GatewayAnalytical
an Aptar pharma company

2009 Kramer Road
Gibsonia, PA 15044
phone: +1 (724) 443 1900
info@gatewatanalytical.com
www.gatewayanalytical.com

Visible Particulate: Foreign Particulate Identification (>100 µm)

- Multi-analytical approach to characterize/identify unknown particulates or material
- Source Determination/Root Cause Analysis/Reference Material Characterization
- Glass Delamination Screening
- Turnaround Time:
  - Standard: 5 samples = 5 business days
  - RUSH: 5 samples = 2 business days with preliminary results in 1 business day

Sub-Visible Particulate: Count, Size, and Characterization (<100 µm)

- USP <787>, <788>, and <789> Methods I & II – Release & Stability Testing
- Method development and verification for plasmid/vector/CGT/vaccine/lyophilized products
- Rinse studies for single-use systems and manufacturing components
- Characterization of sub-visible particulate using Automated Raman or SEM-EDS

MFI Information

- Comprehensive MFI study design tailored to your product and risk profile.
- Image-verified particle characterization with scientific review.
- Orthogonal confirmation for definitive root-cause determination.
- Application-specific testing for real-world stress conditions.

Container Closure Integrity Testing (CCIT)

- Deterministic, non-destructive methods for vials, pre-filled syringes, and flexible containers
- Laser Headspace Analysis (O2 and CO2 headspace detection)
- High Voltage Leak Detection (HVLD)
- Vacuum Decay
- Development, validation, and routine testing for stability and release
- Specialty with cell and gene therapies, and deep-cold and cryogenically-stored products

Extractables and Leachables (E&L)

- 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
- Mass analysis of proteins, peptides, MS/MS sequencing

Functional Suitability Testing and Residual Seal Force

- System-level functional suitability testing aligned to USP <382>
- Comprehensive assessment of container access, sealing, and dose delivery.
- Testing designed to simulate real-world use and worst-case conditions.
- Regulatory-ready data to support development, comparability, and lifecycle changes.

GatewayAnalytical
an Aptar pharma company

2009 Kramer Road
Gibsonia, PA 15044
phone: +1 (724) 443 1900
info@gatewatanalytical.com
www.gatewayanalytical.com

About Gateway Analytical

Gateway Analytical is a specialized analytical testing lab that supports Analytical, Quality Control, and Manufacturing teams with foreign particulate investigations, subvisible particulate testing, packaging development, and beyond.

Our Parent Company Aptar Pharma: Advancing Patient Safety, Together

We are proud of our partnerships. Aptar Pharma's expertise enriches Gateway Analytical; enhancing our drug delivery and analytical services. Together, we offer advanced solutions for healthcare challenges as worldwide leaders in pharmaceutical device design, development and manufacturing as well as manufacturing and distribution of pharmaceutical packaging components.

Commitment to Quality: Inspections, Accreditations, & Licensures

cGMP-Compliant Laboratory
FDA Registered & Inspected
Health Canada Inspected
EMA Inspected
21 CFR Parts 210 & 211
21 CFR part 820
ISO/IEC 17025:2017 Accredited
ISO 9001:2015 Accredited
DEA Drug Schedule II, III, IV, & V licensed
Recognized Leader in PDA Community