aragen

Custom Manufacturing Solutions

One CDMO partner. Every stage. From milligram development to multi-tonne commercial API supply.



In every molecule is the possibility for better health.

Integrated Small Molecule CDMO

Your Science. Our Solutions.

Aragen is a trusted development and manufacturing partner to global pharmaceutical, biotech and agrochemical innovators. We combine deep chemistry expertise, world-class GMP infrastructure and an unwavering commitment to quality to move your molecule from discovery to commercial supply — reliably, safely and at speed.

Why Global Innovators Choose Aragen

- Integrated CDMO — discovery, development and commercial manufacturing under one roof
- Complex, high-value chemistry: cryogenics, cyanation, Grignard, chlorination, phosgenation and HPAPI handling
- Global regulatory track record: USFDA, EMA, PMDA, WHO GMP and 12+ major regulatory authority approvals
- Cost-efficient India operations delivered to Western quality and compliance standards
- ~500KL Additional capacity committed over FY27–FY29 to expand capacity, containment and digital capability





Manufacturing Excellence
Late-Stage & Commercial Manufacturing

370+ KL	15	2
Reactor volume	Commercial APIs	cGMP facilities

Aragen is well-positioned to support commercial supply of APIs, key starting materials and intermediates for pharmaceutical and specialty chemical customers — backed by two GMP-accredited facilities of process chemists, engineers and quality experts.

Production Facilities	9 production blocks, including HPAPI, plus 2 kilo labs
Scale	Multiple kilo-lab trains up to a 12,500-litre reactor train
Batch Size	0.5 kg to 500 kg, fully flexible
Cleanrooms	8 cleanrooms (6 in Unit I, 2 in Unit II)
Waste Management	Zero liquid discharge facility
Cryogenic Operations	-70°C to +220°C temperature range
Complex Chemistry	Cyanation, Grignard, chlorination, phosgenation, cyclopropanation
High-Potency APIs	Cytotoxic and non-cytotoxic handling
Solvent Recovery	Integrated recycling systems
Automation	DCS automation across critical operations and utilities

Two Units, One Standard of Excellence
Manufacturing Sites — Unit I & Unit II

Unit I
Nacharam, Hyderabad

- 8 blocks, 170 KL capacity
- 101 reactors, 20 L to 6,000 L
- Cryo reactors: 5 KL, down to -80°C
- Hydrogenation reactors: 3.7 KL (10–30 PSI)
- Capacity: 300 MT per annum

Unit II
Visakhapatnam, Andhra Pradesh

- 3 blocks, 193 KL capacity
- 51 reactors, 20 L to 12,500 L
- Cryo reactors: 32 KL, down to -100°C
- Hydrogenation reactors: 7.1 KL (10–30 PSI)
- Capacity: 600 MT per annum

A Business Continuity Plan spans both units to safeguard critical operations and ensure resilience against any disruption.

Investing In Your Future

Growth Roadmap: FY27-FY29

Aragen is committing ~$90+ million over three years to expand manufacturing excellence, regulatory compliance and technology — adding 500 KL of new capacity.

- New GMP block (250 KL) plus a green-field GMP block (250 KL)
- OEB4 and OEB5 non-cyto formulation capabilities
- Analytical Stability Centre of Excellence and enhanced analytical labs
- GMP flow chemistry, prep-HPLC, lyophilizer and solvent recovery systems

Our Signature Platform

OneHP™ — One Platform. Ultra-High Containment.

A unified HPAPI platform spanning discovery through commercial cGMP manufacturing — a single, accountable partner from milligram discovery to multi-kilogram commercial supply, with no tech-transfer friction and no compromise on containment.

10 ng/m³	mg → kg	ADC
Ultra-high Containment (OEL)	Full-scale platform	Bioconjugation-ready

Trusted Worldwide

Global Regulatory Excellence

A 200+ member Global Quality and Regulatory Affairs team — headed by the Chief Quality Officer and directly accountable to the MD & CEO — ensures consistent quality, compliance and regulatory excellence at every Aragen site, worldwide.

Inspection Track Record

USFDA (7) · EDQM · PMDA (2)
MFDS · WHO Geneva · WHO GMP (CDSCO/DCA)

Standards & Systems

ICH · 21 CFR 210/211/11/58 · EMEA/EU
ISO 9001:2015 · ISO 17025:2017 · OECD GLP

Global Filings & CMC

USDMF · EDMF · CEP (eCTD & NeeS)
CMC support for IND / IMPD / NDA filings

SPEED | PREDICTABILITY | REGULATORY CONFIDENCE



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The Aragen Advantage

Why Aragen for Small-Molecule CDMO Solutions

Five reasons emerging biotechs and global pharma choose Aragen as their development and manufacturing partner.

Integrated End-to-End Capability

Discovery to commercial supply under one partner
Drug substance and drug product on one campus
0.5 kg to 500 kg batch-size flexibility

Complex Chemistry & Technical Depth

Cryogenic operations, -70°C to +220°C
Cyanation, Grignard, chlorination, phosgenation
HPAPI and cytotoxic handling capability

Quality as a Differentiator

USFDA (7), EDQM, PMDA (2), MFDS, WHO GMP
15 commercial APIs to pharmacopeial grades
Digital thread for traceability and data integrity

World-Class Infrastructure

2 cGMP sites; 9 blocks plus 2 kilo labs
370+ KL volume, trains up to 12,500 L
500KL expansion committed FY27–FY29

Reliable Execution & Governance

95% on-time delivery; 25% TAT reduction
Right-first-time execution for predictability
Leadership-led quality and performance reviews

Committed To Responsible Growth

Protecting People. Strengthening Systems.

Aragen's EHSS framework rests on four pillars — People, Systems & Infrastructure, Culture & Governance, and Sustainability — reinforced by leading external recognition.

Gold EcoVadis score 84	**Zero** Landfill by 2025	**50.4%** Emissions cut by 2032	**2035** Water neutrality goal

Active Pharmaceutical Ingredients List

Commercially Available

Products	Therapeutic Category	Documents Availability
Betahistine Di HCl	Anti-Vertigo	DMF (CEP in process)
Benserazide HCl	Parkinson's Disease	DMF (CEP in process)
Dobutamine Hydrochloride	Cardiovascular	CEP/USDMF
Ezetimibe	Antihyperlipidemic	DMF/KDMF
Fingolimod HCl	Multiple Sclerosis	DMF

Products	Therapeutic Category	Documents Availability
Gatifloxacin Sesquihydrate	Antibiotic	DMF
Lamotrigine	Anticonvulsant	CEP/DMF
Moxifloxacin Hydrochloride	Antibiotic	CEP/DMF/KDMF
Pentosan Polysulfate Sodium	Interstitial Cystitis	USDMF/KDMF/DMF
Pralidoxime Chloride	Antidote	DMF
Tramadol Hydrochloride	Analgesic	CEP/USDMF/KDMF/JDMF
Trimetazidine Dihydrochloride	Cardiovascular	CEP/DMF/CADIFA

Disclaimer: Products covered by valid patents in any country are not offered or supplied to those countries.
The customer should verify the patent position in the concerned country.

Products Under Development

Products	CAS.NO	Therapeutic Usage
Lisdexamfetamine Dimesylate	608137-33-3	CNS stimulant
Vibegron	1190389-15-1	Urinary incontinence/ OAB (over active baldder)
Dexpanthenol	81-13-0	Gastrointestinal stimulants and topical dermatological agents.
Idebenone	58186-27-9	Antioxidants and neuroprotective agents
Benzhexol.HCl	52-49-3	Antiparkinsonian agents
Ticonazole	65899-73-2	Antifungal medication used primarily to treat vaginal yeast infections.
Butamirate Citrate	18109-81-4	Antitussive (cough suppressant)
Brompheniramine	86-22-6	Antihistamine / Anti-allergic
Trimecaine.HCl	1027-14-1	Local Anesthetic



Name of the Intermediates	CAS No.
Aripiprazole 7-(4-Bromobutoxy)-3,4-Dihydroquinoline-2 (BBQ)	129722-34-5
Carvedilol 4- (2,3 –Epoxypropoxy) carbazole (CVD4)	51997-51-4
Lamotrigine Hydrazine carboxidazole -2 – [cyano (2,3 – dichlorophenyl)] methane (LA2) 2, 3 Dichloro benzoyl Nitrile(LA1)	84689-20-3 77668-42-9
Lansoprazole 2-(3-Methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl) methylthio-1H-benzimidazole (LS)	103577-40-8
Benserazide 2,3,4-Trihydroxybenzaldehyde DL-Serinehydrazide monohydrochloride	2144-08-3 55819-71-1
Pralidoxime (E)-Picolinaldehdye oxime	873-69-8

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From discovery to commercial-scale API supply, Aragen is the integrated CDMO partner built for your speed, your science and your standards.

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Aragen is a trusted R&D and manufacturing partner to the global life sciences industry. From concept to commercial, we transform your ideas into solutions for better health. We have more than 25 years of experience providing a range of contract research, development and manufacturing services across the drug development continuum, with a focus on early-stage discovery and development of new molecular entities (NMEs). Whether large pharma or biotech, an agrochemical or animal health company, we provide you global resources and proven capabilities at every stage of the biopharma lifecycle, in small and large molecules. Our ability to offer end-to-end solutions or support standalone programs is underpinned by an innovation mindset, enabling technologies, and a partnership approach to every engagement.
At Aragen, we recognize your work is vital, urgent and impacts lives. Our purpose, 'In every molecule is the possibility for better health' motivates us to drive the success of your programs, so that we can together transform hope into health for millions of people around the world.

For more information, contact info@aragen.com

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