



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
- No minimum sample requirement (single particulate >100 µm can be analyzed)
- 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

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 therapy products
- Storage for deep-cold and cryogenic 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
- Structural elucidation via MS/MS Fragmentation
- Mass analysis of proteins, peptides, MS/MS sequencing
- Examination of post-translational modifications

Glass Delamination Testing

- please get in touch with Account Manager for more information.

Residual Seal Force (RSF) and ISO Mechanical Testing

- please get in touch with Account Manager for more information.

Aptar Stoppers

- Parent company of Gateway Analytical, Aptar Pharma, manufactures and distributes elastomeric closures for parenteral drug product filling. Please get in touch with Account Manager for more information.



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 (last inspection 2021-no 483s)
- Health Canada inspected (no major/significant findings)
- 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, and V licensed
- Recognized leader in PDA community

