



Gateway Analytical, is a specialized analytical testing laboratory that businesses around the world trust to provide solutions for their most challenging foreign particulate characterization and materials analysis needs. Gateway's

expert scientists, specialized test methods and comprehensive suite of instrumentation allow us to deliver the fast, accurate and reliable results that customers in the pharmaceutical, materials and medical device industries demand. Gateway Analytical is now part of the AptarGroup, Inc., family of companies. To learn more visit www.gatewayanalytical.com.

Certifications

- cGMP
- ISO 17025:2017
- ISO 9001:2015
- ICH Q7
- FDA Registered and Inspected
- DEA Drug Schedule II, III, IV and V Licensed
- ANAB 17025:2017 accredited

Instrumentation

- HIAC
- SEM-EDS (Manual and Automated)
- Fluorescence Microscopy
- Comparison Microscopy
- Polarized Light Microscopy
- Raman Spectroscopy (Manual and Automated)
- LIBS
- Falcon II Raman Chemical Imaging
- FTIR Spectroscopy

Specialized Service Areas

- Foreign Particulate Matter in Cytotoxic Materials
- Particle Sizing
- Particle Counting
- Wear Debris
- QC Testing
- Polymer Analysis
- Metals and Alloys
- Ceramic and Composites
- Parenteral Products
- Oral/Nasal Inhaled
- Suspensions
- Transdermal
- Semi-Solids
- Tablets, Capsules
- Time Release
- MDI and DPI Device Testing
- Pre-Filled Syringe Testing
- USP <787> / <788> / <789> Methods I & II
- Container Closure Integrity Testing (CCIT)
- Testing for Cellular Therapeutics

Particulate Contamination Identification

- Deviation and OOS Investigation Support
- Materials/Foreign Particulate Identification
- Particle Sizing
- Particle Count
- Source Determination
- Root Cause Analysis
- Particulate Defect Library Database Creation

Bioequivalence Testing

- Excipient and API Sizing and Distribution
- Agglomerates, Aggregates, and Polymorphs
- Generic to Brand Comparison
- Raw Material Analysis
- Ingredient-specific Particle Sizing
- Automated Raman Spectroscopy

Glass Delamination

- USP <1660> Testing
- Delamination Analysis
- Thermal or Mechanical Glass Failures
- Glass Defect and Mold Dope Contamination
- Product Return

Turnaround Times:

Standard: 4-5 Days

Expedited: 3 Days

Rush: 24 Hours

**INDUSTRY LEADING
TURNAROUND TIME**

**MULTI-DISCIPLINED
ANALYTICAL EXPERTS**

**FULLY CERTIFIED &
ACCREDITED LAB**

**PERSONALIZED
CUSTOMER SERVICE**

