

# Analytical Solutions Laboratory



## 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 Studies
- Leachable Studies
- Ink Migration Studies
- Tubing Contact Studies
- Filter Contact Studies
- Adhesive Migration Studies
- Glass Delamination Studies
- Nitrosamines
- Phosphate Binding Studies
- Invitro Dissolution Studies
- Medical Devices
- Genotoxic Impurities
- Impurity Profiling
- Method Development
- Method Validation
- Method Verification
- Microbiology Studies
- Physical Characterization (DSC, TGA, XRD, PSD)
- Elemental Analysis
- Reverse Engineering
- Packing Material
- Ion Chromatography

## Regular Analytical Services

- Method Development and Validations (ICH, ANVISA, USP, EP, BP, IP, JP, etc)
- Pharmacopeial Analysis (USP, EP, BP, IP, JP, etc)
- Raw Material Analysis
- Excipients
- Microbiology (MLT, BET, AET, etc)
- Forced Degradation Studies
- Impurity Profiling (Organic, Inorganic, Ionic and Genotoxic Impurities)

## Expertise in Stability Studies

- Developmental Stability
- All ICH Stability Conditions
- 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

- 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

## Accreditations and Approvals



Let's begin the conversation



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[in /company/aragen-life-sciences](https://www.linkedin.com/company/aragen-life-sciences)  
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