

Analytical Solutions



Aragen with a team of experts converge to offer a diverse range of analytical capabilities. With our flexible service models, including Full-Time Equivalent (FTE) and Fee-for-Service (FFS), we tailor our support to your specific needs. Whether you require dedicated research partners through FTE or on-demand access to our advanced instrumentation and expertise through FFS, ASL is your gateway to precise and insightful analytical solutions, driving progress and innovation in your projects.

cGMP Analytical Solutions Overview



Quality Control & Release Testing



Analytical Method Development & Validation



Stability & Photo Stability Testing, Storage & Management



Impurity Profiling & Elemental Analysis



Microbiology



Physicochemical Characterization



Dissolution Testing



Extractable & Leachable Studies

Experts in Advanced Studies

- Extractable for pharmaceutical packaging, container closure & manufacturing component. EPDM packaging, HDPE, PP, LDPE container, tubing, gasket & O Ring
- Adhesive, ink migration study for labels & delamination study for glass
- Leachable studies for Injectable, ophthalmic, inhalation, vaccine, parenteral, topicals and dermal patches
- Chemical characterization for medical devices
- Nitrosamine and NDSRI assessment at PPB & PPT level
- Life cycle management, complex product management, USP 1220
- Reference standard management
- Dissolution study - USP III, II and I
- Invitro binding study / phosphate binding study & sameness study experience with sevelamer, Colesevelam, cholestyramine
- Microbial kill rate study & zone inhibition study
- Physical characterization by XRD, DSC, TGA, IR
- Polymorphic screening & quantification for OSD, injectable & topical product
- Genotoxic impurity profiling & characterization
- Method development & validation for small & large molecules

Regular Analytical Services

- Method development and validation as per ICH guideline
- Assay & related substance by chromatographic technique
- Content uniformity and force degradation study
- Microbiology (MLT, BET, AET, sterility and microbial assay)
- Elemental impurity by ICPMS
- Impurity profiling for organic, inorganic, and genotoxic impurity
- Physical characterization, crystallinity, amorphous content

Expertise in Stability Studies

- All ICH stability conditions
- 90,000 L stability storage facility
- Developmental stability
- Photostability studies
- cGMP registration stability programs
- Development and validation of stability indicating methods including dissolution testing
- Validated monitoring system, 21 CFR part 11 compliant
- Walk-in and backup reach-in chambers
- Comprehensive documentation

Quality Management System

- Operates in full compliance with US-FDA and cGMP requirements.
- Electronic data handling compliant with FDA 21 CFR part 11
- DMS(Document Management System)
- LMS(Learning Management System)
- 200+ GMP client-initiated audits since 2017
- Implementation of quality systems in accordance with cGMP, ISO 17025

Infrastructure

- | | |
|--------------------|----------------------------|
| • LC/MS/MS | • FT-IR |
| • Qtrap 4500 | • UV |
| • Xevo-TQ-XS | • PSD |
| • Xevo-Micro | • pXRD |
| • QTOF | • DSC |
| • Orbitrap | • TGA |
| • Xevo TQ Absolute | • IC |
| • UHPLC – MS/MS | • TOC |
| • HPLC – MS/MS | • Stability chambers |
| • ICP-MS | • Photo stability chambers |
| • GC-HS-MS/MS | • HPLC-UV |
| • GC-ALS-MS/MS | • HPLC-PDA |
| • GC-HS-MS | • HPLC-RI |
| • GC-ALS-MS | • DT |
| • GC-HS-FID | • KF |
| • GC-ALS-FID | • Potentiometer |
| • Dissolution | |

Accreditations and Approvals



ISO 9001:2015 - Quality Management Systems Surveillance Audit.
ISO 45001:2018 - Occupational Health and Management System
ISO 14001:2015 - Environment Management System
ISO 50001:2018 - Energy Management System

Let's begin the conversation

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