

Trusted Technical Expertise.

Columbia Analytical is a registered contract testing laboratory providing cGMP-compliant testing to the raw material suppliers, CMOs, and product developers/sponsors of the pharmaceutical industry. To ensure regulatory compliance, Columbia Analytical is FDA inspected and registered and DEA licensed. We maintain a comprehensive quality unit that ensures all data is scientifically sound and accurately documented.



Monograph Testing

Columbia Analytical utilizes USP/NF, EP, JP, BP, AOAC and ACS compendial methods for raw material and final product testing. Examples include residual solvents USP <467>, microbial limit tests USP <61> and infrared absorption USP <197>. Columbia Analytical also conducts analyses using client supplied methodology after appropriate method transfer protocols.

Method Development and Validation

Our professional scientists have extensive experience in analytical chemistry and routinely provide method development and validation for pharmaceutical testing. Methods are validated to current USP/ICH guidelines.

Engineering Studies/Process Validation

Columbia Analytical's scientists are accustomed to non-routine testing and have the knowledge and resources to solve your analytical problems. Examples of this may include analytical support for cleaning studies or manufacturing processes.

Stability Testing

Columbia Analytical provides analytical support to your stability study testing. This may include assay testing, physical testing, and impurity and degradation product monitoring. Development and validation of stability indicating assays is also available.

Instrumental Testing Capabilities

- High-Performance Liquid Chromatography Inductively Coupled Plasma Mass Spectrometry (HPLC-ICP/MS)
- High-Performance Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)
- High-Performance Liquid Chromatography (HPLC) with various detection methods such as Fluorescence, UV/Visible, and Diode Array
- Gas Chromatography (GC) with various identification and detection methods such as Mass Spectroscopy, Flame Ionization Detector, Thermal Conductivity Detector (TCD)
- Metals Analysis by Inductively Coupled Plasma Mass Spectrometry (ICP/MS), Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP/AES), Atomic Absorbance (AA), and Graphite Furnace Atomic Absorbance (GFAA)
- Ion Chromatography (IC)
- Ultraviolet/Visible (UV/Vis) Spectroscopy <731>
- Infrared Spectroscopy (FT-IR) <197>
- General instrumental methods including Water Determination by Karl Fischer <921>, Optical Rotation <781>, Refractive Index <831>, Dissolution <711>, Viscosity <911>, Titrimetry <541>, Water Conductivity <645>, and Melting range <741>