GatewayAnalytical
an Aptar pharma company

NextBreath
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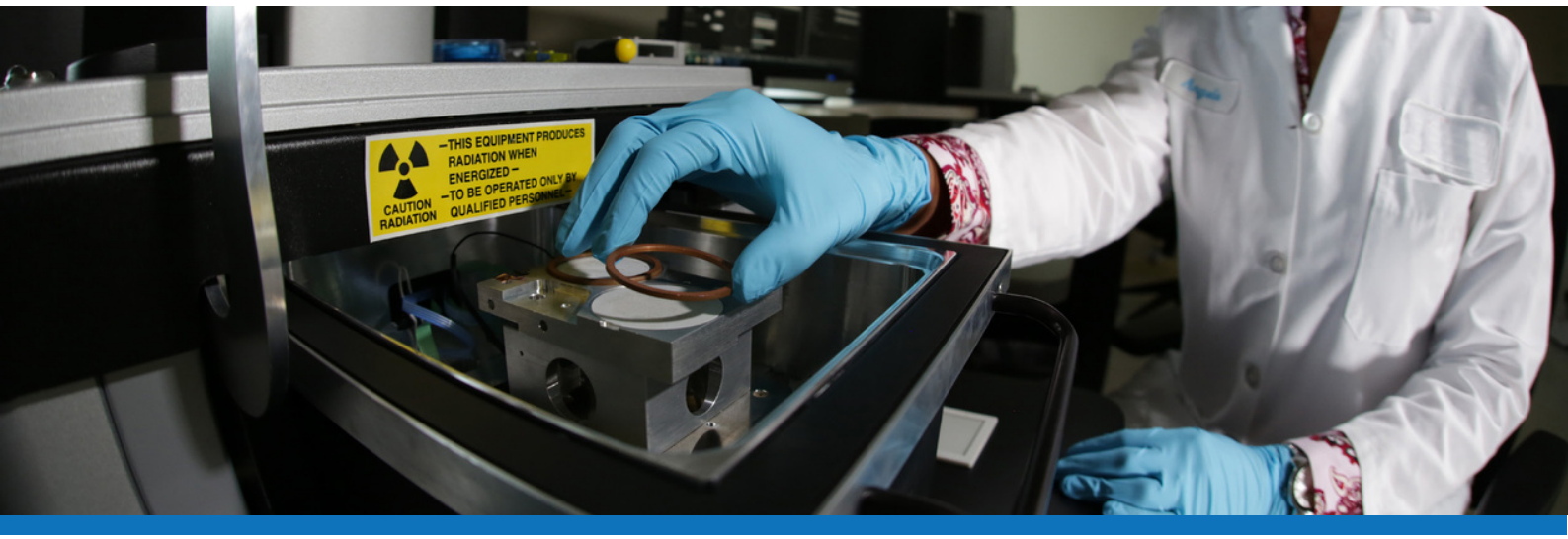


Strategic Partnership to Support pMDIs, DPIs, and Nasal Drug Product Development

Overview

Dry powder Inhalers (DPIs), pressurized Metered Dose Inhalers (MDIs), and Nasal drug products are complex delivery systems and their development requires key specialized expertise. To this end, Gateway Analytical and Next Breath are pleased to announce a strategic partnership to provide drug developers with analytical and product development support from R&D through submission and batch release for Abbreviated New Drug Applications (ANDAs-generics), New Product Applications (NDAs), and 505(b)(2) products.

This partnership will provide strategic and streamlined analytical guidance for developers of generic and new products. Next Breath and Gateway will leverage their complementary services to create customized development packages focusing on container closure screening, API selection, deformulation (reverse engineering) support, and complete CMC characterization including stability.

Comprehensive Development Support

No matter what phase of the drug development process you are in, from R&D through submission, our analytical services can support you each step of the way. Below is a listing of our combined comprehensive services for pMDIs, DPIs and Nasal drug products.

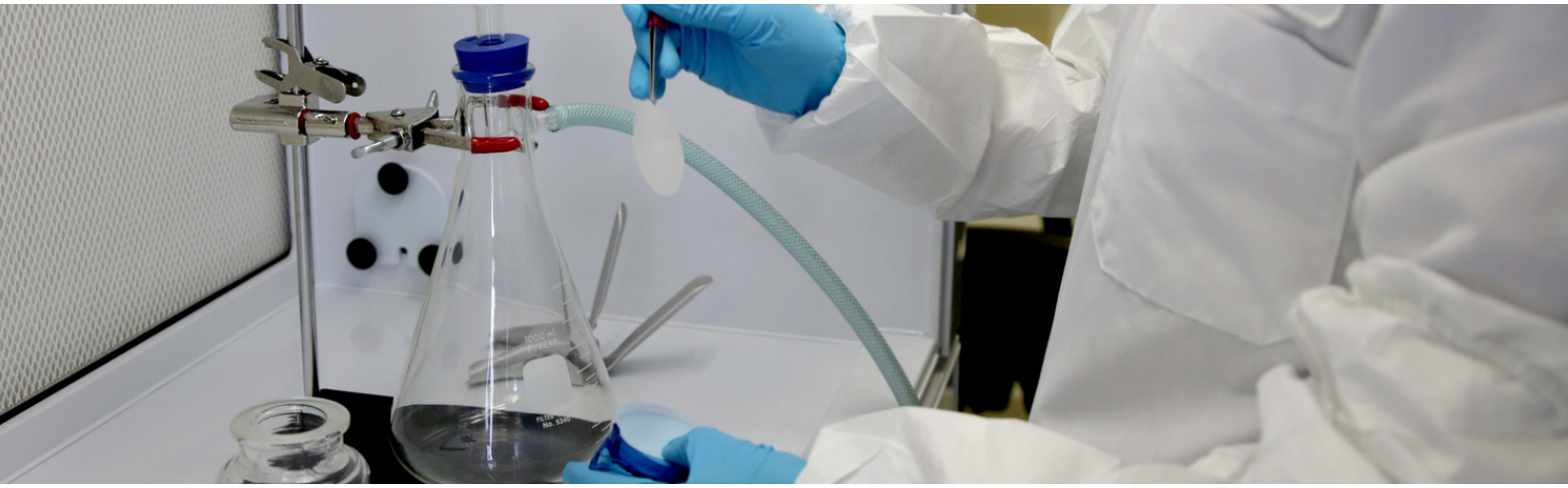
Gateway Analytical Key Services	Next Breath Key Services
• Agglomerate/aggregate identification and characterization • Chemically-specific PSD analysis • Contaminant source determination • Device testing • Foreign particulate identification • Formulation component analysis of API(s) and excipient(s) • Formulated drug product to the pure material comparison • Glass delamination analysis • Lot-to-lot reproducibility studies • Micronization process suitability • Particle morphology testing • Particulate analysis • Polymorph characterization	• Assay and impurities/degradation • Cascade impaction • Clinical batch release and finished product release • Complete CMC support • Complete IVBE packages • Container closure selection • Device robustness testing • Formulation development • Nasal cast studies • Particle/droplet size analysis • Physical characterization • Process development support • Spray pattern / Plume geometry • Stability studies / ICH stability storage • Temperature cycling
Specialty Services for Generics	**Specialty Services for Generics**
• Active pharmaceutical ingredients and excipients selection testing • In-vitro bioequivalence studies • Guidance for ANDA data submissions	• RLD characterization and container closure selection • In-vitro bioequivalence studies • Statistical analysis
Regulatory Support	**Regulatory Support**
• Stability studies • Support with FDA deficiency letters or regulatory requests for additional analysis	• Certified by ANVISA as an Equivalence Center (EQFAR) for in vitro pharmaceutical equivalence (IVPE) • Global regulatory support for FDA, EMA, Brazil, and ROW

Instrumentation & Techniques	Instrumentation & Techniques
• Optical Microscopy • Polarized Light Microscopy • Raman Spectroscopy (confocal and automated) • Raman/LIBS (RapID SPE-ls raman.ID + metal.ID) • Raman, Visible, Fluorescence and Near Infrared Chemical Imaging • Fourier Transform Infrared Spectroscopy (micro and ATR) • Scanning Electron Microscopy / Energy Dispersive Spectroscopy (automated or manual)	• Cascade impaction capabilities • Automated actuation system MDx (pMDI) and Vereo (nasal spray) • Breath simulator • Copley Critical Flow Controller • Electrostatics expertise • Gas chromatography • Humidity controlled room • Karl Fisher moisture meter • LC-MS • Pamasol 2-step filling equipment • Polarized light microscope • Spray force tester (pMDI) • SprayView (nasal/pMDIs) • Stability chambers on site • Unit Dose Sampling Apparatus for MDIs/DPIs

About Gateway Analytical

Gateway Analytical is a full service analytical testing laboratory that provides regulatory guidance and comprehensive particle characterization services to identify the physical and chemical properties of API and excipient components within a formulation. Their methods provide chemically-specific data on each particle, allowing for precise spectral identification and visual separation of the active ingredient from the excipients, even in complex formulations with multiple APIs.

Next Breath, a member of the AptarGroup, is a full service laboratory specializing in analytical testing of a range of drug delivery systems from early stage to commercialization. They provide comprehensive solutions to the drug product development process from formulation development to CMC support for generics and new product submissions to regulatory agencies worldwide.



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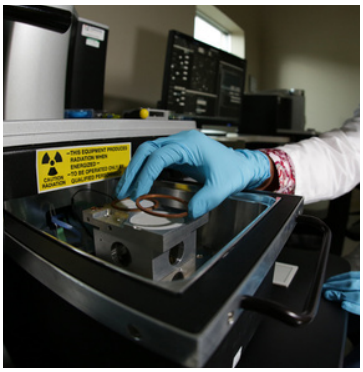

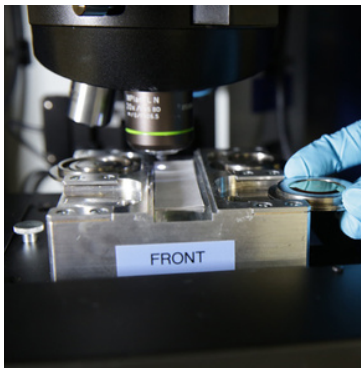

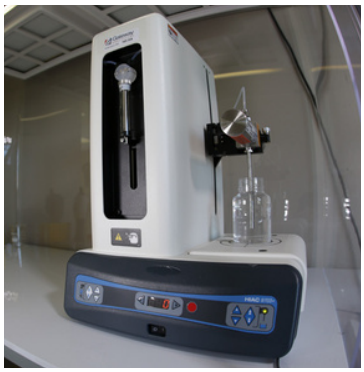

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