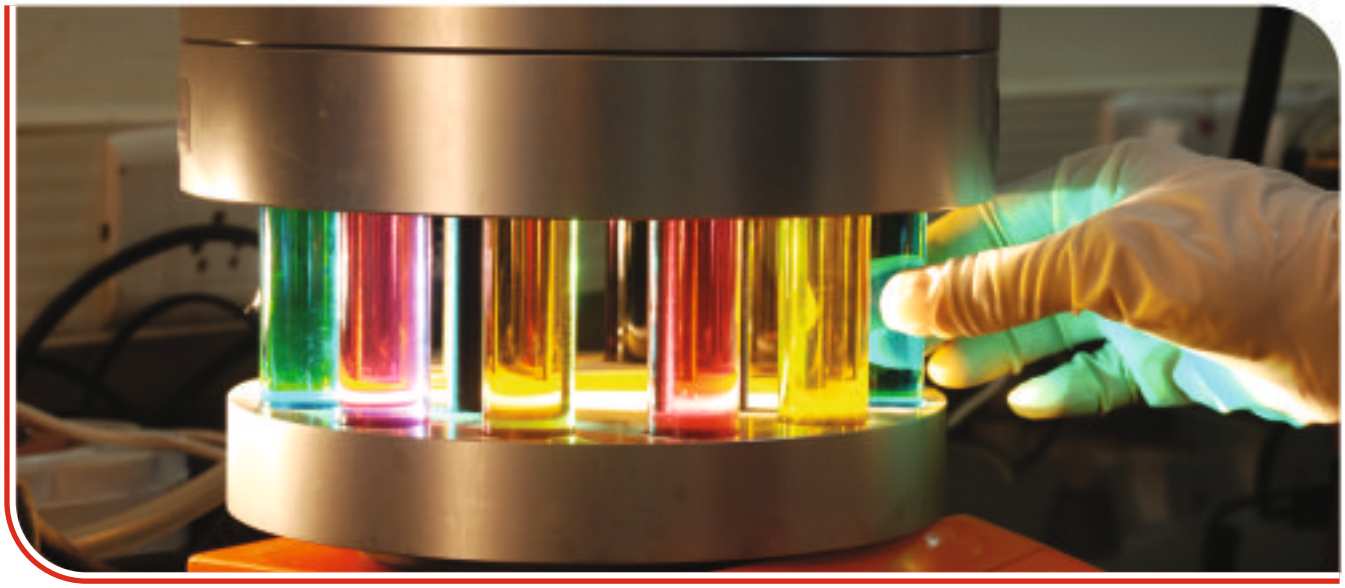
Inogent

Excellence through

Innovation



Providing Scientific Edge

The capabilities and expertise of our scientists match the most exacting International Standards. Backed by outstanding academic credentials, core domain knowledge and proven track records, they bring rich industry expertise and global experience to our service offering.

Enduring Partnerships

We are committed to maintaining open and transparent communication that fosters long term partnerships. We recognize that each client and program is as unique as the products they aim to create. We take the time and effort to understand preferences and working styles, so our clients maximize the benefits from collaboration.

Complete Confidentiality

We fully comprehend the importance of confidentiality and protection of intellectual property. Our clients trust us completely with their proprietary information. Whether it is a FTE (Full Time Equivalent) based partnership of process R&D or a FFS (Fee for Service) based custom manufacturing program, sensitivity to client confidentiality permeates all our operations. Our watertight systems encompass people, process and policies.

Smooth Program Management

We focus on the delivery and the deliverables. We have developed comprehensive reporting and monitoring systems that keep clients in close touch with their programs. Our rigorous, result oriented approach includes optimum staffing, critical analysis of dependencies, proactive regulatory compliance policies and strategies for risk mitigation. A project manager serves as a single point interface, making sure the program is progressing on the desired path.

Contract Research & Manufacturing

Services

Inogent provides process development and optimization services across multiple therapeutics and chemistry disciplines to create robust and cost effective processes for clients. Inogent has created expertise in chiral synthesis, enzymatic process, preparation of nucleosides, protected amino acids in addition to a host of other synthetic reactions. Our services focus on high quality, timely deliveries and include:

Contract Research, Process R&D and Analytical

- Route identification and synthesis on lab scale
- Process development, optimization and validation
- Analytical method development and validation
- Impurity profiling for API and key starting materials
- Polymorph identification and quantification
- Stability studies

Manufacturing

- Custom synthesis from Kilogram to multi-ton quantities (GMP/non-GMP)
- Manufacture of NCEs and Intermediates

Capabilities

Chemistry Capabilities

- Alkylation & Acylation
- Aminations (Reductive / Chiral)
- Asymmetric hydrogenations (Catalytic, Hydrogen transfer)
- Chiral synthesis
- Grignard reactions
- Organometallics (Alkyl lithium / LDA)
- Reductions (LAH / DIBAL / Borohydride)
- Biocatalytic reactions (Asymmetric reduction, Resolutions)
- Resolutions (Kinetic, Diasterioselective)

- Boronic Acids (Specialists in trans-propen-1-ylboronic acid synthesis)
- Suzuki coupling
- Nitration
- Cyanation
- Phosgenation (Triphosgene)
- Thiophosgenation (Small scale)
- Diazotization
- Azidation
- Sulfonation
- Halogenations

Analytical Capabilities

- Analytical method development
- Degradation studies
- Physical & chemical characteristics
- Standard test procedures for:
  - Raw material, intermediates and finished product
  - In-process controls
  - Cleaning methods
- Impurities isolations by preparative HPLC/SFC
- Characterization data for impurities and reference standards
- Report for "Cut-Off "/ "Carry over studies" data with scientific rationale
- Impurity profiling for key starting materials and final product.
- Report on Holding study (Wet & packaged)
- Report on indicative stability studies
- Evaluation of reference standard (Qualification)
- Stability studies (ICH conditions)
- Analytical method qualification / validation report for final product & key starting materials (KSMs)
- Analytical method transfer
- Physical state characterization & polymorph screening

Process R&D and Custom Chemical Synthesis (CCS)

Process R&D

- Route scouting
- Feasibility studies
- Optimization
- Synthetic demonstration
- Large scale manufacturing
- Salt screening
- Enzymes screening
- Polymorph studies

CCS

- Process development & Optimization
- Piloting and Scale-up
- Validations
- Impurities – Identification, characterization and synthesis
- cGMP manufacturing

Resources

- Total Reaction Volume: 1,40,900 L
- 6 manufacturing Blocks A-F: Varied capacities from 20 L to 6000 L
- Reactors: All glass, glass lined, SS & Hastelloy reactors
- Hydrogenation capabilities: 100 L to 1000 L at 20 bar and large scale column chromatography
- Class 100,000 cleanroom, kilolabs and powder processing area
- Stability chambers for conducting stability studies at all conditions

Major Utilities

Utility	Capacity
Steam @ 3.5 kg/cm^2	3 ton/hr, 5 ton/hr* & 400 kg/hr
Hot Oil	2 Lakh Kcal/hr, Thermo Pack
Power Back-up	3 nos. DG Sets (380, 380, 1165 KVA)
Chilled Brine (-10^0 & -30^0 C)	130 TR (Aqueous MeOH)
Chilled Water (5^0 C)	110 TR (Vapor absorption machine)
Cooling Water	900 TR cooling towers
Nitrogen	PSA N_2 plants (20+15 Nm^3/hr)
Compressed Air	430 CFM
DM Water	5 m^3/hr
Purified Water	2.5 m^3/hr plant complying to USP-30
Softener Plant	5 m^3/hr
Liquid Nitrogen (-65^0 C)	5 kl

* Under process

Differentiators

- Non-conflicting business model. No in-house development programs
- Synthesizing variety of complex organic molecules in multiple steps for Pharma/Fine Chemicals/ Electronic Industry from grams to MT
- One site process development, scale-up and manufacturing facility ensuring speed, quick tech transfer & efficiency
- Ability to invest in infrastructure/ capacity and expand as needed to meet client expectations.
- High quality product under practical and safe manufacturing conditions
- On-time delivery in full (OTIF)

Facilities

Manufacturing Infrastructure – A snap shot

Description	Block	Number of reactors	Volume
Kilo Labs	Block-D	10	1200 L
Pilot Plant	Block-C	13	9300 L
Large Scale Manufacturing ➢ Intermediate Area ➢ Cleanroom Module-3 ➢ Powder Processing	Block-A Block-B	28 08	55000 L 19900 L
High Pressure & Special Reactions ➢ High Pressure Reactions ➢ Supporting Reaction & Work-up ➢ Column Chromatography	Block-E	12	38100 L
Custom Synthesis ➢ Kilo Labs -2 nos ➢ Pilot Plant Module ➢ Cleanroom Module – 1 no. ➢ Powder Processing Area	Block-F	23	17500 L
Total	**6**	**94**	**140,900 L**

Kilo / Pilot Scale

Description	Capability	Capability
Name	Block-D	Block-C
Purpose	Piloting & Scale-up of API/ CCS intermediates	Piloting & Scale-up of API / CCS intermediates
Material of Construction	Glass Lined, All Glass, Stainless Steel	Glass Lined & Stainless Steel
Capacity Range	20 L to 250 L	50 L to 2000 L
Major process equipment	Reactor, Centrifuge, Dryer, Nutsche Filter, Distillation Units	Reactor, Centrifuge, Dryer, Nutsche Filter
Supporting equipment	Miller & Sifter	Miller & Sifter
Utility Capabilities	Vacuum, Hot oil, Chilled Water & Chilled Brine -70^{0} to $+200^{0}$ C	Vacuum, Hot oil, Chilled Water & Chilled Brine -70^{0} to $+200^{0}$ C
Total Reactors & Volume	**10 nos. & 1200 L**	**13 nos. & 9300 L**

Large & Commercial Scale

Description	Capability	Capability
Name	Block-A	Block-B
Purpose	Manufacture of large scale APIs & Intermediates	Manufacture of large scale APIs & Intermediates
Material of Construction	Glass Lined & Stainless Steel	Glass Lined & Stainless Steel
Capacity	500 L to 4000 L	1600 L to 4000 L
Major process equipment	Reactor, Centrifuge, Dryer, Nutsche Filter	Reactor, Centrifuge, Dryer, Nutsche Filter
Supporting equipment	Miller & Sifter	Miller & Sifter
Utility Capabilities	Vacuum, Hot oil, Chilled water & Chilled Brine (-70° to +200°C) Nitrogen, Compressed air, DM water and Purified water of USP 30	Vacuum, Hot oil, Chilled water & Chilled Brine (-30° to+200°C) Nitrogen, Compressed air, DM water and Purified water of USP 30
Finished Product Processing	Class 100,000 cleanrooms – 2 Modules	Class 100,000 cleanrooms – 1 Module & Powder Processing Area
Total Reactors & Volume	**28 nos. & 55000 L Volume**	**9 nos. & 19900 L Volume**

Special Reactions Scale-up

Description	Capability
Name	Block-E
Purpose	Carrying out scale-up of special reactions/hazardous reactions
Material of Construction	Glass Lined, Stainless Steel & Halar lined Reactors
Capacity	Autoclaves, Cryo reactors, Halar lined reactor 3000 L to 6000 L Capacity
Major Process equipment	Reactors, Centrifuge, Nutsche Filter & Autoclaves
Supporting equipment	Scrubbing system
Utility Capabilities	Vacuum, Hot oil, Chilled Water & Chilled Brine -70° to +200° C
Total Reactors & Volume	**12 nos. & 38100 L Volume**

Custom Synthesis & API / Intermediates

Facility	Block-F
Kilo Lab Modules - 2 no.	8 Reactors
Pilot Plant Module	13 Reactors
Cleanroom Module	2 Reactors
Powder Processing	-

Two Kilo Lab Modules - 8 Reactors

- Class 100,000
- AGR, SSR, Hast-C, GLR
- 20 - 200 L Capacity
- -70° to + 200° C
- Single fluid utility

100 g - 1 Kg synthesis of final API

Cleanroom - 2 Reactors

- Class 100,000 for processing of final API
- 500 L GL Crystallizer
- CF, Sparkler, RCVD, VTD
- Purified water, USP 30

1 Kg - 50 Kg synthesis of final API

Pilot Plant - 13 Reactors

- 5 Micron filtered area
- GLR, SS reactors
- 250 – 3000 L capacities
- 13 reactors with 15700 L
- -70° to +200° C
- CF, NF, VTD, TD

1 Kg - 100 Kg synthesis of Intermediates

Powder Processing

- Class 100,000
- Independent of wet area
- Blender, Miller, Sifter etc
- Packing area, Wash area

Independent powder processing up to 100 Kg/batch

Other Capabilities & Systems

Equipment	Specifications
Packed Column - Solvent Recovery (Purification of Methanol, IPA, Acetone etc)	SS 304, 450 mm Dia, 8000 mm height
SS Reactor, Re-boiler - Solvent distillation	SS 316, 3200 L
Jacketed Column – Column chromatography	700 L Volume
Jacketed Column – Column chromatography	220 L Volume
SS 316 Column – Column chromatography	70 L Volume

Technology Transfer - An Integral Part of Development

Proposals

- Identifying major risks / scale-up capabilities
- Estimation of manufacturing expenses
- Estimation of timelines with available tech-pack
- Identifying new infrastructural requirements

Development

- Being integral part of development
- Identifying critical parameters & initiating "what-if" studies
- Identifying likely scale-up issues & planning experiments for further studies
- Quality & safety risk assessment

Scale-up / Piloting

- Hazop study & risk assessment as mandatory task
- Preparation of PFD & PID for all stages.
- Equipment mapping in discussion with pilot plant & manufacturing
- Initiate technology transfer as per the check list.
- Being part of execution team for piloting along with R&D
- Special Focus on solvent recovery/any other opportunities of cost savings

Closure

- Making campaign report
- Identifying improvement opportunities for further campaign
- Capturing learning at each phase of project as summary

Safety, Health & Environment

We at GVK BIO consider Safety, Health and Environment as an integral part of our business operations. We are committed to taking utmost care of employees, local community, preserving & protecting environment by exercising safe work conditions.

Safety Systems:

- Emergency management plan (EMP)
- Work permit systems
- All statutory approvals
- Training modules for each activity

Safety Infrastructure:

- Fire hydrant system for entire site
- Full-fledged biological treatment and reverse osmosis plant
- "Zero liquid discharge" facility
- OHC with full-time medical officer.

"Zero liquid discharge" facility

GMP Compliant Operations

Our quality assurance department, supported by regulatory affairs and quality control groups, monitors the work performed in our facility. All projects related to APIs are managed by comprehensive GMP compliant systems. The GMP system is developed using references from the FDA, ICH guidelines, USP and CFR.

Quality Policy

Inogent Laboratories is committed to:

- Consistently meeting or exceeding quality requirements of customers
- Continual improvement of systems and processes
- Ensuring proper training of employees for better performance
- Recognizing that quality is not just another goal, but a necessity for sustained growth

Intellectual Property

Inogent follows a 'no-conflict' research model. Any intellectual property generated during the course of a project belongs to the client, thereby protecting the long term business interests of the client.

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