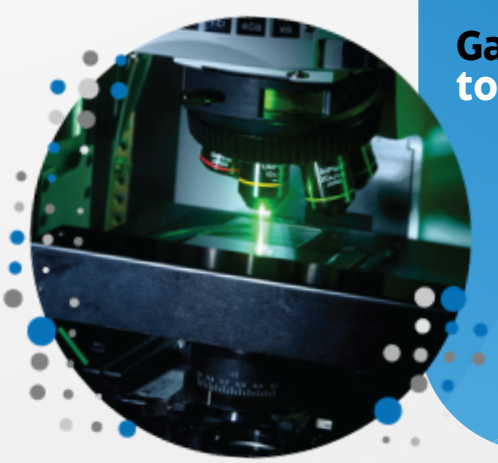

Gateway Analytical Helps You Accelerate Your Mission to Provide Patients Access to *Life-Saving* Medicine

Gateway Analytical provides expert analytical testing services to support the development and commercializing of parenteral medicines for the pharmaceutical and biotechnology industries.

Our laboratory provides comprehensive analytical solutions for drug-container development, validation, or QC/OOS-related investigations involving visible particle characterization, USP/EP/JP subvisible particulate release testing, container closure integrity testing (CCIT), and extractables and leachables (E&L) testing.

Inspections, Accreditations, & Licensures

- cGMP laboratory
- FDA registered and inspected
- Health Canada inspected
- EMA inspected
- ISO/IEC 17025:2017
- ISO 9001:2015
- DEA Drug Schedule II, III, IV, and V licensed

Specialized Service Areas

- Cytotoxic, Hazardous, & Human-Derived Blood Products
- Cell and Gene Therapies
- RNA, DNA Plasmids, Viral Vectors, LNPs, AAVs, mAbs, Vaccines, & Lyophilized Products
- Medical Devices for Intravenous, Infusion, and Transfusion; Catheter Systems
- Deep-cold and Cryogenically stored Products
- AT-Closed Vial®, CZ, Glass, and Plastic Vials; and Glass and COP Prefilled Syringes
- Rinse Studies for Single-Use Systems and Manufacturing Components
- PDA Technical Report No. 78, Particulate Matter in Oral Dosage Forms
- PDA Technical Report No. 79, Particulate Matter Control in Difficult to Inspect Parenterals

Visible Particles

- Foreign or Unknown Particulate Matter Characterization
- USP <1790> Alternative Inspection Strategies for <100µm Particle Counting
- Visible-range Particle Population Counting and Sizing
- Source Determination
- Root Cause Analysis
- Reference Material Characterization and Databasing
- Particulate Defect Library Database Creation

Subvisible Particles

- Testing Protocols Aligned to the Newest Regulatory Bodies' Guidance and Suggestions
- USP <787>, <788>, and <789> Methods I & II – Release and Stability Testing
- Method Development and Verification for Plasmid/Vector/CGT/Vaccine/Lyophilized Products
- Rinse Studies for Single-Use Systems and Mfg. Components
- Combined ISO and USP Particle Count/Size Methods Development/Verification Studies

Container Closure Integrity Testing (CCIT)

- Deterministic CCIT Methods for Vials, Prefilled Syringes, and Flexible Containers
- Specialty with Cell and Gene Therapy Products
- Storage for Deep-cold and Cryogenic stored Products
- AT-Closed Vial, CZ, Glass, and Plastic Vials; and Glass and COP Prefilled Syringes
- Residual Seal Force (RSF) and ISO Mechanical Testing

Extractables & Leachables

- Vast Experience with Single-Use Systems and Manufacturing Materials and Components
- High-resolution, Accurate Mass Spectrometric Instrumentation
- Compound Identification and Molecular Formula Generation for Unknown Compounds
- Structural Elucidation via MS/MS Fragmentation
- Mass Analysis of Proteins, Peptides, MS/MS Sequencing
- Examination of Post-Translational Modifications

Glass Delamination

- USP <1660> Testing
- Delamination Screening and Analysis
- Glass Defect or Mold Dope Contamination Investigation
- Investigations Concerning Product Recalls
- Stability-related Testing
- Testing Comparisons Between Glass Vial Products for Delamination Durability

GatewayAnalytical
an Aptar pharma company

2009 Kramer Road, Gibsonia
Pennsylvania 15044
(phone) +1 724 443 1900
www.gatewayanalytical.com

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.

Specialized Service Areas

- Foreign Particulate 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

Certifications

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

Instrumentation

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

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

INDUSTRY LEADING TURNAROUND TIME

MULTI-DISCIPLINED ANALYTICAL EXPERTS

FULLY CERTIFIED & ACCREDITED LAB

PERSONALIZED CUSTOMER SERVICE

Turnaround Times: Standard: 4-5 Days Expedited: 3 Days Rush: 24 Hours

GatewayAnalytical
an Aptar pharma company

2009 Kramer Road, Gibsonia
Pennsylvania 15044
(phone) +1 724 443 1900
www.gatewayanalytical.com