

Elixir Pharma Chem Private Limited



Introduction

- We are a development, business.
- We started operations in July 2010.
- We are WHO GMP approved, and our manufacturing site is located at Naroda GIDC, Ahmadabad, Gujarat .
- We have commercialized 6 APIs and 20 KSMs (Key Starting Materials). All four APIs are developed in house and are completely backward integrated. Additionally, 9 more APIs and 13 KSMs are under development, and we plans to commercialize them in due course.
- We are supplying our products to 8 out of top 50 generic companies worldwide like Sun Pharma, Torrent, Glenmark, Teva, Dr Reddy's, Mylan, Hikma, MSN etc.
- We generate 60% of its revenue from domestic market and rest 40% comes from international markets.
- We have exported our products to more than 30 countries worldwide located in semi regulated markets.
- Our major International markets include Mexico, Russia, China, Taiwan, Vietnam, Turkey, Indonesia and SAARC countries.

Key Milestones

| | |
|--------|--|
| 2009 : | Started construction & Development of Naroda GIDC Site Completed in house development of Nalidixic Acid and Glibenclamide |
| 2010 : | Commissioning of 50 KL manufacturing plant Received State GMP and ISO 9001, 14001 and 18000 Certificate Commercial Production of Nalidixic Acid and Glibenclamide started First export to Middle East and SAARC Nations |
| 2012 : | WHO GMP Certificate received |
| 2014 : | Received CEP of Nalidixic Acid from EDQM Received CEP of Glibenclamide from EDQM |
| 2020 : | Manufacturing Capacity expanded to 78 KL Installed MME and became a Zero Discharge Manufacturing Unit |
| 2024 : | New R&D and ADL Block with a 10 KL Pilot Plant Under construction, expected to be up and running by Mid of 2024 |



Infrastructure

PRD and Kilo Lab

- 1500 sq ft
- 4 Fume Hoods with utilities
- 20, 50 , 100 and 200 lit all glass assemblies
- VTD, Centrifuge

Manufacturing Plant

- 32,000 sq ft
- WHO GMP facility with HVAC System & 1 Clean Room of Class 100,000
- Reactor volume of ~78 KL
- Temperature
- -5 0C to + 300 0C
- Pressure
- 6 kg/cm2 (6 bar)
- Production Capacity ~200 MT/Year

QC Lab

- IR, UV-Vis Spectrophotometers
- 3 HPLCs with UV & PDA
- 2 GCs/GCs with Head Space
- Auto-titrator; KF; Melting Point
- Microbiology Lab
- Stability Chambers
- Easy Access to NMR, LC-MS, GC-MS, XRD, AAS, ICP

Details of Equipment's

| Sr. | MOC | Volume (lit) | Number | Total (lit) |
|-----|--------------|--------------|-----------|--------------|
| 1 | GLR | 3000 | 3 | 9000 |
| 2 | GLR | 6300 | 3 | 18900 |
| 3 | SSR | 400 | 1 | 400 |
| 4 | SSR | 500 | 1 | 500 |
| 5 | SSR | 1500 | 1 | 1500 |
| 6 | SSR | 2500 | 6 | 15000 |
| 7 | SSR | 3500 | 6 | 21000 |
| 8 | SSR | 5000 | 1 | 5000 |
| 9 | SSR | 7000 | 1 | 7000 |
| | Total | | 23 | 78300 |

| Sr | Unit Operation | Equipment | Type | Number |
|----|----------------|----------------|-----------|--------|
| 1 | Filtration | Centrifuge | 48" SS | 2 |
| | | Centrifuge | 48" MSRL | 1 |
| | | Centrifuge | 36" SS | 5 |
| | | Centrifuge | 36" MSRL | 1 |
| | | Sparkler | 16-24" SS | 2 |
| 2 | Drying | Tray Drier | 36 Tray | 1 |
| | | Tray Drier/VTD | 48 Tray | 3 |
| | | ANFD | 2000 ltr | 1 |
| | | RCVD | 1500 ltr | 2 |
| 3 | Milling | Air jet Mill | 50 kg/hr | 1 |
| | | Multi Mill | 50 kg/hr | 2 |
| | | Pulverizer | 50 kg/hr | 1 |
| 4 | Sifting | Sifter | 50 kg/hr | 1 |
| | | Sifter | 100 kg/hr | 1 |
| 5 | Blending | Blender | 1000 ltr | 1 |

Utilities

Cooling Water (150, 280, 300 TR)

Chilling Plant (20 & 50 TR)

Hot Oil/Thermic Fluid System (400,000 kcal/hr)

Compressed Air -24 & 136 CFM

Vacuum-0.5 Torr

DG Set (200 KVA)

Steam Boiler –1500 Kg/hr

Process Water (10 KL)

Purified Water/RO Water (1KL/Hr)

Scrubbing System-3000 CFM

Nitrogen Generation Plant (99.5% purity)-20 Nm³/h

MEE + Solvent Stripper + ATFD-30 Kl/Day

Quality, EHS and Safety System

- ICH Q7 Compliant Operations regularly audited by our customers
- WHO GMP/State GMP Approved Manufacturing Facility with GLP approved Lab
- ISO 9001:2015, ISO 14001:2015 & ISO 45001:2018 Certified Company
- Well Defined Quality & EHS Policies in place which are endorsed by Top Management
- DUNS No-916131223
- FEI No-301007075665
- SPOR No-100050385

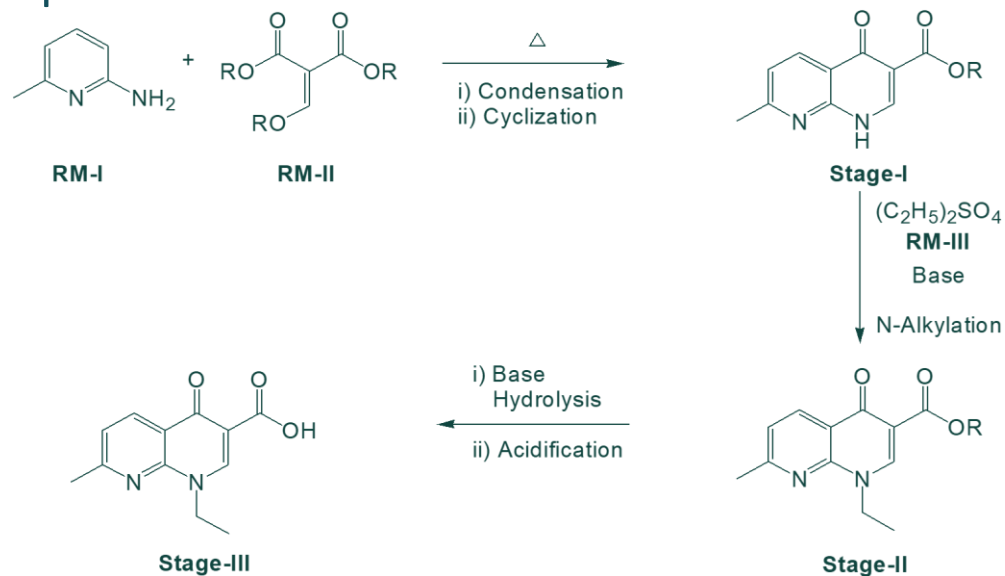
Reaction & Process Capabilities

- Condensation Reaction
- Cyclization Reaction
- N-Alkylation Reaction
- Acid-Base Hydrolysis
- Decarboxylation Reaction
- Addition Reaction
- Hofmann Rearrangement
- Chiral Chemistry

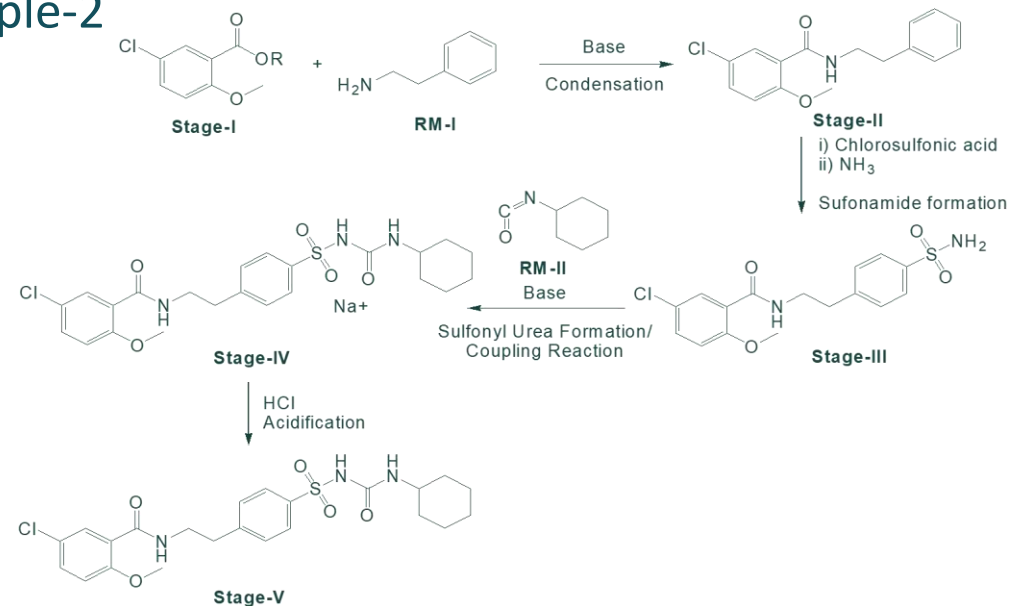
- Racemization of Chiral Isomers
- High Temperature Reaction
- Sulfonation
- Oxidation
- Sulfonyl Urea formation / Coupling Reaction
- Cyclic imide formation
- Bromination/Chlorination
- Esterification

- Nitration
- Hydrogenation
- Reduction
- Friedel Craft Alkylation/Acylation
- Protection/Deprotection (Boc Chemistry)
- Cryogenic Reactions
- Diazotization

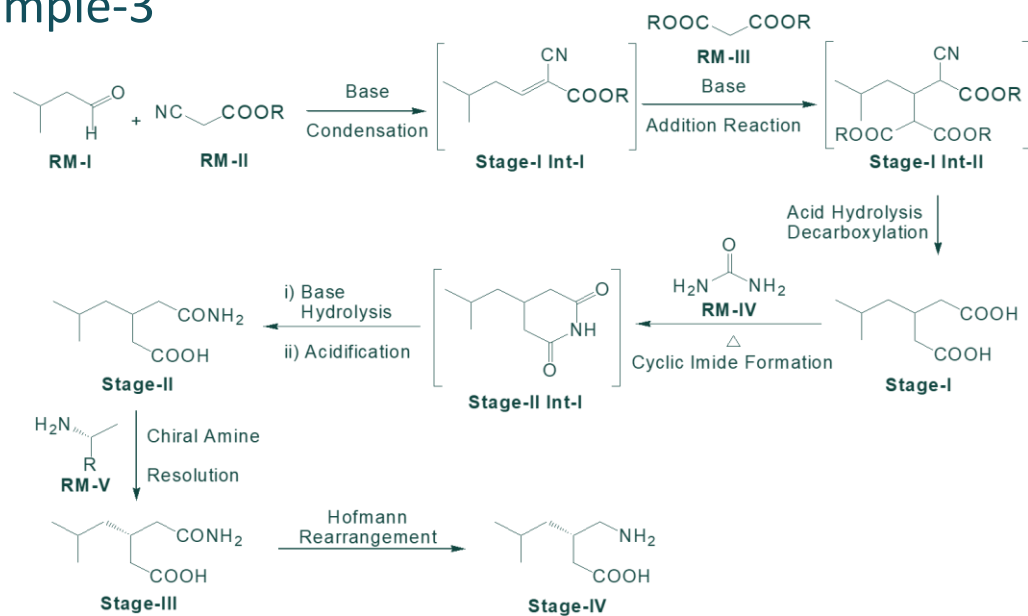
Example-1



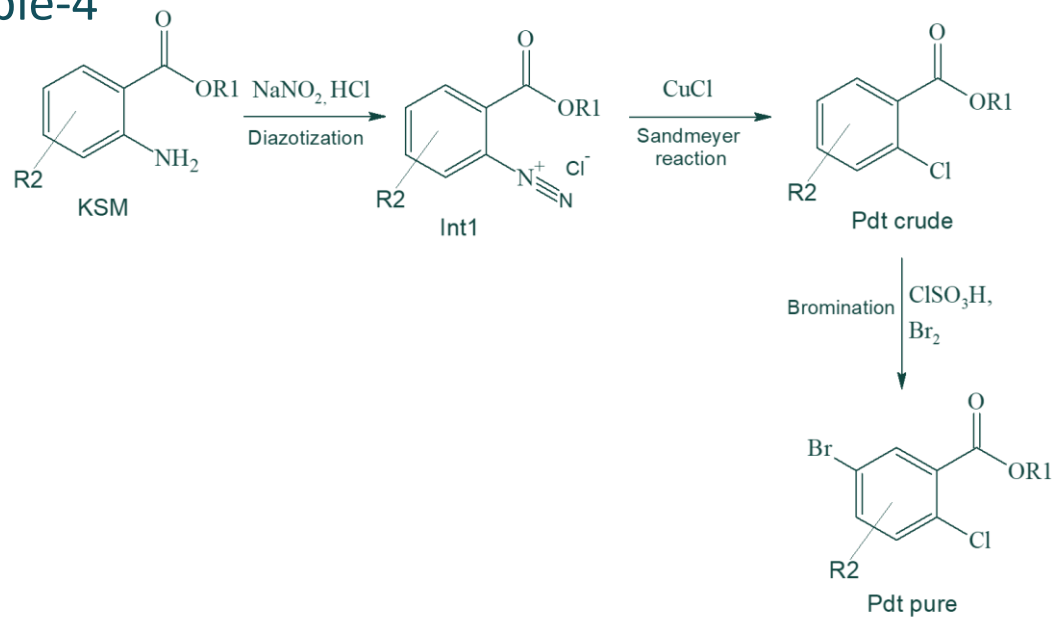
Example-2



Example-3



Example-4



Our Commercial APIs

Nalidixic Acid : IP/EP/BP/USP, DMF, Written Confirmation/WC Available

Glibenclamide : IP/BP/EP/USP, DMF, CEP and Written Confirmation/WC Available

Pregabalin : IP/IH/EP/USP DMF Available

Carbamazepine : IP/BP/EP/USP, DMF Available, CEP Submitted Oct 24

Oxcarbazepine : IP/EP/USP

Linagliptin : IH COPP/DMF Available

Pinaverium Bromide : IH DMF Available

Rosuvastatin : IP/BP/EP/USP

Glimepiride : IP/BP/EP/USP, DMF Available, CEP Submitted Oct 24

Lidocaine : IP/BP/EP/USP

Lidocaine HCL : IP/BP/EP/USP

Under Development APIs

Empagliflozin

Rivaroxaban

Zolpidem

Trelagliptin

Omarigliptin

Ketoprofen

Finerenone

Mirogablin

Elobixibet

Itopride

Commercial Intermediates/KSMs

| |
|---|
| Ethyl chloro[(4-methoxyphenyl)hydrazono]acetate |
| Ethyl (2Z)-chloro[(4-methoxyphenyl)hydrazono]acetate |
| Iminostilbene Carbonyl Chloride |
| 3-[(3-Amino-4-methylaminobenzoyl)pyridin-2-ylamino] propionic acid ethyl ester |
| 3-(Pyridin-2-ylamino)-propionic acid ethyl ester |
| 4-(Methyl amino)-3-nitro Benzoic acid |
| 5-bromo-2-chloro-4'-ethoxydiphenylmethane |
| (5-Bromo-2-chlorophenyl)(4-ethoxyphenyl)methanone |
| 5-Bromo-2-Chlorobenzoic Acid |
| 5-Chloro-2-methoxy-n-[2-(4 sulfamoylphenyl) Ethyl] benzamide |
| N-{2-[4-(aminosulfonyl)phenyl]ethyl}-3-ethyl-4methyl-2-oxo-2,5-dihydro-1H-pyrrole-1-carboxamide |
| 2-(chloromethyl)-4-methylquinazoline |
| 8-Bromo-3-methyl-xanthine |
| 8-Bromo-7-(2-butyln-1-yl)-3-methylxanthine |
| 8-Bromo-7-but-2-ynyl-3-methyl-1-(4-methyl-quinazolin-2-ylmethyl)-3,7-dihydro-purine-2,6-dione |
| 3-Isobutylglutaric acid or CMH Diacid |
| RS-(3-Cabamoylmethyl)-5-Methylhexanoic Acid |
| R-(-)-3-(carbamoylmethyl)-5-methylhexanoic acid or R-Amide |
| Dibenzo-[b,f][1,4]-thiazepin-11(10H)-one (DBT or DTO) |
| 6-Methyl-2-(4-methylphenyl)-imidazo[1,2-a]pyridine |

Thank You