aragen.com

Contract Manufacturing Solutions

Aragen offers long term contract manufacturing solutions for NCEs which are in various phases of the development. Have required expertise for the validations, DMF filing, manufacturing of new chemical entities (NCEs), key starting materials (KSMs), active pharmaceutical ingredients (APIs) and their intermediates. We are already working with several large pharma companies and collaborating with them at various stages of development. We have flexible business models to support various client needs.

We have the following to offer:

- Expertise in chemocatalysis, biocatalysis, nitration, carbonylation, metalation chemistry etc
- Expertise in complex chemistries including sec n butyl lithium, Azide Chemistry, Bromination, Chlorination, Hydrazine chemistry, Hydride reduction, Methylation, Deuterated compound, Cyanation, carbonylation, DIBAL etc
- Flow chemistry, Amidites chemistry expertise
- DoE expertise
- Expertise to handle high potent API OEB4/5 molecules
- Experienced scientific team
- State of the art analytical instrumentation
- Well experienced team and the documentation suits to regulatory submissions (includes IND, NDA, DMF & CMC)
- Impurity identification, characterization and structural elucidation
- Prep and chiral purifications on medium scale
- Focus on speed in early phase projects, cost effectiveness in late phase projects
- Highly efficient supply chain

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

Regulatory Approvals

Manufacturing Infrastructure

Unit-I @ Hyderabad

- Seven GMP production blocks: Reaction volume of 168 Kilo Liters (m3)
- Reactor capacities: 20 L to 6000 L
- Capable of handling reactions from -90°C to 200°C
- 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 chromatography column for separation of Isomers and Products
- Class 100,000 cleanrooms; kilo labs & powder processing area
- QC lab with stability chambers & microbiology
- USFDA, EMA, EDQM, PMDA, MFDS, WHO GMP
- Dedicated HPAPI lab with suitable reactors, isolators; final API handling is done in a glove box

Unit-II @ Visakhapatnam

- Four GMP production blocks: reaction volume of 192 kilo liters (m3)
- Reactor capacities: 20 L to 12500 L
- Capable of handling reactions from-90°C to 200°C
- MoC: stainless steel, glass lined, all glass, hastelloy etc.
- Hydrogenation capabilities : 1.0 Kl t 5.0 KL upto 40 Bar
- DCS based dispensing of solvents & utility operations, automated hydrogenation facility
- Class 100,000 cleanroom; kilo lab & powder processing area
- QC lab including stability chambers
- High Potent API manufacturing capabilities (OEB 4/5)
- MFDS, WHO GMP