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# Analytical Solutions Laboratory

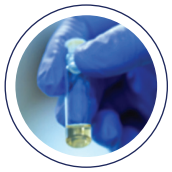
Aragen with a team of experts converge to offer a diverse range of analytical capabilities. With our flexible service models, including Full-Time Equivalent (FTE) and Fee-for-Service (FFS), we tailor our support to your specific needs. Whether you require dedicated research partners through FTE or on-demand 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

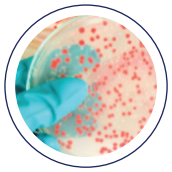
Quality Control & Release Testing

Analytical Method Development & Validation

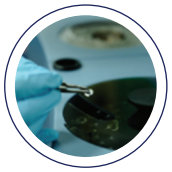
Stability & Photo Stability Testing, Storage & Management



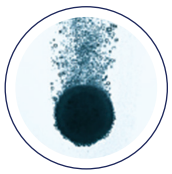
Impurity Profiling & Elemental Analysis



Microbiology

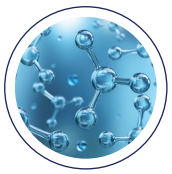


Physicochemical Characterization



Dissolution Testing

Extractable & Leachable Studies



Reference Standards Management & Life Cycle Management of Analytical Procedures, USP 1220

## Experts in Advanced Studies

- Extractable for pharmaceutical packaging, container closure & manufacturing component. EPDM packaging, HDPE, PP, LDPE container, tubing, Gasket & O Ring etc
- 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 assessment – by qualitative & quantitative technique
- Life cycle management, complex product management, reference standards, USP 1220
- Dissolution study – USP Type IV, III, II and I
- NG/G tube studies, IVRT studies, *in-vitro* binding study / phosphate binding study & sameness study experience with sevelamer, colesevelam, cholestryramine
- 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.

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## 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
- 100,000 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

## Accreditations and Approvals

FDA U.S Food and Drug Administration — 2019, 2025

DCA Drugs Control Administration Telangana — Up to 2027

PMDA — 2012, 2018

CDSCO — 2023

WHO — 2023

NABL — 2024

ISO

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

## Infrastructure

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

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