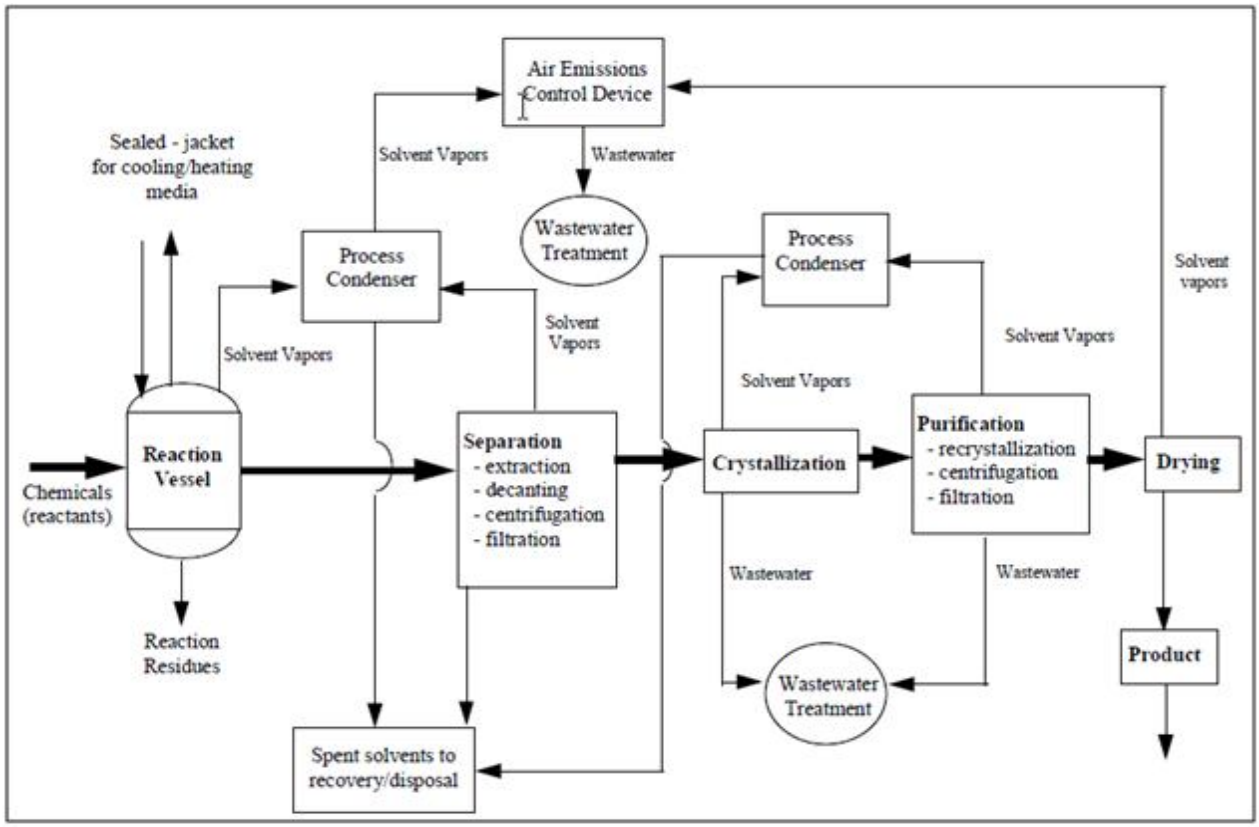
S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	β-Thymidine	70.00	23.33
2	1,4-Dioxane	700.00	233.33
3	Tri ethyl amine	73.00	24.33
4	Trityl chloride	64.00	21.33
5	Toluene	3620.00	1206.67
6	Methyl sulfonyl chloride	26.00	8.67

7	Methanol	1500.00	500.00
8	Sodium azide	14.00	4.67
9	Ammonium chloride	12.00	4.00
10	DMSO	600.00	200.00
11	PTSA Monohydrate	34.00	11.33
12	Sodium carbonate	10.00	3.33
13	Ethyl Acetate	1300.00	433.33
14	Activated Carbon	5.00	1.67

3.3 Manufacturing Process

The manufacturing process of bulk drugs consists of chemical synthesis extending to stages of processing involving different type of chemical reactions. The generalized Flow chart for bulk drug manufacturing is shown in **Flow chart 3.1.**

Flow Chart 3.1: Generalized Flow Chart for Bulk Drug Manufacturing



3.4 Resource – Utilize & Recycling

3.4.1 Water

Water requirement of the project for domestic and industrial activity during operation phase will be 112.78 KLD. The water requirement will be met through groundwater. The detailed water requirement shown in below **Table3.17.**

Table 3.17: WATER REQUIREMENT DETAILS

S. No	Purpose	Water Requirement In KLD
1	Process	32.78
2	Washings	2.00
3	Boiler make up	29.00
4	Cooling towers make up	38.00
5	DM Plant	2.00
6	Scrubbing system	2.00
7	Domestic	2.00
8	Gardening	5.00
	Total	**112.78**

3.4.2 Power Requirement

Power requirement of proposed project will be made available through APSPDCL. Total power requirement of proposed plant shall be 800 KVA.

Two No's of D. G. sets of capacity 380 KVA & 250KVA are available to meet emergency power requirement of the plant.

3.4.3 Fuel Requirement

M/s. Vineet Life Sciences Pvt. Ltd. is proposes to install 2 & 3 TPH coal fired boiler. Total fuel requirement will be around 12.5 TPD. Coal is procured form local sources.

3.5 Quantity of wastes to be generated

3.5.1 Waste Water Generation and utilization

Total effluent generated in the project is 53.34 KLD. The treated water will be reused for plant operations.

The process waste water from Process, floor Washes, scrubbers, QC and R&D are

evaporated in MEE with stripper and ATFD after neutralization. The condensate from MEE and ATFD will be collected and treated in effluents treatment plant along with effluents from utilities followed by RO. RO rejects will be send back to MEE and RO Permeate will be re-used back.

To treat the sewage generated due to domestic activities will be disposed through septic tank following by soak pit.

Table3.18: Wastewater generation and Treatment Method

S. No	Unit	HTDS KLD	LTDS KLD	Effluent Generation in KLD	Treatment Method
1	Process	30.78	4.56	35.34	HTDS effluent sent to ETP with MEE System LTDS effluents treated in ETP – RO Plant / RO Rejects to MEE System and RO permeate to reuse, Condensate from MEE to reuse and MEE residue to ATFD.
2	Washings	0.00	2.00	2.00	
3	Boiler Blow Down	4.00	0.00	4.00	
4	Cooling towers Blow Down	0.00	6.00	6.00	
5	Scrubber System	2.00	0.00	2.00	
6	DM Plant	2.00	0.00	2.00	
7	Domestic	0.00	2.00	2.00	Septic tank followed by soak pit
	Total	**38.78**	**14.56**	**53.34**	

3.5.2Solid waste generation and Disposal

The types of Hazardous and non Hazardous wastes generated from the project, method of disposal is shown in below table 3.19.

Table 3.19: Solid waste generation and Disposal

S. No	Name of the Solid Waste	Quantity Kg/Day	Disposal Method
1.	Inorganic Solid Waste	764.47	Sent to TSDF
2.	Organic solid waste	977.45	Sent to Cement Industries
3.	MEE Salts	1402.18	Sent to TSDF
4.	Spent Carbon	110.39	Sent to Cement Industries
5.	ETP Sludge	50.00	Sent to TSDF
6.	Spent solvents	46648.91	Recovered and reuse
7.	Coal ash from Boiler	5875.00	Sent to Brick Manufacturers
8.	Waste Oils & Grease	2	APPCB Authorized Agencies for

		KL/Annum	Reprocessing/Recycling
9.	Detoxified Containers	300 No's / Month	After Detoxification sent back to suppliers/APPCB Authorized Parties
10.	Used Lead Acid Batteries	4 No's/ Annum	Send back to suppliers for buyback of New Batteries

3.6 Schematic representations of the feasibility drawing which give information of EIA purpose.

The applicability of the S.O 1533 for the proposed project was explored by considering different possibilities & provision made in the said notification. Considering the products & project location of the proposed project it is noticed that the proposed project falls under Category 5 (f) "A" of the Schedule-I of EIA Notification SO 1533.

As per the provision of the SO 1533, it is necessary to get Environmental Clearance by applying to MoEF along with the Environmental Impacts Assessment Study Report for the proposed project prior to commissioning of the project activities. Therefore the EIA is required to conduct to comply with provisions of SO 1533 made for Category 5(f) "A" of schedule –I of the notification.

4.0Site Analysis

4.1 Connectivity

M/s. Vineet Life Sciences Pvt. Ltd. is located at Survey Nos: 1019, 1020/A-2,1020/B & 1021, Jangamaheswara Padu Village, Durgi Mandal, Guntur (Dt), Andhra Pradesh.

- The nearest habitation from the site is Jangamaheswara Padu (Village) at a distance of 1.6Km(N).
- The nearest railway station is Macherla Railway station at a distance of 16 KMs from the site.
- The nearest airport is Gannavaram Air port at a distance of 135 KMs at Gannavaram.
- The Nearest road ways

State **H**ighway **No.89 –** 5.8 KMs

4.2 Land Form, Land use and Land ownership.

The proposed project is located in Non Agricultural Land. There would be no any change in Land Use, Land Cover or Topography of plot. After implementation of project a dense green belt would be developed. Total 33 % of Plant area will be allocated for green belt development.

4.3 Existing Infrastructure.

Proposed project is a located near village and the basic infrastructure is already there.

4.4 Soil classification

The district is mainly covered by three types of soils Sandy Loam, Black clay Loam, Literate types of soil.

4.5 Climatic data from secondary sources.

Temperature Maximum: 47^{o} C
Minimum: 15^{o} C

Normal annual rainfall **889 mm**

4.6 Social Infrastructure available.

Well developed social infrastructure facilities are available at nearby Habitations.

5.0 Planning Brief

Proposed plant activities will be started after getting statutory clearance form related authorities. The project will be completed within two years.

Further proposed project activities will take care of all the rules and regulation of statutory authority and provide the control measure and devices to achieve the standard norms

6.0 Proposed Infrastructure

6.1 Industrial Area

Basic infrastructure developed already and the required plant and machineries will be installed after getting statutory clearance.

6.2 Residential Area

No residential area is involved in the proposed project. The employs are accommodated in nearby Residential areas

6.3 Green Belt:

Approximately 33 % of Green Belt will be provided and maintained.

6.4 Social Infrastructure:

Facilities like road and communication are good..Banks, ATM's and medical facilities are also adequate.

Amenities:

Education- schools including middle, secondary and higher secondary schools, social welfare hostels.

Medical and Health- Community Health Centre, & Primary Health center Are available near villages

Power and water- All the villages are electrified and drinking water facilities are extended to all villages.

Rail and Road- The project site is very well connected by road through State Highway no. 89, Southern railways.

6.5 Water management

Water requirement will be fulfilled through Ground water.

6.6 Sewerage System:

There will be no discharge of industrial effluent (**Z**ero **L**iquid **D**ischarge). The treated effluent will be reused. Domestic waste water will be disposed off through soak pit system.

6.7 Industrial Waste Management:

Due to proposed project, the effluent from cooling and Plant/Equipment washing will be generated and treated in the well designed Effluent Treatment Plant. The treated effluent will be reused.

7.0 Rehabilitation and Resettlement (R & R) Plan

Rehabilitation & Resettlement (R&R) plan is not applicable to proposed project.

8.0 Project Schedule & Cost Estimates

Proposed project activities will be started after getting statutory clearance form related authorities. The project will be completed within two years.

Table 8.1: Project Cost

S.NO	Particulars	Amount Rs in laks
1.	Land	23
2.	Building, Civil works& site development	250
3.	Plant and Machinery	850
4.	Furniture, Fixtures and other assets	18
5.	Preliminary Pre operative	40
6.	Liasoning work	20
7.	Marginal money for working capital	30

	Total	**1231**
8.	Means of Finance	
9.	Promoters Capital	400
10.	Term loan	831
	Total	**1231**

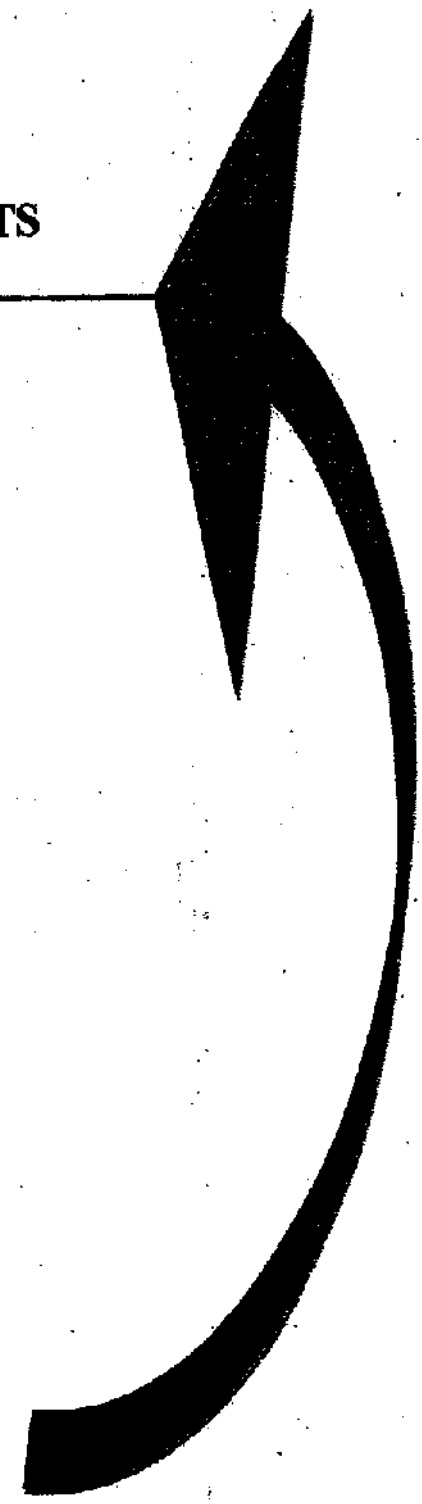
9.0 Analysis of proposal (Final Recommendations)

Proposed activity will provide benefits to the local people in terms of financial and social welfare.

- Local people will get direct financial benefit by way of employment.
- Local people will get some contracts of supply and services to get indirect income.
- Company will contribute in improving education and health facilities in nearby area.

ENCLOSURES

LIST OF BY- PRODUCTS



LIST OF BY- PRODUCTS

S. No	Name of the By-Product	Quantity In Kg/Day
1	Triethyl Amine HCl	63.93
2	Thio acetic Acid	10.00
3	Sodium citrate	114.12
4	Lithium Chloride	367.00
5	4-Nitro phenol	22.83

LIST OF RAW MATERIALS

1. ALBENDAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	2-Nitro-4-Thiocyano aniline	74.00	123.33
2	n-Bromo propane	46.38	77.30
3	Sodium hydroxide	30.16	50.27
4	n-Propanol	2250.00	3750.00
5	Sulphuric acid	36.98	61.63
6	Sodium hydro sulphide	42.28	70.47
7	Cyanamide Solution	90.00	150.00
8	Methyl chloro formate	35.58	59.30
9	Sodium bicarbonate	31.63	52.72
10	Methanol	750.00	1250.00

2. AMLODIPINE BESYLATE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Phthalic anhydride	100.50	55.84
2	Mono ethanolamine	42.00	23.34
3	Toluene	1516.00	842.39
5	Sodium Hydride	58.00	32.23
6	Ethyl-4-Chloroacetoacetate	115.00	63.90
7	Hydrochloric Acid (35%)	138.00	76.68
8	Acetic Acid	858.00	476.76
9	Sodium Chloride	115.00	63.90
10	Ortho chloro benzaldehyde	90.00	50.01
11	Hexane	240.00	133.36
12	Piperidine	6.00	3.33
13	Methyl-3-amino crotonate	160.00	88.91
14	Ethyl Acetate	1199.00	666.24
15	Mono methyl amine	700.00	388.97
16	Benzene Sulphonic Acid	50.00	27.78
17	Methanol	673.00	373.96
18	Activated Carbon	10.00	5.56

3. EFAVIRENZ

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(S)-5-Chloro-a-(Cyclopropylethynyl)-2-(4'-methoxy enzylamino) (Trifluoromethyl) benzene methanol	110.00	220.00
2	Toluene	1755.00	3510.00
3	DDQ	63.00	126.00
4	Sodium Bicarbonate	20.00	40.00
5	Methanol	385.00	770.00
6	Sodium Borohydride	13.00	26.00
7	Acetic Acid	45.00	90.00
8	Sodium hydroxide (10%)	380.00	760.00
9	n-Hexane	275.00	550.00
10	Acetone	60.00	120.00
11	Triphosgene	27.00	54.00
12	Ethyl Acetate	65.00	130.00

4. EMTRICITABINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)-[1,3]Oxa thiolane-2-carboxylic acid-2-isopropyl-5-methyl cyclo hexyl ester	200.00	200.00
2	IPA.HCl (25%)	73.20	73.20
3	Dipotassium hydrogen phosphate	25.00	25.00
4	Sodium Hydroxide flakes	5.00	5.00
5	Ethanol	950.00	950.00
6	Sodium borohydride	19.00	19.00
7	Toluene	1200.00	1200.00
8	Activated carbon	32.00	32.00
9	Isopropyl alcohol	1700.00	1700.00
10	Hydrochloric Acid	28.40	28.40
11	Tri ethylamine	47.00	47.00
13	Methanol	1200.00	1200.00
14	MDC	1500.00	1500.00
15	Hyflow	10.00	10.00

5. FAMOTIDINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1,3-Dichloro acetone	53.00	106.00
2	Guanyl thiourea	50.00	100.00
3	Potassium Iodide	2.40	4.80
4	Acetone	170.00	340.00
5	Thiourea	25.13	50.26
6	Sodium hydroxide	40.00	80.00
7	N-Sulfamyl-3-chloro propionamidine HCl	74.00	148.00
8	Acetic acid	25.00	50.00
9	Methanol	3436.00	6872.00
10	Ammonia (23%)	24.00	48.00
11	Activated carbon	6.00	12.00

6. FLUCONAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	1,3 Difluoro benzene	50.00	33.33
2	Chloro Acetyl chloride	49.50	33.00
3	Aluminium Chloride	15.00	10.00
4	MDC	800.00	533.33
5	1,2,4-triazole	26.00	17.33
6	Triethyl Amine	37.00	24.67
7	Ethyl Acetate	700.00	466.67
8	Tri methyl Sulfoxonium iodide	78.00	52.00
9	Potassium Hydroxide	20.00	13.33
10	Toluene	800.00	533.33
11	1,2,4-Triazole	24.00	16.00
12	Cetyl tri methyl Ammonium Bromide	10.00	6.67
13	Potassium carbonate	47.00	31.33
14	DMF	650.00	433.33
15	Hydrochloric Acid	25.00	16.67
16	Magnesium Sulfate	5.00	3.33
17	IPA	450.00	300.00
18	Activated Carbon	10.00	6.67

7. LAMIVUDINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L(+)Menthol	82.60	20.650
2	Glyoxalic Acid (35%)	112.00	28.000
3	Sodium Bisulfate	63.00	15.750
4	Sodium Carbonate	15.00	3.750
5	Formaldehyde	16.00	4.000
6	Sulphuric Acid	3.00	0.750
7	Cyclohexane	1100.00	275.000
8	2,5 Diethane	80.00	20.000
9	Acetic Acid	43.00	10.750
10	Triethyl Amine	3.00	0.750
11	Toluene	1010.00	252.500
12	n-Hexane	430.00	107.500
13	Activated Carbon	5.00	1.250
14	Hyflo	5.00	1.250
15	Cytosine	58.55	14.638
16	HMDS	15.00	3.750
17	Thionyl Chloride	63.00	15.750
18	Dimethylformamide	54.00	13.500
19	Triethyl amine	102.00	25.500
20	MSA	1.00	0.250
21	Methylene Dichloride	1100.00	275.000
22	Ethyl Acetate	150.00	37.500

8. LEVO SULPRIDE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(Amino sulfonyl)-2-methoxybenzoic acid	70.00	46.67
2	S-1-(1-Ethylpyrrolidin-2-yl) Methanamine	38.81	25.87
3	Triethyl amine	30.60	20.40
4	Ethyl chloro formate	32.90	21.93
5	Acetone	300.00	200.00
6	Ethyl acetate	400.00	266.67
7	MDC	225.00	150.00

9. LOPINAVIR

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L-Phenyl alanine	75.00	25.00
2	Potassium carbonate	207.00	69.00
3	Benzyl chloride	173.50	57.83
4	Ethanol	2595.00	865.00
5	n-Heptane	280.00	93.33
6	Methanol	1224.00	408.00
7	Sodamide	43.00	14.33
8	Acetonitrile	18.75	6.25
9	Citric acid monohydrate	232.00	77.33
10	MTBE	1889.00	629.67
11	Sodium chloride	210.00	70.00
12	Benzyl magnesium chloride	46.00	15.33
13	Citric acid monohydrate	103.00	34.33
14	THF	1097.00	365.67
15	Sodium Boro hydride	10.00	3.33
16	Methane sulphonic acid	156.00	52.00
17	Triethyl amine	106.00	35.33
18	1,2-Dimethoxy ethane	1058.00	352.67
19	Ammonium chloride	200.00	66.67
20	Imidazole	18.90	6.30
21	TPA	55.00	18.33
22	Ethyl acetate	2670.00	890.00
23	Ammonium formate	31.00	10.33
24	Palladium carbon	20.60	6.87
25	L-Pyro glutamic acid	31.54	10.51
26	DMF	395.00	131.67
27	HCl	8.00	2.67
28	IPA	125.00	41.67
29	Dimethyl acetamide	160.00	53.33
30	MDC	1170.00	390.00
31	2,6-Dimethyl phenoxy acetyl chloride (DPC)	35.00	11.67
32	Sodium bicarbonate (10%)	170.00	56.67
33	Sodium sulphate	20.00	6.67
34	Acetone	500.00	166.67
35	Activated carbon	20.00	6.67
36	Hyflow	5.00	1.67

10. N-BUTYL LITHIUM

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	N-Butyl chloride	80.00	800.00
2	Lithium	12.00	120.00
3	Hexane	203.00	2030.00

11. PANTOPRAZOLE SODIUM

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	Maltol	85.00	42.50
2	Dimethyl sulphate	45.00	22.50
3	Potassium carbonate	55.00	27.50
4	Acetone	1000.00	500.00
5	Ammonium Carbonate	65.00	32.50
6	Toluene	800.00	400.00
7	Phosphorous oxy chloride	35.00	17.50
8	Sodium Hydroxide	129.00	64.50
9	Methylenedichloride	2850.00	1425.00
10	Hydrogen peroxide (30%)	50.00	25.00
11	Methanol	875.00	437.50
12	Acetic Acid	10.00	5.00
13	Acetic Anhydride	45.00	22.50
14	Chloroform	200.00	100.00
15	Thionyl chloride	39.00	19.50
16	5-diFluoromethoxy-2-mercapto-benzimidazole	70.00	35.00
17	Sodium hypochlorite (4%)	500.00	250.00
18	Ammonium Chloride	25.00	12.50
19	Activated Carbon	10.00	5.00

12. RITANAVIR

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	(R,Z)-5-Amino-2-(dibenzyl amino)-1,6-diphenyl hex-4-en-3-one	114.00	38.00
2	Sodium Borohydride	10.00	3.33
3	Methane sulphonic acid	156.00	52.00
4	Triethyl amine	106.00	35.33
5	Potassium carbonate	34.00	11.33
6	1,2-Dimethoxy ethane	1400.00	466.67
7	Di-tert butyl oxy diformate	60.00	20.00
8	MTBE	937.00	312.33
9	Ammonium chloride	200.00	66.67
10	Sodium chloride	95.50	31.83
11	Methanol	1700.00	566.67
12	Acetic acid	14.70	4.90
13	Succinic acid	15.37	5.12
14	Palladium carbon	22.00	7.33
15	Ammonium formate	31.00	10.33
16	Sodium hydroxide	78.30	26.10
17	IPA	1677.00	559.00
18	Di methyl acetamide	160.00	53.33
19	5-Hydroxy methyl thiazole (5-HMT)	50.00	16.67
20	4-Nitro phenyl chloro formate	88.00	29.33
21	Sodium bicarbonate	36.50	12.17
22	Pyridine	2.00	0.67
23	Ethyl acetate	2289.00	763.00
24	Ethanol	355.00	118.33
27	Sodium bicarbonate	24.00	8.00
28	Aq.Ammonia solution (25%)	10.00	3.33
29	Hydrochloric acid	18.00	6.00
30	Hyflow	10.00	3.33
31	Iso butyramide	30.00	10.00
32	THF	1333.00	444.33
33	Phosphorous penta sulphide	15.50	5.17
34	Ethyl acetate	360.00	120.00
35	1,3-dichloro acetone	31.30	10.43

36	Mono methyl amine	7.70	2.57
37	MDC	500.00	166.67
38	Ammonium chloride	13.00	4.33
39	Phenoxy carbonyl –L-Valine	40.00	13.33
40	Lithium hydroxide	3.25	1.08
41	MTBE	610.00	203.33
42	Toluene	276.00	92.00
43	1-hydroxybenzotriazole hydrate	15.00	5.00
44	N-ethyl-N'-dimethylaminopropyl-carbodiimide	12.00	4.00
45	N-Heptane	1178.00	392.67
46	Activated Carbon	10.00	3.33

13. TRICLABENDAZOLE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	5-(2,3-dichlorophenoxy)-6-chloro-1H-benzo[d]imidazole-2-thiol	110.00	183.33
2	Dimethyl Sulphate	42.00	70.00
3	Methanol	1195.00	1991.67
4	Acetone	300.00	500.00
5	Liq.Ammonia	10.00	16.67
6	CS.Flakes	26.00	43.33
7	Activated carbon	10.00	16.67
8	Liq.Ammonia	10.00	16.67
9	EDTA	1.30	2.17
10	Hydrose	1.30	2.17

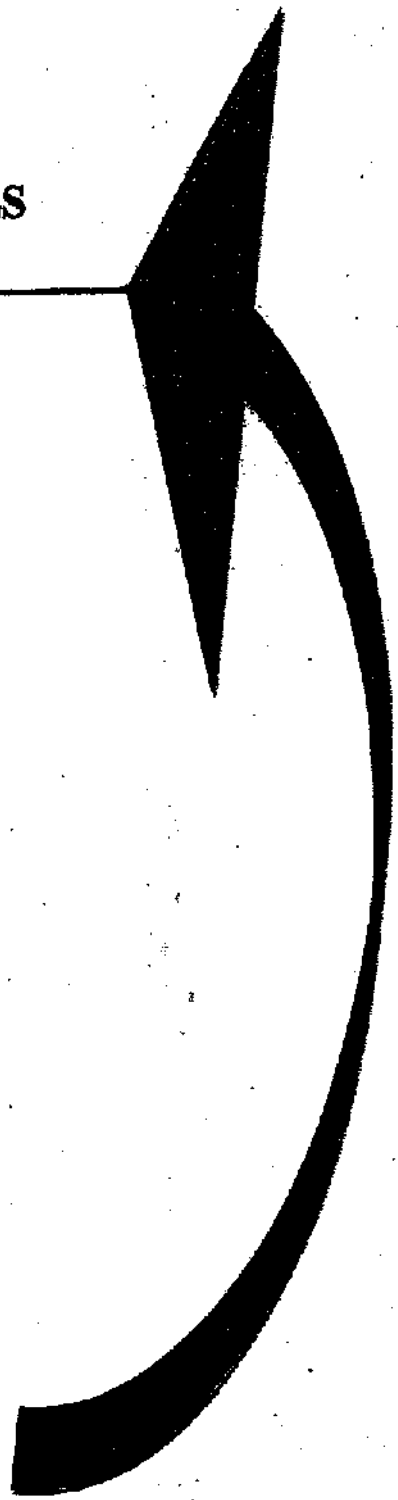
14. VALSARTAN

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	L-Valine	45.00	15.00
2	Thionyl Chloride	45.70	15.23
3	Methanol	800.00	266.67
4	Toluene	2500.00	833.33
5	4-Bromomethyl-biphenyl-2-carbonitrile	82.00	27.33
6	Potassium carbonate	45.00	15.00
7	Valeryl Chloride	34.00	11.33
8	TEA	20.00	6.67
9	Sodium bicarbonate	25.00	8.33
10	Sodium Sulphate	10.00	3.33
11	Sodium Azide	16.00	5.33
12	Tri butyl tin chloride	80.00	26.67
13	Hydrogen	0.50	0.17
14	Sodium hydroxide	20.00	6.67
15	Xylene	240.00	80.00
16	MDC	500.00	166.67
17	Acetic Acid	40.00	13.33
18	N-Hexane	200.00	66.67
19	Activated Carbon	10.00	3.33

15. ZIDOVUDINE

S. No	Raw Material	Consumption/ Batch in Kgs	Consumption/ Day in Kgs
1	β-Thymidine	70.00	23.33
2	1,4-Dioxane	700.00	233.33
3	Tri ethyl amine	73.00	24.33
4	Trityl chloride	64.00	21.33
5	Toluene	3620.00	1206.67
6	Methyl sulfonyl chloride	26.00	8.67
7	Methanol	1500.00	500.00
8	Sodium azide	14.00	4.67
9	Ammonium chloride	12.00	4.00
10	DMSO	600.00	200.00
11	PTSA Monohydrate	34.00	11.33
12	Sodium carbonate	10.00	3.33
13	Ethyl Acetate	1300.00	433.33
14	Activated Carbon	5.00	1.67

WASTE WATER DETAILS



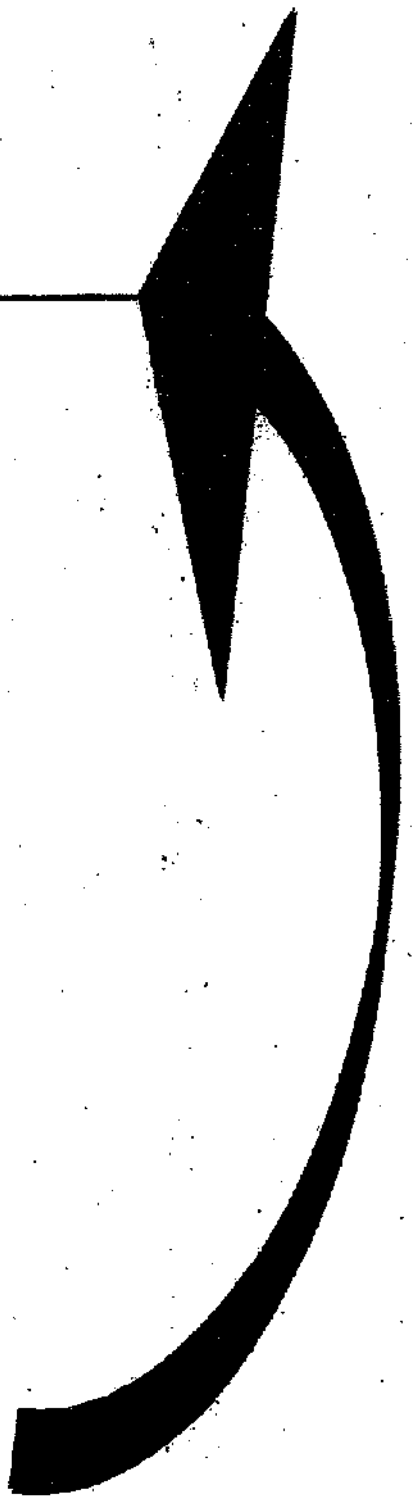
WASTE WATER DETAILS

S.NO	Unit	Effluent Generation in KLD
1	Process	35.34
2	Washings	2.00
3	Boiler Blow Down	4.00
4	Cooling towers Blow Down	6.00
5	Scrubbing System	2.00
6	DM Plant Regeneration	2.00
7	Domestic	2.00
	Total	**53.34**

HTDS &LTDS EFFLUENT GENERATION

Unit	HTDS KLD	LTDS KLD	Effluent Generation in KLD	Treatment Method
Process	30.78	4.56	35.34	HTDS effluent sent to ETP with MEE System LTDS effluents treated in ETP – RO Plant / RO Rejects to MEE System and RO permeate to reuse, Condensate from MEE to reuse and MEE residue to ATFD.
Washings	0.00	2.00	2.00	
Boiler Blow Down	4.00	0.00	4.00	
Cooling towers Blow Down	0.00	6.00	6.00	
Scrubbing System	2.00	0.00	2.00	
DM Plant Regeneration	2.00	0.00	2.00	
Domestic	0.00	2.00	2.00	Septic tank followed by soak pit
Total	**38.78**	**14.56**	**53.34**	

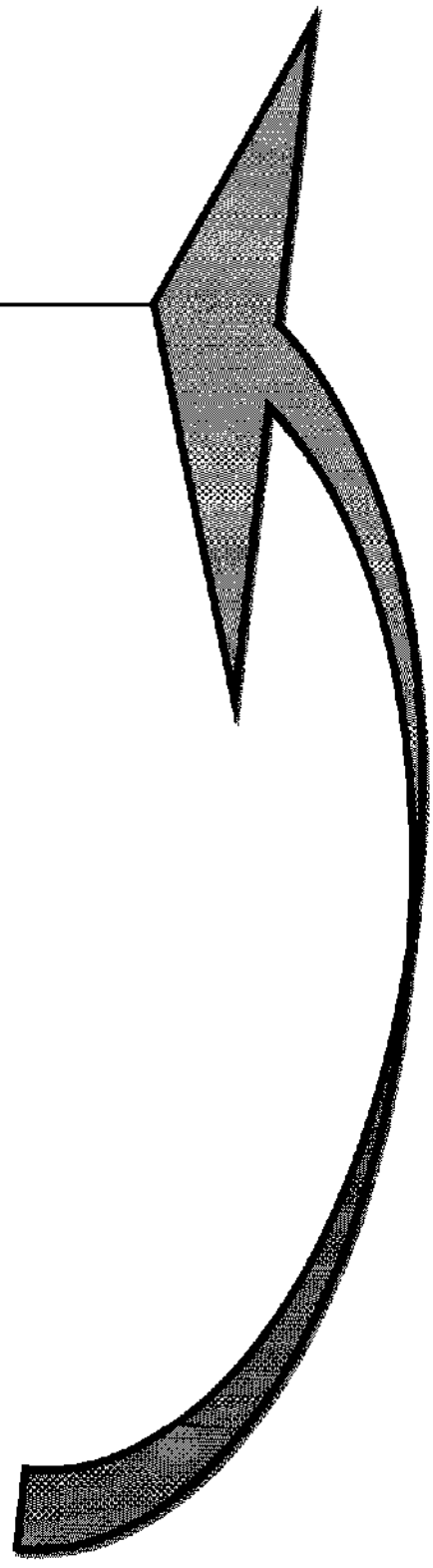
ETP FLOW CHART



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.

SOLVENTS DETAILS



Solvent Details

S. No	Product Name	Solvent Name	Per Day					
			Solvent Input	Solvent Recovery	Solvent Loss	Solvent to waste water	Solvent to Residue	Fugitive Loss
1	Albendazole	n-Propanol	3750.00	3562.50	187.50	37.50	112.50	37.50
		Methanol	1250.00	1187.50	62.50	12.50	37.50	12.50
	Total		***5000.00***	***4750.00***	***250.00***	***50.00***	***150.00***	***50.00***
2	Amlodipine Besylate	Toluene	831.11	789.56	41.56	8.31	24.93	8.31
		n-Hexane	133.36	126.69	6.67	1.33	4.00	1.33
		Ethyl acetate	666.24	632.93	33.31	6.66	19.99	6.66
		Monomethyl amine	388.97	369.52	19.45	3.89	11.67	3.89
		Methanol	373.96	355.27	18.70	3.74	11.22	3.74
	Total		***2393.65***	***2273.96***	***119.68***	***23.94***	***71.81***	***23.94***
3	Efavirenz	Toluene	3510.00	3334.50	175.50	35.10	105.30	35.10
		Methanol	760.00	722.00	38.00	7.60	22.80	7.60
		n-Hexane	550.00	522.50	27.50	5.50	16.50	5.50
		Acetone	120.00	114.00	6.00	1.20	3.60	1.20
		Ethyl acetate	130.00	123.50	6.50	1.30	3.90	1.30
	Total		***5070.00***	***4816.50***	***253.50***	***50.70***	***152.10***	***50.70***
4	Emtricitabine	IPA	1700.00	1615.00	85.00	17.00	51.00	17.00
		Ethanol	950.00	902.50	47.50	9.50	28.50	9.50
		Toluene	950.00	902.50	47.50	9.50	28.50	9.50
		Methanol	1200.00	1140.00	60.00	12.00	36.00	12.00
	Total		***4800.00***	***4560.00***	***240.00***	***48.00***	***144.00***	***48.00***

5	Famotidine	Acetone	340.00	323.00	17.00	3.40	10.20	3.40
		Methanol	6872.00	6528.40	343.60	68.72	206.16	68.72
	Total		***7212.00***	***6851.40***	***360.60***	***72.12***	***216.36***	***72.12***
6	Fluconazole	MDC	533.33	506.67	26.67	5.33	16.00	5.33
		Ethyl acetate	466.67	443.33	23.33	4.67	14.00	4.67
		Toluene	533.33	506.67	26.67	5.33	16.00	5.33
		DMF	433.33	411.67	21.67	4.33	13.00	4.33
		IPA	300.00	285.00	15.00	3.00	9.00	3.00
	Total		***2266.67***	***2153.33***	***113.33***	***22.67***	***68.00***	***22.67***
7	Lamivudine	Cyclohexane	275.00	261.25	13.75	2.75	8.25	2.75
		Toluene	252.50	239.88	12.63	2.53	7.58	2.53
		n-Hexane	107.50	102.13	5.38	1.08	3.23	1.08
		Ethyl acetate	37.50	35.63	1.88	0.38	1.13	0.38
		DMF	13.50	12.83	0.68	0.14	0.41	0.14
		MDC	275.00	261.25	13.75	2.75	8.25	2.75
	Total		***961.00***	***912.95***	***48.05***	***9.61***	***28.83***	***9.61***
8	Lopinavir	n-Heptane	93.33	88.67	4.67	0.93	2.80	0.93
		Methanol	408.00	387.60	20.40	4.08	12.24	4.08
		Acetonitrile	6.25	5.94	0.31	0.06	0.19	0.06
		MTBE	629.67	598.18	31.48	6.30	18.89	6.30
		Ethanol	865.00	821.75	43.25	8.65	25.95	8.65
		THF	365.67	347.38	18.28	3.66	10.97	3.66
		1,2-Dimethoxy ethane	352.67	335.03	17.63	3.53	10.58	3.53
		MDC	390.00	370.50	19.50	3.90	11.70	3.90
		Dimethyl acetamide	53.33	50.67	2.67	0.53	1.60	0.53
		IPA	41.67	39.58	2.08	0.42	1.25	0.42

		DMF	131.67	125.08	6.58	1.32	3.95	1.32
		Acetone	166.67	158.33	8.33	1.67	5.00	1.67
		Ethyl acetate	890.00	845.50	44.50	8.90	26.70	8.90
	Total		***4393.92***	***4174.22***	***219.70***	***43.94***	***131.82***	***43.94***
9	n-Butyl Lithium	n-Hexane	2706.67	2571.33	135.33	27.07	81.20	27.07
	Total		***2706.67***	***2571.33***	***135.33***	***27.07***	***81.20***	***27.07***
10	Omeprazole	Methanol	750.00	712.50	37.50	7.50	22.50	7.50
		Toluene	1000.00	950.00	50.00	10.00	30.00	10.00
		Acetone	250.00	237.50	12.50	2.50	7.50	2.50
	Total		***2000.00***	***1900.00***	***100.00***	***20.00***	***60.00***	***20.00***
11	Pantoprazole sodium	Acetone	500.00	475.00	25.00	5.00	15.00	5.00
		Toluene	400.00	380.00	20.00	4.00	12.00	4.00
		MDC	1425.00	1353.75	71.25	14.25	42.75	14.25
		Methanol	437.50	415.63	21.88	4.38	13.13	4.38
	Total		***2762.50***	***2624.38***	***138.13***	***27.63***	***82.88***	***27.63***
12	Ritanavir	1,2-Dimethoxy ethane	466.67	443.33	23.33	4.67	14.00	4.67
		MTBE	312.33	296.72	15.62	3.12	9.37	3.12
		Methanol	566.67	538.33	28.33	5.67	17.00	5.67
		Dimethyl acetamide	53.33	50.67	2.67	0.53	1.60	0.53
		IPA	559.00	531.05	27.95	5.59	16.77	5.59
		Ethyl acetate	883.00	838.85	44.15	8.83	26.49	8.83
		Ethanol	118.33	112.42	5.92	1.18	3.55	1.18
		THF	444.33	422.12	22.22	4.44	13.33	4.44
		MDC	166.67	158.33	8.33	1.67	5.00	1.67

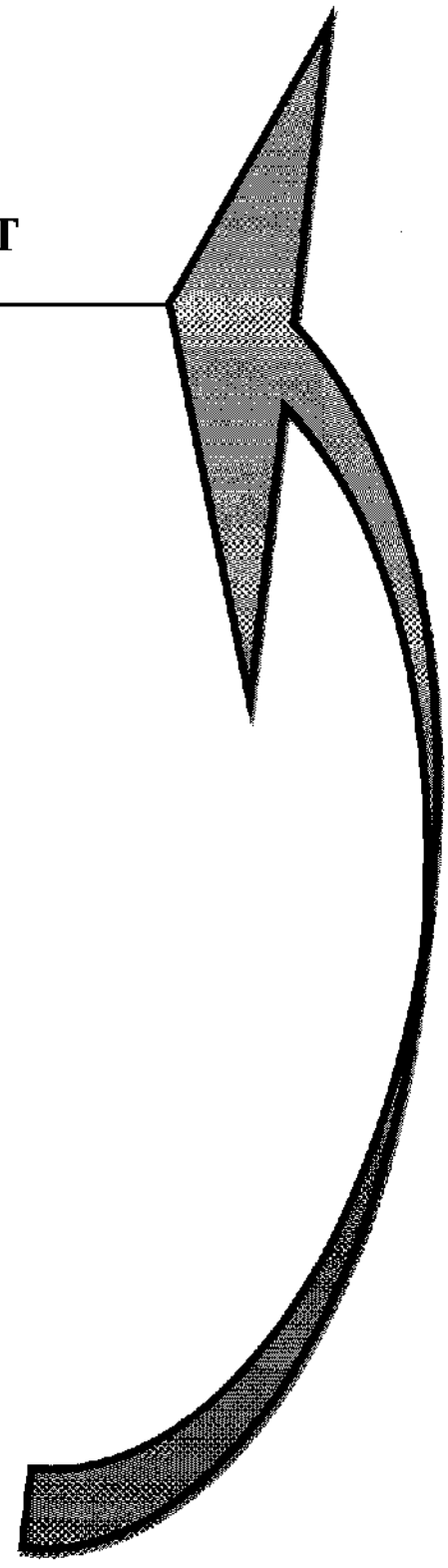
		Toluene	92.00	87.40	4.60	0.92	2.76	0.92
		n-Heptane	392.67	373.03	19.63	3.93	11.78	3.93
	Total		***4055.00***	***3852.25***	***202.75***	***40.55***	***121.65***	***40.55***
13	Triclabendazole	Methanol	1991.67	1892.08	99.58	19.92	59.75	19.92
		Acetone	500.00	475.00	25.00	5.00	15.00	5.00
	Total		***2491.67***	***2367.08***	***124.58***	***24.92***	***74.75***	***24.92***
14	Valsartan	Methanol	266.67	253.33	13.33	2.67	8.00	2.67
		Toluene	833.33	791.67	41.67	8.33	25.00	8.33
		MDC	166.67	158.33	8.33	1.67	5.00	1.67
		n-Hexane	66.67	63.33	3.33	0.67	2.00	0.67
		Xylene	80.00	76.00	4.00	0.80	2.40	0.80
	Total		***1413.33***	***1342.67***	***70.67***	***14.13***	***42.40***	***14.13***
15	Zidovudine	1,4-Dioxane	233.33	221.67	11.67	2.33	7.00	2.33
		Toluene	1206.67	1146.33	60.33	12.07	36.20	12.07
		Methanol	500.00	475.00	25.00	5.00	15.00	5.00
		DMSO	200.00	190.00	10.00	2.00	6.00	2.00
		Ethyl acetate	433.33	411.67	21.67	4.33	13.00	4.33
	Total		***2573.33***	***2444.67***	***128.67***	***25.73***	***77.20***	***25.73***
	Grand total of all products		***50099.73***	***47594.74***	***2504.99***	***501.00***	***1502.99***	***501.00***

POLLUTION LOAD DETAILS

S.No	Product Name	Prodn /Month	Water Input	Effluent Details								Solid waste Details				Emissions	
				Water In Effluent	Inorganics in water	Organics in water	TDS	COD	HTDS	LTDS	Total Effluent	Organic	Inorganic	Spent carbon	Total solid waste	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	Albendazole	5000.00	2666.67	2667.78	110.38	20.17	110.38	30.17	2154.23	644.05	2798.28	95.97	188.58	0.00	284.55	69.68	250.00
2	Amlodipine Besylate	2000.0000	3755.56	3814.57	156.18	1.11	156.18	3.47	3492	479.87	3971.87	76.03	0	5.56	81.59	1.61	110.00
3	Efavirenz	3000.00	7690	8356.06	111.84	32.4	111.84	56.78	6853.28	1647.02	8500.3	342.2	123	0.00	465.2	49.9	245.40
4	Emtricitabine	3000.00	1200	1182	91.3	2	91.3	4.8	1275.3	0.00	1275.3	33.74	0	42.00	75.74	2	327.00
5	Famotidine	6000.00	1650.00	1726.22	58.8	2	58.8	3	0	1787.02	1787.02	110.04	146	12.00	268.04	0	356.00
6	Fluconazole	2000.00	1733.33	1741.63	130.07	19.53	130.07	32.57	1891.23	0.00	1891.23	25.47	0	6.67	32.14	9.97	113.33
7	Lamivudine	1500.00	1700.00	1720.65	29.63	1	29.63	1.86	1751.28	0.00	1751.28	0.54	15.75	2.50	18.79	8.47	45.00
8	Levo sulpride	2000.00	666.67	666.67	27.73	9.93	27.73	14.81	704.33	0.00	704.33	3.67	0	0.00	3.67	8.87	30.00
9	Lopinavir	1000.00	1851.67	1932.51	100.98	5	100.98	8.87	2038.5	0.00	2038.5	47.42	110.55	8.33	166.3	35.27	217.00
10	n-Butyl Lithium	15000.00	0.00	0	0	0	0	0	0	0.00	0	53	0	0.00	53	0	30.00
11	Pantoprazole sodium	1500.00	2612.50	2899.7	147.75	5.5	147.75	11.8	3049.95	3.00	3052.95	52.89	33.65	5.00	91.54	31.36	146.25
12	Ritanavir	1000.00	2367.33	2376.92	124.69	5.46	124.69	11.3	2507.07	0.00	2507.07	49.97	66.67	6.67	123.31	23.36	205.00
13	Triclabendazole	5000.00	2600.00	2609.5	37.67	21	37.67	31.5	2668.17	0.00	2668.17	29.23	76.93	16.67	122.83	0	120.00
14	Valsartan	1000.00	766.67	773.1	54.86	2.66	54.86	8.32	830.63	0.00	830.63	14.57	3.33	3.33	21.23	20.21	70.67
15	Zidovudine	1000.00	1516.67	1515.5	40.3	5.33	40.3	13.04	1561.13	0.00	1561.13	42.72	0	1.67	44.39	2.48	128.00
	Total	**50000.00**	**32777.07**	**33982.81**	**1222.18**	**133.09**	**1222.18**	**232.29**		**4560.96**		**977.46**	**764.46**	**110.40**	**1852.32**	**263.18**	**2393.65**

Production Capacity
Water Input
TDS
COD
HTDS
LTDS
Total Effluent
Organic Residue
Inorganic Residue
Spent carbon

LAND DOCUMENT



आंध्रप्रदेश आन्ध्र प्रदेश ANDHRA PRADESH

Sl. No: 1782 Date: 8/3/14 Rs: 100/-

Sold to: K. Murali Mohan. S/o. Veeranjaneyulu, R/o. Hyd.

From: M/s. Vineet Life Sciences pvt. Ltd., Hyd.

AZ 458382

M. PRAKASH REDDY
Licensed Stamp Vendor
License No. 15-02-014/2013
H.No. 4-6-53, Khas Bagh,
Hayathnagar, R.R. Dist.
Pin-501505. Cell: 9912059067

AGREEMENT OF SALE

This Deed of Agreement of Sale is made and executed on this the 11th day of March, 2014 by and between:

1. **SRI.KANDIMALLA SRINIVASA RAO, S/O.PEDDA SAMBAIAH,** aged about 32 years, Occupation: Teacher, R/o.Potharam Village, Chilakaluripeta Mandal, Guntur District.

2. **SMT.KANDIMALLA SEETHARAMANJAMMA, W/O.PEDDA SAMBAIAH,** aged about 49 years, Occupation: Housewife, R/o.Potharam Village, Chilakaluripeta Mandal, Guntur District.

3. **SRI.KANDULA MURALI MOHAN, S/O.VEERANJANEYULU,** aged about 35 years, Occupation: Business, R/o.Flat No.202, Sridevi Residency, Siva Ganga Colony, L.B.Nagar, Hyderabad.

4. **SMT.KANDULA BHARATHI, W/O. MURALI MOHAN,** aged about 30 years, Occupation: Housewife, R/o.Flat No.202, Sridevi Residency, Siva Ganga Colony, L.B.Nagar, Hyderabad.

(HEREINAFTER Called the 'VENDORS')

1. K. Srinivasa Rao 2. [illegible]

3. K. Murali Mohan 4. K. Bharathi

IN FAVOUR OF

M/S.VINEET LIFE SCIENCES PVT. LTD., A company incorpprated under companies Act 1956 having its registered office at Flat No.202, Sridevi Residency, Siva Ganga Colony, L.B.Nagar, Hyderabad. Represented by its Managing Director: **SRI.KANDULA MURALI MOHAN, S/O.VEERANJANEYULU**

(HEREINAFTER Called the 'VENDEE')

(the terms the Vendors and the Vendee herein used shall wherever the context so admits mean and includes their respective heirs, executors, successors, legal representatives, administrators, and assignees, etc., as the parties themselves)

WHEREAS, the Vendors are the sole and absolute owners, pattedars and peaceful possessors of the land admeasuring Ac.3.40 Cents, in Survey Nos.1019, 1020/A-2, 1020/B and 1021, situated at JANGAMAHESWRAPADU VILLAGE, Durgi Revenue Mandal, Guntur District, under Jangamaheswrapadu Grampanchayath, Vide Pattedar Pass Book bearing Nos. 380726, 380727, 432017, 380728., Title Deed bearing Nos. 380726, 380727, 432017, 380728., and Patta Nos. 1238, 1239, 1591, 1240., issued by the Mandal Revenue Officer, Durgi Mandal, Guntur District and since then Vendor have been in continuous physical possession and enjoyment of the said land uninterruptedly without any demur.

WHEREAS, the Vendors being in need of money for their family necessities and therefore offered to sell the above said land (hereinafter called the said property, and morefully described in the schedule hereto), to the Vendee for a total sale consideration of Rs.17,00,000/- (Rupees SEVENTEEN LAKH only) and the Vendee has agreed to purchase the same for the said consideration from the Vendors as per the terms and conditions hereinafter appearing and to avoid the future complications, the parties hereto have agreed to reduce the terms and conditions agreed upon among them into writing as under:

NOW THIS AGREEMENT OF SALE WITNESSES AS FOLLOWS:

IN PURSUANCE of the said offer, acceptance, of both the Vendors and the Vendee, and in consideration of the sum of Rs.17,00,000/-. (Rupees SEVENTEEN LAKH only) and the Vendee has paid Rs.1,70,000/- (Rupees ONE LAKH SEVENTY THOUSAND only) to the Vendors on this day towards advance and part sale consideration and the Vendors herein have received the sale consideration and admit, acknowledge the same and passed a separate receipt in favour of the Vendee.

1. K. Srinivasa Rao 2. [illegible]

3. [illegible] 4. K. Bharathi

1. WHEREAS, the Vendee has agreed to pay the remaining sale consideration of Rs.15,30,000/- (Rupees FIFTEEN LAKH THIRTY THOUSAND only) to the Vendors within 4 months from day of this Agreement of Sale.

2. WHEREAS, the Vendors hereby declare that they are the absolute owners with full rights over the said property and that they are having legal, subsisting, valid and marketable title to sell the same to the Vendee and nobody else has any right or claim over the same.

3. WHEREAS, the Vendors further declare that the said property is free from all sorts of encumbrances, dues, liabilities, Bank Sureties, Court attachments, Civil litigations before any Authority or Courts, mortgages, prior assignments of sale and charges etc.,

4. WHEREAS, the Vendors assures the Vendee to make good of all such losses, damages, costs, expenses, etc., that may be caused to the Vendee or that may be incurred by the Vendee, due to the defect in the title of the Vendors over the said property at any future date.

5. WHEREAS, the Vendors hereby declares that the property hereby conveyed is not an assigned land under the provisions of A.P. Assigned Lands Act No.9 of 1977.

6. WHEREAS, the Vendors shall execute the regular registered sale deed or any other conveyance as per the wishes of the Vendee with usual terms in the name of the Vendee or in his nominee's name as may be directed by the Vendee.

7. THAT the fees, charges, and stamp duty for the execution and registration of the sale deed shall be borne by the Vendee at the time of the registration.

8. WHEREAS, the Vendors shall handover all the Original documents, E.C. connected title deeds to the Vendee for their record purpose, before the registration.

9. WHEREAS, the Vendors assures the Vendee that he will not claim any further sum in future except the remaining sale consideration from the Vendee under any circumstances.

10. If the Vendors fails to register the sale deed even after offer of the remaining sale consideration by the Vendee, the Vendee shall be entitled to proceed against the Vendors in a Court of Law and the Vendors shall be held responsible for all the costs and consequences arise thereupon.

1. K. Srinivasa Rao 2. [illegible]

3. [illegible] 4. K. Bharathi

SCHEDULE OF THE PROPERTY

ALL that piece and parcel of the land admeasuring Ac.3.40 Cents, in Survey Nos.1019, 1020/A-2, 1020/B and 1021, situated at JANGAMAHESWRAPADU VILLAGE, Durgi Revenue Mandal, Guntur District, under Jangamaheswrapadu Grampanchayath, under registration Sub District Macharla, and bounded by:

NORTH	::	Road.
SOUTH	::	Neighbours Land.
EAST	::	Land of M/S.Satyadeva Organosys Pvt Ltd.
WEST	::	Neighbours Land.

IN WITNESS WHEREOF the parties hereto have set their hand to this Deed of Agreement on the date first above mentioned in the presence of the following witnesses.

1. K. Srinivasa Rao
2. కందిపల్లి సుబ్బారావు
3. [illegible]
4. K. Bharathi

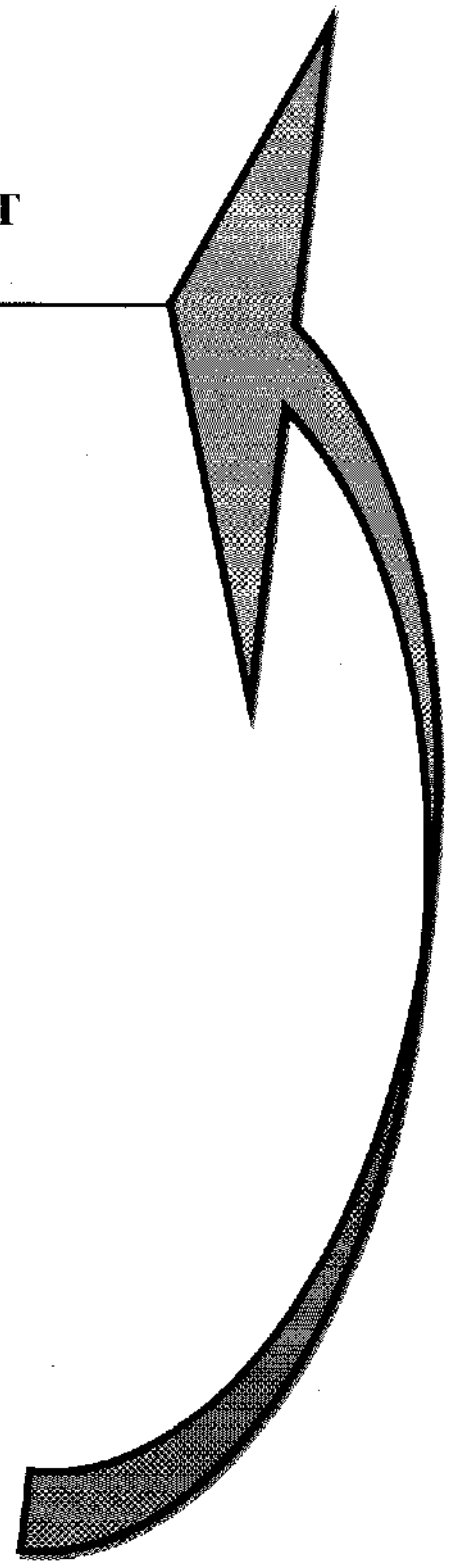
WITNESSES: **SIG.OF THE VENDORS**

1.

SIG.OF THE VENDEE

2.

NOC FROM
GRAMA PANCHA YAT



OFFICE OF THE GRAMA PANCHAYAT SECRETARIAT-JANGAMAHESWARA PADU

Mdl.Durgi Dist.Guntur.(A.P)

గ్రామ పంచాయితీ సచివాలయము - జంగమహేశ్వరపాడు

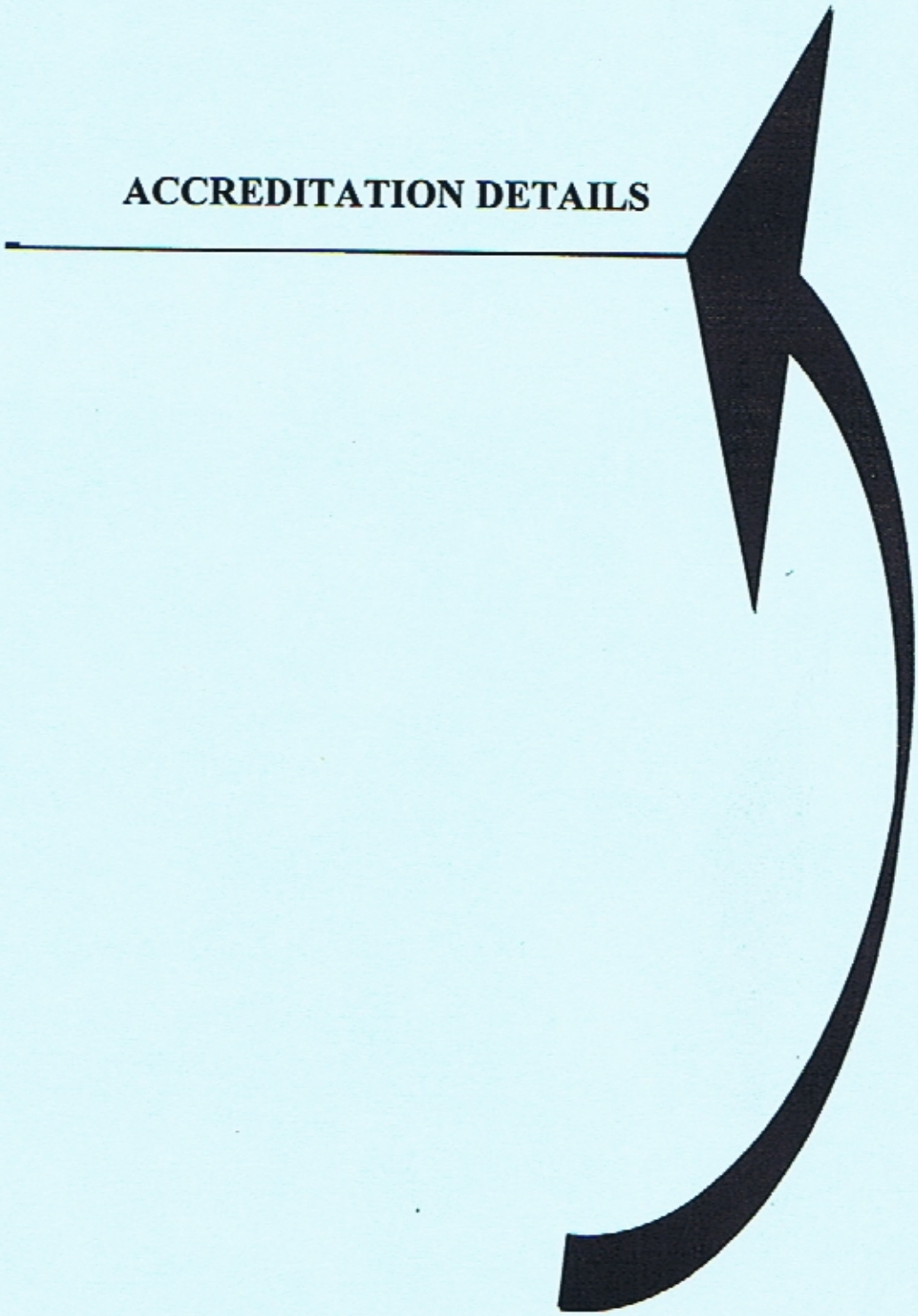
మం॥ దుర్గి జిల్లా : గుంటూరు (ఆంధ్రప్రదేశ్)

NO OBJECTION CERTIFICATE

This is to Certify that M\s.**Vineet Life Sciences Pvt.Ltd**. is establishing a factory to manufacture Bulk Drugs and Intermediate at Survey No's 1019,1020/A-2,1020/B &1021 Jangamaheswara Padu Village, Durgi Mandal, Guntur (D.t) AndraPradesh. Which is in the limits of GramaPanchayat, JangamaheswaraPadu.

This GramaPanchayat have no objection for establishing factory. Any Construction will not start before the permission of this Office.

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