

Contract Manufacturing Solutions



GVK BIO offers long term Contract Manufacturing Solutions in development, validations, DMF filing, manufacturing of New Chemical Entities (NCEs), Key Starting Materials (KSMs), Active Pharmaceutical Ingredients (APIs) and Intermediates. We have flexible business models to support various client needs:

- a. Process optimisation, technology transfer, validations and DMF filing followed by manufacturing upon commercialization
- b. Technology development, validations, DMF filing support and commercial manufacturing
- c. Technology absorption and commercial manufacturing

Our manufacturing expertise is designed to handle a wide range of operating conditions with flexible scales. Our commercial manufacturing facility is co-located with our pilot plant, providing end-to-end API solutions from feasibility phase in R&D to commercial launch. Our process development, technology transfer and commercial execution teams collaborate seamlessly to provide concept to commercialization timelines.

GVK BIO's manufacturing facility at Hyderabad has approvals from worldwide regulatory authorities like USFDA, EDQM, PMDA, KFDA and WHO. These accreditations facilitate faster and easier approvals of DMFs/dossiers for our business partners.

Regulatory Approvals



Ministry of Food and
Drug Safety

Zero Liquid Discharge facility



Manufacturing Infrastructure

Unit-1 @ Hyderabad

- Six GMP production blocks: Reaction volume of 177 Kilo Liters (m³)
- Reactor capacities: 20 L to 6000 L
- MoC: Stainless steel, Glass lined, all glass, Halar coated, Hastelloy-C, etc.
- Hydrogenation capabilities: 50 L to 2,000 L, up to 25 bar; Large scale Column Chromatography
- Class 100,000 cleanrooms; Kilo Labs & powder processing area
- QC Lab with stability chambers & microbiology
- USFDA, EMEA, EDQM, PMDA, MFDS, WHO GMP



Unit-2 @ Visakhapatnam - Under Commissioning

- Two GMP production blocks: Reaction volume of 87 Kilo Litres (m³)
- Reactor capacities: 100 L to 6000 L
- MoC: Stainless steel, Glass lined, all Glass, Halar coated etc.
- DCS based dispensing of solvents, automated hydrogenation facility
- Class 100,000 cleanroom; Kilo lab & powder processing area
- QC lab including stability chambers



Leading CDMO
INOGEN

Discovery CRO of Choice
GVK BIO

Large Molecule Discovery Partner
ARAGEN

To know more, contact us at:
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