

Development & Scale-up Capabilities

Hikal's process development labs provide a complete range of support services which allow smooth and rapid technology transfer to our commercial facilities. We operate under the highest global quality standards. Hikal's range of scale up, launch and commercial plants covers the entire cycle from pre development through development to the commercial launch of intermediates / API. Our primary focus is on design, optimization and implementation of commercial processes.



Kilo Laboratory (Bangalore & Pune, India)

Our cGMP Kilo laboratory (class 100,000) allows the scale up of processes developed at our R&D labs or tech transferred from our customers. We offer process development from laboratory to production scale and development of innovative and cost-effective routes for the synthesis of intermediates/APIs

- 20 Liter Glass Reactors
- 50 Liter Glass Reactors
- 20 Liter high vacuum distillation unit
- Heating /Cooling system - 90°C to +200°C
- Pressure Nutsche Filter, Centrifuge
- Vacuum Tray Dryer
- Miller & Sifter



Pilot Plant (Bangalore, India)

Hikal's scale up plant manufactures batches for pre-clinical studies & clinical trials to validation quantities for APIs

- cGMP compliant facility
- Capable of manufacturing advanced intermediates & APIs
- Flexible equipment configuration to suit product requirements
- Reactor Volume: 2.95 m³
- 5 Reactors of capacities ranging from 0.1 m³ to 1.2 m³ of Stainless Steel, Glass Lined & Hastelloy MOC





Launch Plant (Bangalore, India)

- cGMP compliant facility (Class 100,000 area)
- Suitable for producing advanced intermediates and APIs
- Flexible equipment configuration to suit product requirements
- Reactor Volume: 26.3 m³
- Number of reactors: 13
- MOC: SS316, GL
- Reactor size: 0.25 - 4 m³
- Independent sections for:
 - Hydrogenation (15 Kg/cm², Capacity - 100 Liter)
 - Cryogenic Reactions: -60°C with Huber System
 - Cracking Reactions: up to 270°C
 - High Pressure and High Temperature Reactions (15 kg/cm² and 250°C)
 - High Vacuum Distillation (1 Torr) with 5m packed column and magnetic reflux divider
- Down Stream Processing
 - Agitated Nutsche Filter Dryer (ANFD) of Glass lined / Hastelloy MOC
 - Top and Bottom discharge Halar Lined Centrifuges
 - Rotary Cone Vacuum Drier (RCVD)
 - Rotary Vacuum Paddle Drier (RVPD)
 - Vacuum Tray Dryer (VTD)
 - Air Tray Dryer (ATD)
 - Finishing areas with Milling & Sifting Facility



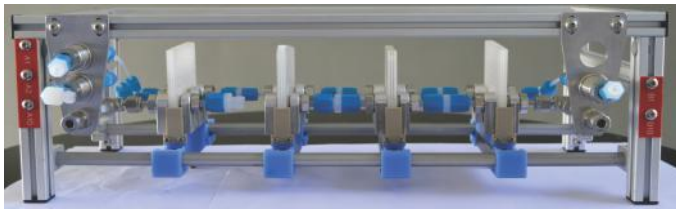
Multipurpose Pilot Plant (Bangalore, India)

Our multipurpose pilot plant offers scale-up capabilities and can provide validation and launch quantities from US FDA site for advanced intermediates and APIs

- cGMP compliant facility
- Class 100,000 manufacturing area
- Reactor Volume: 7.71 m³
- Number of reactors: 14
- Reactor size: 63-1000 Liter
- Hydrogenator (SS316): 500 Liter
- Centrifuges: 18 inch & 24 inch (SS316/Halar coated)
- Nutsche Filters: 500 Liter
- Nauta Dryer: 600 Liter
- Rotary Vacuum Dryer: 250 Liter
- Customization of PSD
- Multimill: 150 Kg/hr
- Airjet mill (microniser): 10 Kg/hr
- PLC Controlled Operation

Biocatalysis at Hikal

- Enzymatic Process Development / Optimization
- Commercialization of Enzymatic Chemistry



Process Intensification Laboratory

Our process intensification lab caters to multiple process intensification requirements with state-of-the-art equipment

- Continuous Stirred Tank Reactor (CSTR)
 - Capacity: 2 Liter
 - MOC: Glass
 - Can be used to estimate the key unit operation variables to reach a specified output
 - Carrying out two phase reactions
 - Liquid - Liquid Reactions
 - Gas - Liquid Reactions
 - Solid - Liquid Reactions
- Corning Advanced Flow Reactor (AFR)
 - Flow Rate: 30 -200 ml/min
 - Capacity: 30 -150 TPA
 - Can be used effectively for heterogeneous and homogenous reactions
 - Decreases waste generation & energy consumption
 - Suitable for different types of reactions: Hydrogenation, Nitration, Oxidation Bromination, Chlorination, Grignard reaction & Polymerization

Analytical Instruments

- HPLC
- LCMS
- GC
- GCMS
- UPLC
- NMR 400 MHz
- Stability Chambers
- Malvern Particle Size Analyzer
- Microbiology Analysis



- Pinch Tube Reactor
 - MOC: Glass/SS316
 - Used for carrying out continuous two phase reactions
 - Liquid - Liquid Reaction
 - Gas - Liquid Reaction
 - High Efficiency set up
 - Successfully established for APIs
- Vapor Phase Reactor
 - MOC: SS316
 - For carrying out chemical reactions with efficient control as needed over a vapor phase
 - Used for Ammoxidation reaction (Production of Nitriles using Ammonia & Oxygen)

High Potent Facility (Pune, India)

- Capable of handling Highly Potent compounds with OEL value of approximately $10 \mu\text{g}/\text{m}^3$
- Suitable for lab development work
- About 100 g material can be prepared



Solid State Lab*

Features:

- Polymorph screening and optimization
- Particle size engineering
- Crystallization Process development
- Solid State Characterization



Spray Dryer

Instruments / equipment:

- pXRD
- DSC, TGA
- Hot stage microscope
- Spray Dryer
- Turbidity Probe, FBRM probe
- Jet mill



pXRD



Jet mill

*Solid State Lab to be operational by February 2018

Chemistry Capabilities

- Ammoxidation
- Asymmetric Hydrogenation
- Asymmetric Desymmetrization
- Carbon Disulfide Chemistry
- Continuous Processing
- Cryo Reactions especially using BuLi
- Cyanide Reactions
- Diazotization
- Enzymatic Reactions
- Free Radical / Ionic Halogenation especially Bromination with almost complete recovery of bromine
- Grignard Reactions
- High Temperature Cracking (DCPD to CPD)

For more information, contact us at:

USA: brain_treco@hikal.com | Japan: toshiaki_hashimoto@hikal.com | Europe & India: yogesh_jain@hikal.com