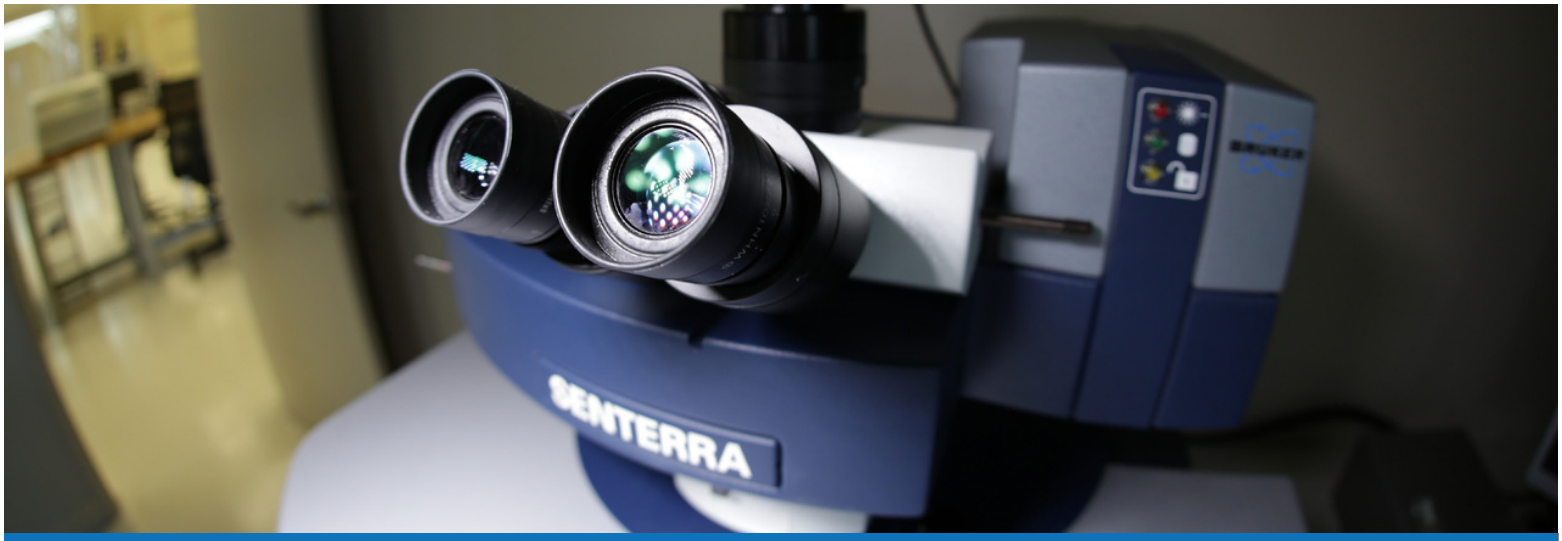
GatewayAnalytical
an Aptar pharma company

Analytical Services Suite for the Product Development of MDIs and DPIs

Providing expert analytical support and guidance for establishing bioequivalence, new drug submission, and meeting FDA regulatory contamination requirements.



Regulatory Expertise & Guidance

Our scientists have extensive experience in testing pharmaceuticals for performance factors such as particle size distribution, morphology, and stability. Our analytical methods and expertise with regulatory requirements can guide drug developers in determining bioavailability, establishing bioequivalence and identifying the source of impurities, degradants, or contaminants. We provide our customers with the data and insight they need to move to the next phase of their process by providing detailed reports combined with hands-on scientific guidance for FDA submissions. In addition, we also have the ability to transfer required customer protocols, allowing us to easily adapt your necessary process for analysis.

A Total Particle Characterization Solution

Gateway Analytical scientists have at their disposal a wide array of technology and methods for the analysis of MDIs and DPIs. Utilizing techniques such as automated Raman Chemical Imaging, Raman Spectroscopy, Laser- induced breakdown spectroscopy, and Scanning Electron Microscopy / Energy Dispersive Spectroscopy allows us to provide in-depth, chemically specific analysis of single particles or large particle populations. These methods prove invaluable when it comes to the analysis of drug-specific aggregates/agglomerates, drug products that contain more than one active pharmaceutical ingredient, and the identification of foreign particulates.

A Full Range of cGMP Services to Support MDI & DPI Product Development

Discovery & Development

Gateway Analytical provides comprehensive characterization services to identify the physical and chemical properties of the active ingredient and excipient components within a final formulation. Our methods provide chemically-specific data on each particle, which allows us to easily identify and separate the active ingredient from the excipients, and identify multiple active ingredients in more complex formulations. Having multiple technologies means we can provide customers with their products chemical and elemental information including particle by particle identification in a final formulation or as pure material.

Testing Capabilities

- API selection report
- Chemically-specific particle size distribution
- Agglomerate/aggregate identification and characterization
- Polymorph characterization
- Particle morphology
- Hydrates and solvates
- Morphic and amorphous forms
- Moisture and/or residual solvent content
- Microbial quality
- Foreign particulate identification
- Formulated drug product to the pure material comparison
- Micronization process suitability
- Drug/excipent compatibility
- Lot-to-lot reproducibility
- Determining bioavailability

Preclinical Research

Gateway Analytical provides analysis in order to help our customers establish bioequivalence of the test and reference DPI or MDI drug product. We then provide *in vitro* stability testing services that determine particle size distribution and dosage consistency of the drug product during actuation in addition to overall device and wear debris testing to ensure clinical efficacy so our customers can move forward into initiating clinical studies.

In Vitro Testing Capabilities

- Chemically-specific static particle size distribution analysis
- Microscopic evaluation and particle sizing
- Impurities & degradation product testing (devise testing as a source of particulate/ leachable contamination)
- Particulate identification
- Contamination source determination
- Spray pattern and plume geometry characterization

FDA Submission

Gateway Analytical provides guidance and analysis to help customers with all analytical results on their drug product for FDA New Drug Application submission. We can help you determine requirements for the necessary analysis and appropriate amount of data for submission, report contents and provide any additional analysis/consulting necessary for a successful submission.

Support Capabilities

- Formulation component analysis of the active ingredients and excipients
- Bioavailability and Bioequivalence studies for *In-vitro* testing of drug products.
- Micronization testing to determine the best suited process for reproducible particle size distribution of the drug product
- Guidance for New Drug Application data submission

Manufacturing & Safety Monitoring

Gateway Analytical supports drug manufacturing and safety by providing an array of services for out-of-specification issues such as foreign particle identification. We can provide single particle and large population particle characterization to determine the foreign particulates and overall particle identification. Our expertise in particle characterization combined with an extensive database of known contaminants allows us to provide a fast 1-5 day turnaround time for particle identification and guidance to identify the source of contaminations throughout your manufacturing process.

Testing Capabilities

- Particulate identification
- Product return analysis
- Source determination
- Root cause analysis
- Materials characterization
- Drug/excipients particle micronization process evaluation
- Glass adhesion & delamination analysis
- Defect analysis
- Counterfeit drug investigation
- Particulate contaminant database development
- Support answering FDA deficiency letters or regulatory requests for additional analysis
- On-site process evaluation for contaminations

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A Partner to Go the Distance

At Gateway Analytical, we understand that drug development is a complex process that requires astute attention to detail each step of the way. Having an analytical laboratory that can help you from start to nish is a key factor to your success. We offer a complete analytical service suite designed to support your analytical testing to meet FDA regulatory requirements, no matter where you are in the drug development process, from formulation through commercialization.

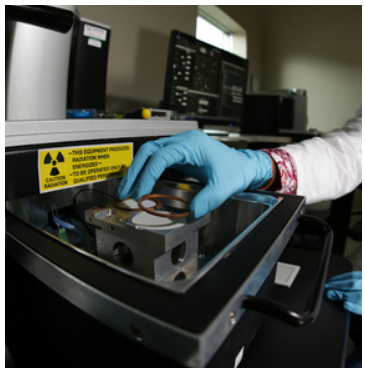
Instrumentation & Techniques

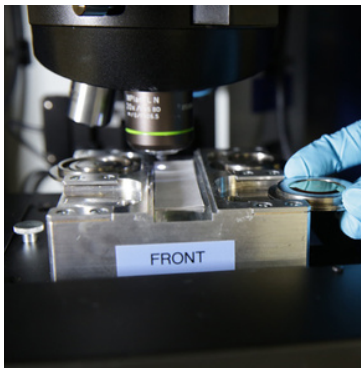
- Optical Microscopy
- Polarized Light Microscopy
- Raman Spectroscopy
- Raman/LIBS (SPE-ls raman.ID + metal.ID)
- Raman, Visible, Fluorescence and Near Infrared Chemical Imaging
- Fourier Transform Infrared Spectroscopy
- Scanning Electron Microscopy / Energy Dispersive Spectroscopy

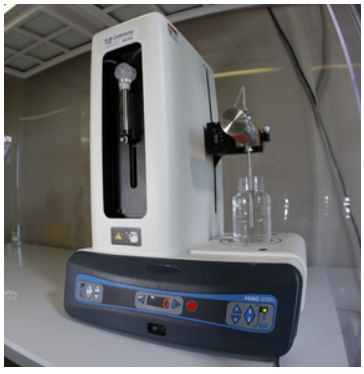
Laboratory Accreditations

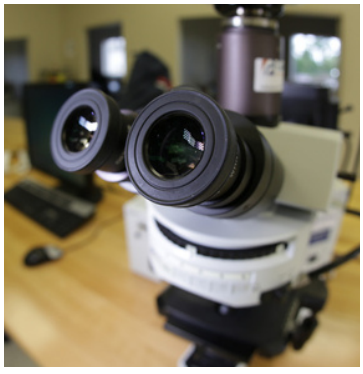
- cGMP-Compliant*
- FDA Registered & Inspected • ISO 17025:2005
- ISO 9001:2008
- 21 CFR parts 210 & 211
- 21 CFR part 820
- ICH Q7

*Raman Chemical Imaging analysis is offered as a research and development service under the ISO 17025:2005 scope of accreditation only.









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