



VISION
STATEMENT



- We aspire to be a trusted partner offering quality Active Pharmaceutical Ingredients , intermediates and CRAMS services globally*

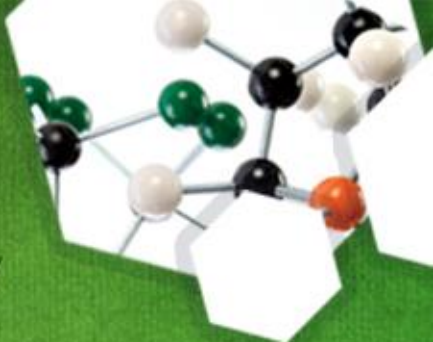


Quality Policy

- To provide customers, a quality product, in agreed timelines and strive to enhance their satisfaction
- To provide healthy atmosphere to the personnel working in the factory and to provide them a healthier life style by educating them and catering their needs.
- Strive for continuous up-gradation of Technology and productivity by adhering to Quality Management System.



Environmental Policy



- Comply with all Applicable laws and other requirements to manufacture API's and their intermediates.
- Prevent Pollution and waste with effective controls.
- Work continuously to improve effectiveness of Environment Management system
- Communicate and Re-in force this policy to all our employees, suppliers, and other interested parties





Company

Profile

- Incepted in the year 2000 by an enterprising technocrat (Doctorate in Chemistry) having more than three decades of industry experience with leading Indian pharmaceutical MNCs that includes Warner Hindustan, Standard Organics Limited and Dr. Reddys Laboratories Ltd. (As Sr. Vice President).
- Shodhana Laboratories Limited, today has steadily established itself as a fast-growing company with a wide range of APIs and intermediates extending across various therapeutic categories.
- Today we are a partner of choice, and our customers include innovator companies and leading manufacturers of generic and finished dosage formulations globally.



Our Team

- The VP Technical has about 25 years work experience that includes Dr.Reddys Laboratories as Director R&D and has been contributing to Shodhana as Vice President Technical since 2006.
- The director holds a bachelors degree in Chemical Engineering along with masters degree in Industrial Systems Engineering (majoring in Management) from University of southern California. His short association with a blue chip company as a quality Engineer (Abbott Vascular) helped him enhance his working skills.As a director for Shodhana, his role is to build and execute strategies for the company.
- The company holds strength of about **140** people working who carry out office and manufacturing functions.

Infrastructure



- A ware house to store the raw materials as per cGMP norms (with sampling ,dispensing ,rejected areas).
- All necessary utilities for carrying out all production activities which also includes:
 - Autoclaves,
 - Stand-by power generator (for the whole plant)
 - Vacuum systems (for high vacuum distillations).
- Clean rooms (class 100 thousand) for processing final bulk actives(APIs) .
- Stability chambers for carrying out Long term Accelerated Stability studies.
- Well established Quality control lab with all necessary equipments (GCs, HPLCs, UV, FTIR spectrophotometers, Autopol Polarimeter) to carry out impurity profiles and regular analysis.
- Multiple Effect Evaporator installed to meet the effluent treatment needs.

Infrastructure



- Shodhana has 5 Production blocks with a total of 65 reaction vessels (ranging from 100lts to 5000lts capacities of all types , with all kinds of different agitators)



Infrastructure



- At present Shodhana Constitutes a total reaction volume of upto 200kl
- Its subsidiary units constitute a total volume of around 300kl
- Total present working volume is around 500kl
- Regarding future expansion plans, Shodhana has acquired lands which can gear up the reaction volume to another 250kl.

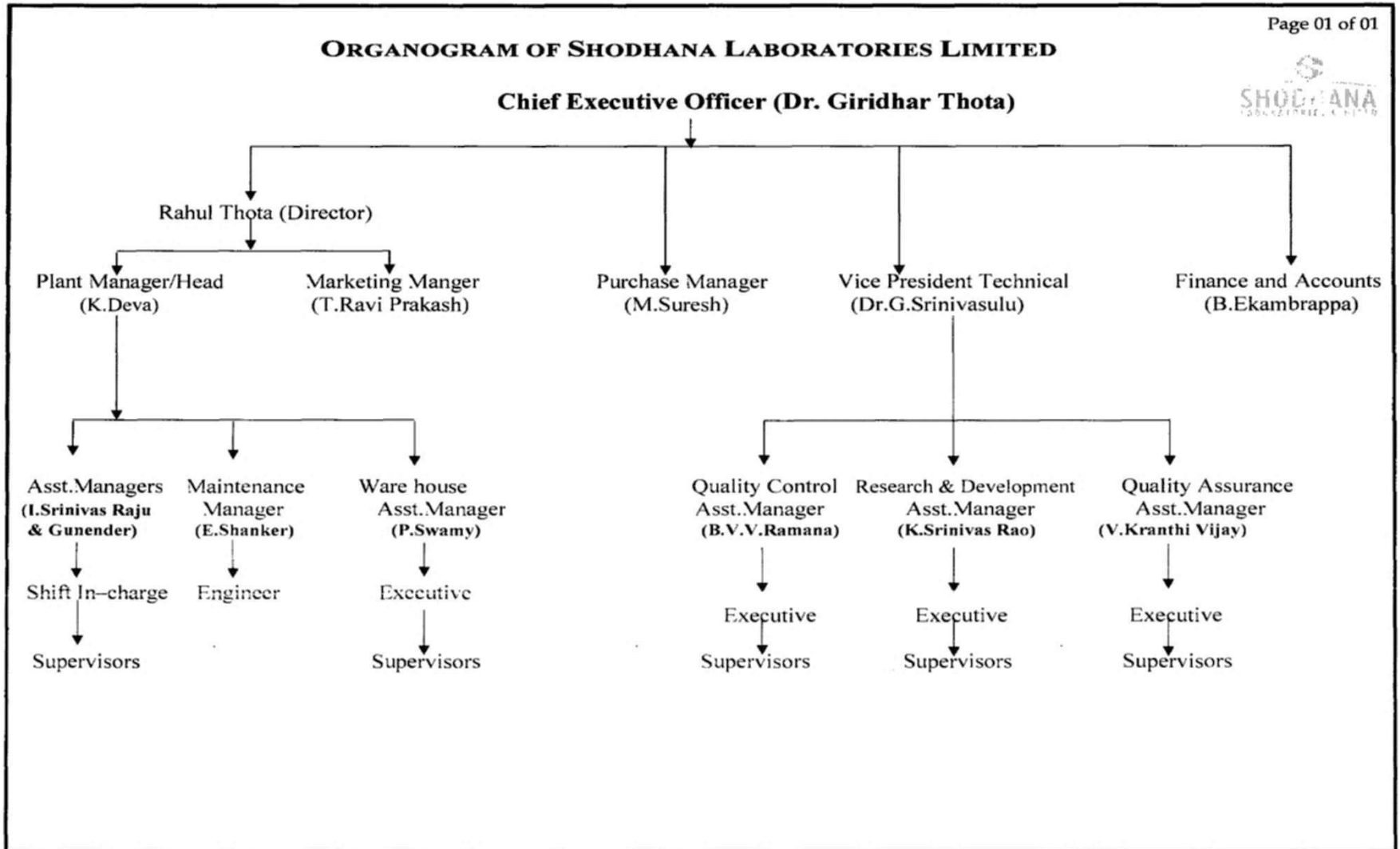


Clean Room Facility



INSIDE PRODUCTION BLOCK

Organogram Of Shodhana



Activities



- All the Subsidiary units of Shodhana are headed by individual Plant managers to cater all the production and administrative activities.
- The Quality Systems(Quality control, Quality Assurance) for Shodhana as well for all the other subsidiary facilities are all monitored by Vice President (Technical) who is also responsible for all the R&D activities.



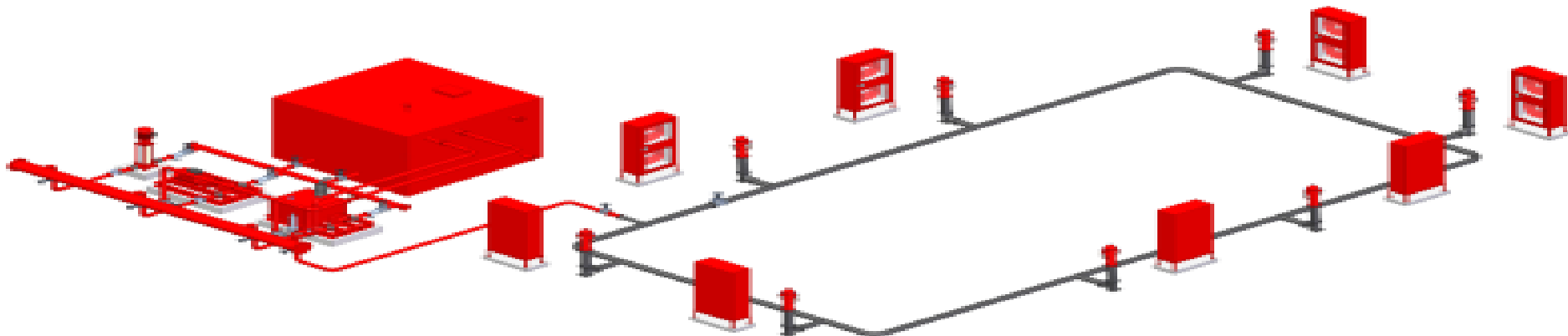
Infrastructure Of Subsidiary Units Of Shodhana

- **Medha** has 18 reaction vessels.
- **Sheethal** has 15 reaction vessels
- **Spica** laboratories has 25 reaction vessels



Fire & Safety

- The Entire Plant is equipped with FIRE HYDRANT System, about 7kg pressure water in System with Separate pump with backup Generator.



Safety System @ Shodhana

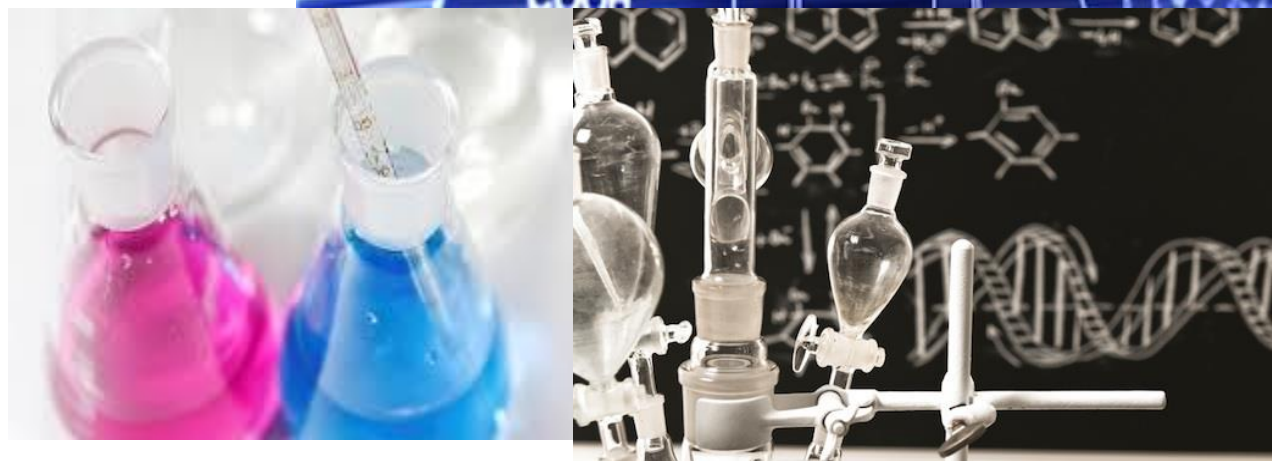
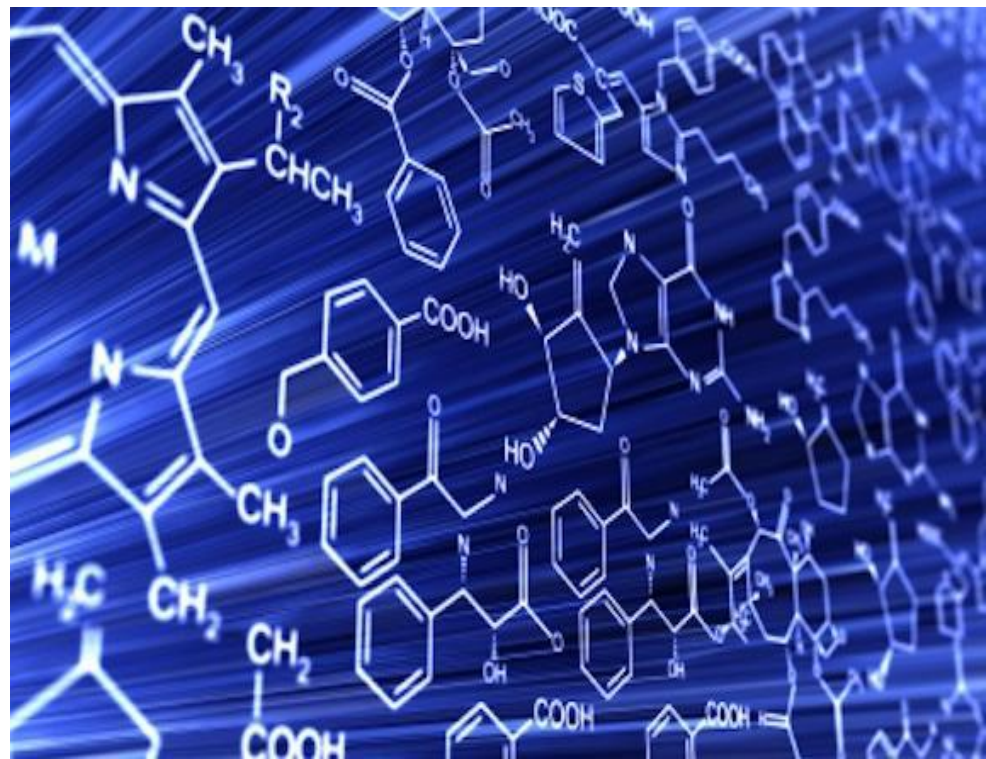
- Fire extinguisher
 - Carbon Dioxide Fire Extinguishers
 - Dry Chemical (ABC & BC) Fire Extinguishers
 - Mechanical FOAM

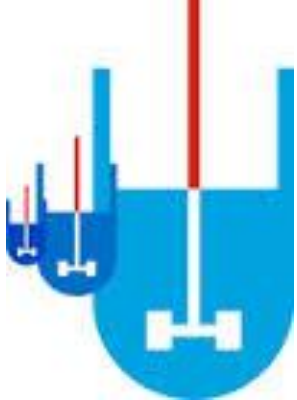


Hands - on experience in various chemical reactions

To name a few....

- *Reductions*
- *Resolutions & racemizations*
- *Oxidations*
- *Dieckmann Reaction*
- *Darzen's glycidic ester synthesis*
- *Alkylations*
- *Grignard reactions*
- *Cyclisation*
- *Amidations*
- *Fischer indole synthesis*
- *Aromatization*





Strengths and Capabilities

- *Shodhana has a well-equipped R&D center and an integrated Quality Control laboratory.*
- *A dynamic team comprising of about 30 scientists who work round the clock to develop new processes*

Custom Chemical Synthesis

- *The company has strong R&D capabilities for Custom Chemical Synthesis. Shodhana has already developed products for the US, Europe and Australian markets by scaling up from lab process to kilogram scale with quantities ranging from gram level to hundred kilograms.*
- *Besides successfully fine tuning several rough processes in the lab, Shodhana also has the capabilities to develop novel/alternate processes.*



Customer Profile

- *Shodhana has a status of preferred business partners / vendor for several companies*
- *It also has the preferred approved vendor status at various European Pharma companies to which it is supplying the intermediates.*
- *It supplies bulk actives to various countries like Korea, Japan, Brazil, Chile, Singapore, Indonesia, Malaysia, South Africa, Spain, Portugal, Latvia, Pakistan, Bangladesh, Mexico, Taiwan, Iran and Argentina besides the local domestic market.*
- *Shodhana is working closely with some US / European Pharma companies for developing and supplying new custom chemicals.*



Achievement & Accreditations

- ✓ *WHO GMP Certified*
- ✓ *ISO 9001: 2008 certified*
- ✓ *ISO 14001 : 2004 certified*
- ✓ *KFDA (Kora) - Audited and approved*
- ✓ *COFEPRIS (Mexico), TGA (Australia) - Audited and approved*



Regulatory Approvals & Accreditations

**GOVERNMENT OF TELANGANA
DEPARTMENT OF DRUGS CONTROL ADMINISTRATION, HYDERABAD**

L.Dis.No.3261/P&B/2014 Dated: 06-02-2015.

From: M.Amruth Rao, M.Pharm, L.L.M.,
Designated Officer, Deputy Director,
Licensing & Controlling Authority
Drugs Control Administration,
Vengalraonagar, Hyderabad – 500 038.

To: M/s.Shodhana Laboratories Ltd,
Plot No.24, 25 & 26, Phase-I,
I.D.A., Jeedimetla,
Hyderabad – 500 055.
Telangana State

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate – Regarding.


Ref: 1. Your letter dated: 10.09.2014
2. Joint inspection report dated: 16.12.2014 & 17.12.2014


-x-x-x-x-


With reference to your application cited, I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of CDSCO, Hyderabad and Drugs Control Administration, Telangana State vide reference 2nd cited.

This Certificate is valid for a period of Two years from the date of issue. This certificate is meant for Export of drugs only.

Yours faithfully,


DESIGNATED OFFICER, DEPUTY DIRECTOR,
LICENSING & CONTROLLING AUTHORITY





CERTIFICATE
The TÜV CERT Certification Body
of TÜV Rheinland Cert GmbH
certifies in accordance with
TÜV CERT procedures that

Shodhana Laboratories Limited
Factory: Plot # 26, Phase 1, IDA, Jeedimetla, Hyderabad – 500 055, India
Office: 705, Aditya Trade Centre, Ameerpet, Hyderabad – 500 016, India

has established and applies a quality management system for
**Process Design, Development, Manufacture and
Supply of Active Pharmaceutical Ingredients,
Intermediates and Fine Chemicals**

An audit was performed, Report No. 058447
Proof has been furnished that the requirements according to
DIN EN ISO 9001: 2000
are fulfilled.
The certificate is valid until 2011-07-06
Certificate Registration No. 01 100 058447

Cologne, 2008-09-19
First Certification: 2005

TÜV CERT Certification Body of
TÜV Rheinland Cert GmbH
www.tuv.com

- WHO -GMP - Approved (Government of India)
- ISO 9001:2008-Certified Quality Management System

DMFs and CEPs

- **CEP Granted for Carvedilol, Ondansetron HCl, Citalopram HBr , Duloxetine HCl**
- **CEP Filed & Under review for Rivastigmine base**
- **EDMFs filed for Escitalopram Oxalate, Rivastigmine Hydrogen Tartrate, Rivastigmine base (in 31 European countries)**
- **UK DMF for Citalopram Hydrobromide**
- **US DMF for Duloxetine Hydrochloride**
- **TDMFs (Taiwan) for Carvedilol , Duloxetine Hydrochloride, Carbidopa, Escitalopram Oxalate, Ondansetron Hydrochloride Dihydrate and Citalopram Hydrobromide**



US FDA

- *Facility Registered in US FDA*
- *US DMF*
 - *Duloxetine HCl (DMF No. 28398)*



FUTURE PLANS



- Scaling up of the reaction volume to another **250 kL** and expanding our manufacturing capabilities to cater to global demand.
- Construction of a new, dedicated, world-class **research facility** at Hyderabad.
- Has purchased about **4.5 acre land in Vizag Pharma city** for future expansion.

PRODUCT PROFILE



Bulk Actives

1. Carvedilol (CAS No: 72956-09-3)
2. Carvedilol Phosphate (CAS No: 610309-89-2)
3. Citalopram Hydrobromide (CAS No: 59729-32-7)
4. Duloxetine Hydrochloride (CAS No: 136434-34-9)
5. Escitalopram oxalate (CAS No: 219861-08-2)
6. Ondansetron hydrochloride dihydrate (CAS No: 103639-04-9)
7. Ondansetron (CAS No: 99614-02-5)
8. Rivastigmine hydrogen tartrate (CAS No: 129101-54-8)
9. Rivastigmine (123441-03-2)
10. Ranolazine (CAS No: 95635-55-5)
11. Mizolastine (CAS Number: 108612-45-9)
12. Carbidopa (CAS No : 28860-95-9)
13. Racecadotril (CAS No: 81110-73-8)

PRODUCTS UNDER SCALE UP

- **Nebivolol**
(CAS No:118457-14-0)
- **Dapoxetine /HCl**
(CAS No: 129938-20-1)
- **Tolterodine Tartrate**
(CAS No:124937-52-6)
- **Etofenamate**
(CAS No: 30544-47-9)



PRODUCTS UNDER DEVELOPMENT

- **Sildenafil (CAS No; 160970-54-7)**
- **Amtolmetin Guacil (CAS No. 87344-06-7)**
- **Darifenacin (CAS No: 133099-04-4)**
- **Repaglinide (CAS No: 135062-02-1)**
- **Tapentadol HCl (CAS No:175591-09-0)**
- **Lidocaine / HCl**
(CAS No: 137-58-6 / 73-78-9)
- **Carteolol hydrochloride**
(CAS No: 51781-21-6)
- **Fesoterodine fumarate**
(CAS No: 286930-03-8)
- **Valsartan (CAS No: 137862-53-4)**
- **Sitagliptin (CAS No: 486460-32-6)**
- **Lacosamide (CAS No:175481-36-4)**
- **Ziprasidone (CAS No:146939-27-7)**

CARVEDIOL INTERMEDIATES

- 1,2,3,9-Tetrahydro-4H-carbazol-4-one (CAS No.15128-52-6)
- 4-Hydroxy carbazole (CAS No. 52602-39-8)
- 4-(2,3-Epoxy propoxy) carbazole (CAS No. 51997-51-4)
- 2-(2-Methoxy phenoxy) ethyl amine (CAS No.1836-62-0) / HCL –salt (CAS No.18366-20)
- N-[2-(2-Methoxy phenoxy) ethyl] benzyl amine / HCL (CAS No.3246-03-5)
- 1,3-Cyclo hexane dione

CITALOPRAM HYDROBROMIDE / ESCITALOPRAM OXALATE INTERMEDIATES

- 4-[(4'-Dimethyl amino)-1-(4''-fluorophenyl)-1-hydroxy butyl]-3-(hydroxy methyl) benzonitrile hydrobromide (CAS No. 103146-26-5)
- Citalopram base (CAS No. 59729-33-8)
- 1-(4'-Fluoro phenyl)-1,3-dihydro isobenzofuran-5-carbonitrile (CAS No. 64169-67-1)
- 5-Bromo-1-(3-dimethyl amino propyl) –1-(4' fluoro phenyl)-1,3-dihydro isobenzofuran oxalate
- 3-(N,N'-dimethylamino)-1-propylchloride hydrochloride (CAS No. 5407-04-5)

Ondansetron hydrochloride dihydrate Intermediates

- 9-Methyl-1,2,3,9-tetra hydro 4H carbazol-4-one (Cas No. 27387-31-1)
- 3-[(NN-Dimethyl amino) methyl]-9-methyl-1,2,3,9-tetra hydro 4H-carbazol-4-one hydrochloride (CAS No. 119812-29-2).
- Ondansetron base (99614-02-5)

Duloxetine Intermediates

- 3-Dimethyl amino-1- (2-thienyl)-1-propanone hydrochloride
- RS-N,N-Dimethyl-3-hydroxy-3-(2-thienyl)-1-propanamine (CAS No.116817-84-6)
- S(-)-N,N-Dimethyl-3-hydroxy-3-(2-thienyl)-1-propanamine (CAS no.132335-44-5)
- RS-N,N- Dimethyl-3-(1-Naphthalenyloxy)-3-(2-thienyl)-1-propanamine oxalate
- S-(+)-N,N- Dimethyl-3-(1-Naphthalenyloxy)-3-(2-thienyl)-1-propanamine oxalate (CAS No.132335-47-8)
- (+) N-Methyl -3-(1-naphthyloxy)-3-(2-thienyl) propanamine hydrochloride (CAS No.136434-34-9)

Rosiglitazone intermediates

- 4-(2-(N-methyl-N-(2-pyridyl)amino)ethoxy)benzaldehyde – CAS No (122321-03-3)
- 2,4-Thiazolidinedione – CAS No. (2295-31-0)
- 5-[4-[2-[N-Methyl-N-(2-pyridinyl)amino]ethoxy]benzylidene]-2,4-thiazolidinedione- CAS No.(122320-74-5)

Ranolazine intermediates

- 2-chloro-N-(2,6-dimethylphenyl)acetamid - CAS No (1131-01-7)
- N-(2,6-dimethylphenyl)-2-(piperazin-1-yl)acetamide CAS No. (5294-61-1)
- 2-((2-methoxyphenoxy)methyl)oxirane - CAS No. (2210-74-4)

Rivastigmine intermediates

- a-(meta hydroxy phenyl) ethyl dimethyl amine (CAS No 105601-04-5) / HCl (CAS No. 5441-61-2)
- S (+)-a-(meta hydroxy phenyl)ethyl dimethyl amine (CAS No. 139306-10-8)
- Racemic Rivastigmine hydrochloride (CAS No. 105601-14-7)

Repaglinide

- N-Acetyl glutamic acid salt of S-(2-pyridino-phenyl)-3-methyl-1-butylamine

Valsartan

- L-Valine methyl ester hydrochloride (CAS No.6306-52-1)
- L-Valine benzyl ester hydrochloride (CAS No.2462-34-2)
- N-[(2'-Cyanobiphenyl-4-methyl)-(L)-Valine methyl ester Hydrochloride - CAS No (137863-89-9)

Darifenacin intermediates :

- 3-(S)-(+)-(1-carbamoyl-1,1-diphenylmethyl) pyrrolidine - L-(+)-tartrate CAS No (134002-26-9)
- 5-(2-chloroethyl)-2,3-dihydrobenzofuran – CAS No (943034-50-2)

Vildagliptin intermediate :

- (S)-1-(2-chloroacetyl)pyrrolidine-2-carbonitrile -CAS No (207557-35-5)

Sitagliptin intermediate :

- 3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine hydrochloride– CAS No (762240-92-6)

Nebivolol Intermediates

- (S)- 6-Fluoro-3,4-dihydro-2H-1-benzopyran-2-carboxylic acid (CAS Number : 129101-36-6)
- (R)-6-Fluoro-3,4-dihydro-2H-1-benzopyran-2-carboxylic acid (CAS Number :129101-37-7)
- (6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl)(piperidin-1-yl)methanone (CAS Number : 878208-57-2)
- 6-Fluoro-3,4-dihydro-2-oxiranyl-2H-1-benzopyran (Mixture of Two Diastereomers) (CAS No : 99199-90-3).
- 2-(benzylamino)-1-(6-fluorochroman-2-yl)ethanol
- N-Benzyl Nebivolol Hydrochloride

Intermediates Cont..

- N-Methyl-1-Naphthyl methyl amine hydrochloride (CAS No. 65473-13-4) (for Terbinafine and Butenafine)
- 2,3:4,5-Bis-O(1-methylethylidene)-b-D-fructopyranose(CAS No.20880-92-6) (Topiramate intermediate)
- N-Boc-Prolinamide (CAS No. 15761-39-4)
- L-Prolinamide (CAS No. 7531-52-4)
- L- Valinamide
- 2-Methyl cyclohexane 1,3-dione (CAS No 1193-55-1)
- 6-Chloro oxindole (Ziprasidone Intermediate) – CAS 56341-37-8
- (+)-O,O- Di-p-toluoyl-D-Tartaric acid -((+)-DPTTA) - CAS No 32634-68-7
- (-)-O,O-Di-p-toluoyl-L-Tartaric acid – ((-)-DPTTA)- CAS No 32634-66-5



OFFICE AND FACTORY ADDRESSES

Office :

*Shodhana Laboratories Limited.,
Office # 6-B, 6th Floor, Krishe' Sapphire,
Madhapur-Hi-Tech City Main Road,
Madhapur, Hyderabad - 500081.
Telangana- India.
Tel : +91-40-66463620 (5 Lines)*



Factory:

*Plot No:24,25,26, Phase-1, IDA,
Jeedimetla, Hyderabad
Telangana, INDIA-500055.
Tel: +91-40 - 23194182*





SUPPORTING PLANTS ADDRESSES

- *Sheetal Chemicals Pvt Ltd: Survey No 296/7/9 IDA, Bollarum Hyderabad-502325*
- *Medha Dye Chem: Plot No.169& 171 Phase-III, Jeedimetla Hyderabad-500055*
- *Spica Laboratories Pvt Ltd: Survey. No.270/C2, S.Lingotam Choutuppal (Mandal) Nalgonda Dist*

Thank you...

