

Analytical Solutions at Aragen

Overview

Aragen Life Sciences offers a comprehensive suite of analytical services tailored to support drug development across preclinical, clinical, and commercial stages. With flexible engagement models exhibit (FTE & FFS), a robust infrastructure, and strong regulatory compliance, we deliver insightful, reliable, quality and timely data to drive your programs forward.

Quality & Regulatory Compliance

- USFDA, PMDA, and cGMP Compliance
- Zero Form 483s in Last 2 USFDA Inspections (2019, 2025)
- 21 CFR Part 11 Compliant Electronic Systems
- Document Management System (DMS) & Learning Management System (LMS)
- ISO 17025-Aligned Practices

Core Capabilities

- Method Development & Validation (ICH-compliant)
- Nitrosamine Risk Assessment & Analysis
- Impurity Profiling
- Extractables & Leachables
- Medical Device Chemical Characterization
- Microbiology Testing
- IVRT & NG/G Tube Studies
- Phosphate Binding & Sameness Studies
- Dissolution Studies
- Microbial Kill Rate & Zone Inhibition Studies
- Reference Standards Management & Life Cycle Management of Analytical Procedures, USP 1220

Stability Services

- All ICH Conditions | 100,000 L Capacity | Photostability & Developmental Stability
- Walk-in & Reach-in Chambers & Total Number of Chambers - 11
- Stability-Indicating Method Development
- Fully 21 CFR Part 11 Compliant Systems

Temperature	Humidity	Capacity (Ltr)	Type
25°C ± 2°C	60% RH ± 5% RH	2000	Reach-in
		16000	Walk-in
30°C ± 2°C	65% RH ± 5% RH	2000	Reach-in
	75% RH ± 5% RH	16000	Walk-in
40°C ± 2°C	75% RH ± 5% RH	16000	Walk-in
		2000	Reach-in
40°C ± 2°C	20% RH ± 5% RH	600	Reach-in
25°C ± 2°C	40% RH ± 5% RH	600	Reach-in (2)
5°C ± 3°C	NA	2000	Reach-in
Photo Stability Chamber		100	Reach-in

Instrumentation Highlights

Category	Details
Solid State Characterization	PXRD, TGA, PSA, DSC
HPLC	18 HPLC & 02 UPLC (Agilent Technologies, Model: 1260 Infinity Series. Waters (Alliance), Model: e2695 Separation Module & 2489 UV/Vis., Arc HPLC.) with Empower 3
GC, GC-HS, GC-MS, GC-MS/MS	Agilent Technologies, Model: GC-7890B; HS-7697A; MSD-5977D. Agilent Technologies, Model: GC-7890B; HS-7697A; MSD-7010B GC/TQ, ALS- 7693. ECM Server
Dissolution Studies	Electrolab, Model: EDT-14LX (14 Bowls), EDT-8LX (08 bowls), No of Apparatus: 06
LC-MS/MS	AB Sciex, Model: API 4000, LC Agilent.
	AB Sciex, Model: Qtrap 4500.
	Waters, Model: Xevo-TQ-XS, Xevo-TQ-Absolute, Xevo-Micro
HRMS (Development Lab)	QTOF, Orbitrap, Q Extractive
HRMS (GMP)	Orbitrap
ICP-MS	Agilent Technologies, Model: 7800 with ECM Server
IC	Thermo, Model: ICS-5000 Plus; Chromeleon Software