Regulatory Experience Around the World

We have a proven track record of working with regulatory agencies to ensure a higher product approval rate.

US (FDA)
- Guidance for Industry: Bioavailability and Bioequivalence for Nasal Aerosols and Nasal Sprays for Local Action, Draft 2003.
- Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products CMC Guidance, Draft 2002.
- Guidance for Industry: MDI and DPI Drug Products CMC Documentation, Draft 1998.

EU (European Medicines Agency) & Australia
- Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products, EMEA 2006.

Canada (Health Canada)
- Guidance for Industry, Pharmaceutical Quality of Inhalation and Nasal Products, Health Canada, 2006.

Americas
- Review of the Pharmacopeial Processes in the Americas: Argentina, Brazil (ANVISA), and Mexico.
- Brazil: Technical Standard No. 001/2013/CEFAR/GTFAR/GGMED/ANVISA.
- Brazil: Guidance for Pharmaceutical Equivalence and Bioequivalence of Nasal Sprays and Aerosols, 2009.

India
- Guidance for Industry on Preparation of Common Technical Document for Import/Manufacture and Marketing Approval of New Drugs for Human Use, 2010.

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Development Services for DPIs, MDIs, Nebulizers, and Nasal Sprays

Providing Global Regulatory Expertise with Individualized Customer Attention

NEXT BREATH

A Partner to Accelerate Your Product

Finding a devoted analytical services partner can often be an arduous task of trial and error, and in an environment where the “First to Market” wins, choosing the right one is critical. Next Breath understands the challenges companies face, and works with customers at each step of the process to ensure not only customer satisfaction, but also product stability and quality for meeting regulatory demands.

Comprehensive Solutions

Next Breath is a member of the Aptar Pharma group, and a full service cGMP compliant laboratory specializing in analytical testing of a range of drug delivery systems from early stage to commercialization. We provide comprehensive solutions for the product development process from formulation and CMC support, to finished batch release and post approval stability to regulatory agencies worldwide.

Qualifications:

- cGMP compliant laboratory, ISO 17025 Accredited and EQFAR certified laboratory through ANVISA
- Registered with FDA (last inspection January 2016 – no 483s)
- DEA license for controlled drug substances (schedule II-V)
- Subject matter experts in:
  - Analytical chemistry
  - Inhalation physical tests
  - Spray characterization
  - Particle size analysis

Instrumentation

- Next Generation Impactor
- Andersen Cascade Impaction
- Unit Dose Sampling Apparatus
- Copley Critical Flow Controller
- SprayView (spray characterization)
- Automated actuation systems
- Polarized light microscope
- Spray force tester
- Breath simulator
- Karl Fischer
- FTIR
- Waters HPLC systems
- GC-MS
- GC-HS
- LC-MS

Focused Development Services

Our scientists utilize the latest instrumentation and methodologies to provide customers with the highest quality of analytical analysis of MDI’s, DPI’s, nebulizers, and nasal drug products. We develop a specific program to meet all requirements necessary including stability storage conditions and determining the relevant experiments needed according to the industry guidance. At the completion of each project, we provide customers with detailed reports ready for regulatory submission.

Development → **CMC** → **Post Approval**

Services

- Formulation Development Support
- Device Selection
- Method Development
- Method Qualification
- Method Transfer
- Method Validation
- R&D Stability Studies
- IND Enabling Studies

- ICH Stability
- Clinical Batch Release
- Process Validation
- Temperature Cycling
- Prime Reprime
- Effect of Dosing Orientation
- Cleaning
- Device Robustness
- Photostability
- Priming and Repriming
- Device Profiling
- Effect of Moisture
- Effect of Varying Flow Rate
- Device Resistance
- Extractables & Leachables
- Spacer testing

- Finished Product Batch Release
- Device Batch Release
- Post Approval Stability
- Stability Reporting
- Annual Product Review

Methods (Available with any Service)

- Assay
- Impurities and Degradation
- Related Substances
- Preservative Assay
- Particle Size
- Droplet Size by Laser Diffraction
- Aerodynamic Particle Size
- Dose Content Uniformity
- Spray Pattern
- Plume Geometry
- Pump Delivery
- Shot Weight
- Surface Tension
- Viscosity
- Moisture Content
- Osmolality
- Microbial limits
- Particulate Matter
- Identification
- Appearance
- Color
- Weight loss
- Net Content
- Nasal Cast Deposition
- Spray force