

INTERTEK PHARMACEUTICAL SERVICES

ORALLY INHALED AND NASAL DRUG PRODUCT (OINDP) DEVELOPMENT AND TESTING

Support for Metered Dose Inhalers,
Dry Powder Inhalers (DPIs), Nasal sprays and other
classes of OINDP



ORALLY INHALED AND NASAL DRUG PRODUCT DEVELOPMENT AND TESTING

Our inhaled and nasal product development team focus on the critical parameters that can affect the efficacy of drug delivery to the intended target across all respiratory product classes including dry powder inhalers (DPIs), pressurised metered dose inhalers (pMDIs), nebulisers and nasal sprays (solution, suspension or dry powders), as well as a range of novel respiratory delivery systems.

We have been working in the inhaled and nasal fields for over 25 years and have the necessary experience to support your entire product development process, delivering formulation development / optimisation, product performance testing, stability / CMC support and clinical manufacturing services that are designed to provide the right information at the right time.

With Intertek as your development partner, we provide full support for your chemistry, manufacturing, and controls (CMC) activities for the submission of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for inhalation and nasal drug products.

- Method Development / Validation
- Bioequivalence Studies
- Comparator Studies
- Device / Excipient Compatibility Studies
- Quality by Design (QbD) Studies
- ICH and Accelerated Stability Studies
- Formulation Development
- Clinical Trials Materials Manufacturing
- Product Characterisation Studies (e.g. patient in-use / misuse, spacer and cleaning studies, etc.)
- Device Verification Testing
- Foreign Particulates Analysis and Identification



OINDP product development and testing

Our experts provide high quality cGMP analytical services to the pharmaceutical, biotech and consumer healthcare industries for inhalation and aerosol-based products

Alongside typical drug product specification testing such as identification, assay, degradation products, moisture and pH, our OINDP services include drug delivery characterisation, aerodynamic particle / droplet size distribution, spray pattern / plume geometry, physical characterisation for particle size, droplet size and powder rheology. With extensive experience in method development and validation, we also perform GMP compliant clinical batch and finished product release testing, EU Import Testing and offer flexible resources for raw materials quality control testing.

To address the control of leachables from device components, we apply our unrivalled knowledge of polymer materials and expertise within extractables / leachables studies to drug / packaging interaction areas.

Inhaled product analytical testing

- Aerodynamic Particle Size Distribution
- Next Generation Impactor (NGI)
- Anderson Cascade Impactor (ACI)
- Abbreviated Impactor
- Particle / Droplet Characterisation:
- Proveris SprayView system for spray pattern and plume geometry
- Proveris Vereo automated actuators
- Malvern Spraytec Laser Particle and Droplet sizing
- InnovaSystems automated actuators
- Malvern Morphologi G3-ID with Morphologically-directed Raman spectroscopy (MDRS)
- Assay and Impurities methods using a range of chromatographic techniques
- Powder Rheology (Freeman FT4)

Extractables / Leachables

- Identification of Extractables
- Development and Validation of Leachable methods (for use in stability programmes)
- Routine Qualitative and Quantitative Extractables Testing

Drug delivery characterisation

- Delivered Dose Uniformity
- Total Active Substance Delivery
- Drug in Small Particles / Droplets
- Morphologically-directed Raman spectroscopy (MDRS)

OINDP stability studies

Our dedicated GMP stability storage facilities allow us to manage all aspects of stability study requirements at every stage of a product's development, from early preclinical to commercial batch stability. We provide both accelerated degradation studies and real time ICH stability studies.

Formulation development

Intertek's integrated formulation and analytical teams carry out early stage pre-formulation support, solubility screening, drug-excipient compatibility, stability testing and device selection support to aid clients working to develop more efficient devices and formulations with both small molecule and biologic drug substances. The development of inhaled biologics brings together two of our core strengths; formulation development for inhalation technologies and biological product characterisation, in particular, applying methodologies to assess potential degradation routes.

Nasal product development

Our nasal drug development scientists provide method establishment, testing, formulation and clinical manufacturing services to help you optimise the performance of your product in either aqueous, powder or propellant-driven forms. Conducted in Good Manufacturing Compliant (GMP) laboratories, our services can support you from early phase formulation development, device screening, CMC support, accelerated and real time studies stability studies, clinical supply manufacture and release testing, through to finished product release testing and EU import testing.

We routinely provide in-vitro bioequivalence studies (IV-BE) for generic products, including full GMP statistical analysis and dossier generation. With our Malvern Morphologi G3-ID capability, which has morphologically-directed Raman spectroscopy (MDRS), we can also perform direct measurement of the active pharmaceutical ingredient (API) particle size in the nasal suspension with robust identification of both drug and excipient. This test has become valuable for developers of generic suspension products, where equivalent data in this test compared with the reference product may be used in-lieu of clinical, pK end-point data.

We meet your product characterisation requirements in line with relevant CMC guidance through patient in-use / mis-use studies, device verification, cleaning studies, dosing to exhaustion and extractables / leachables.

- CMC Testing and Support
- Bioequivalence Studies
- Comparator Studies
- Stability Studies & Accelerated Degradation Studies photo-stability and freeze-thaw studies
- Device Compatibility Studies
- Method Development & Validation
- Clinical Manufacturing
- Product Characterisation Studies (e.g. patient in-use / misuse)
- Device Verification Testing
- Clinical Release & Finished Product Release Testing
- EU Import Testing
- Visible / Sub-visible particulate contamination analysis and identification

Over 25 years' experience in OINDP development services

- Pressurized Metered Dose Inhalers (pMDI)
- Nasal Sprays (aqueous, powder, and propellant driven)
- Dry Powder Inhalers (DPI)
- Nebulizer (Solutions and Suspensions)
- Aerosol Based Healthcare and Cosmetic Products
- Soft Mist Inhalers



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