

# Contract Manufacturing Solutions



Aragen brings extensive expertise in commercial manufacturing, producing key starting materials (KSM), intermediates, and APIs for the pharmaceutical, agrochemical, and specialty chemical industries. Equipped with versatile infrastructure and a team trained in operational excellence, we ensure seamless supply chain management and on-time, in-full (OTIF) project delivery. Our commitment to global safety, environmental, and regulatory standards ensure consistent delivery of high-quality products. What sets Aragen apart is our ability to execute complex unit processes and operations at plant scale under diverse reaction conditions. With a flexible, client-focused approach and tailored business models, we are ready to meet diverse quantity demands.

## Our Service Offerings:

- Expertise in Chemocatalyst, biocatalyst, nitration, carbonylation, metalation chemistry
- Expertise in complex chemistries including sec n-butyl lithium, flow chemistry, amidites, azide chemistry, bromination, chlorination, hydrazine chemistry, hydride reduction, methylation, deuterated compound, cyanation, carbonylation, DIBAL
- DoE expertise
- Capability to handle high potent API OEB4/5 molecules
- Strong scientific team with experience in regulatory submissions (IND, NDA, DMF & CMC)
- State-of-the-art analytical instrumentation; prep and chiral purifications on medium scale
- Focus on speed in early-phase projects, cost-effectiveness in late-phase projects
- Highly efficient supply chain

co-location of manufacturing facilities with R&D labs and pilot plant enable smooth technology transfer providing end-to-end API solutions from feasibility phase in R&D to commercial launch.

## Regulatory Approvals



## Manufacturing Infrastructure

### Unit-I @ Hyderabad

- 7 GMP production blocks; reaction volume of 169 KL
- 4 cleanrooms and 2 kilo labs cleanrooms (ISO-8)
- Reactor capacities: 20 L to 6000 L
- Temperature range: -90oC to +200°C
- MOC: Stainless steel, glass-lined, all-glass, Halar-coated, Hastelloy-C
- Hydrogenation capabilities: 100 to 2000 L up to 20 bar
- Agitated thin film drier and falling film evaporator
- ISO class 100,000 clean-rooms, kilo-lab, and powder processing area
- QC lab with stability chambers and microbiology
- USFDA, EMA, EDQM, PMDA, MFDS, WHO GMP certified/accredited
- High Potent API manufacturing capabilities (facility for OEB 6 is under commissioning)
- Equipped with a solvent recovery system capable of recovering and recycling multiple solvents
- Kilo lab with suitable reactors, isolators; final API handling is done in a glove box

### Unit-II @ Visakhapatnam

- 3 GMP blocks production blocks; reaction volume of 193 KL
- 1 cleanroom and 1 kilo lab cleanroom (ISO-8)
- Reactor capacities: 20 L to 12500 L
- Temperature range: -90oC to +200oC
- MOC: Stainless steel, glass-lined, all-glass, Hastelloy
- Hydrogenation capabilities: 1.0 KL to 5.0 KL up to 25 Bar
- DCS based dispensing of solvents & utility operations, automated hydrogenation facility
- ISO class 100,000 clean-rooms, kilo-lab, and powder processing area
- QC lab with stability chambers
- Equipped with a solvent recovery system capable of recovering and recycling multiple solvents
- MFDS, WHO GMP certified/accredited

