Testing of Orally Inhaled and Nasal Drug Products

Analytical services for orally inhaled and nasal drug substances and drug products

- Aerodynamic particle size distribution
- Plume Geometry and Spray Pattern
- Foreign particulate matter
- Content and delivered dose uniformity

solvias

OINDP development poses unique challenges, often leading to project delays and increased costs. Solvias stands out as your ideal partner to navigate these complexities. Leveraging our expertise in E&L, solid state characterization, biopharmaceuticals, and OINDP services, we offer **end-to-end analytical support across the entire OINDP portfolio** with one overarching goal: to expedite the journey of your products to market.

Analytical Services for a Spectrum of OINDPs

Solvias provides expert support across the entire OINDP development cycle on a wide range of products.

- ✓ **Pressurized metered dose inhalers (pMDI)**
- ✓ **Dry powder inhalers (DPI)**
- ✓ **Nebulizers**
- ✓ **Nasal sprays**
- ✓ **Soft mist inhalers (SMI)**

Accelerated Turnaround Time

The success of our customers is closely tied to **time-to-market**. We actively collaborate throughout the product development phase to design analytical testing plans that conform to regulatory standards, maintain the highest safety and quality benchmarks, and expedite product launches. We will collaborate closely with you to ensure that the **appropriate tests are done right, the first time, and on time**.

As fast as 10 business days

Our Technology

Solvias boasts state-of-the-art analytical tools, including impactors (**NGI**) and dosage unit sampling apparatus (**DUSA**) for accurate assessment of inhaler performance. Our automated systems (**Vertus** and **DecaVertus**) ensure reproducible testing outcomes, and our spray measurement systems (**Sprayview** and **Spraytec)** are designed to meet the rigorous testing standards for spray characterization.

Navigate Regulatory Landscape

Benefit from the profound knowledge of our Technical Project Leads and direct access to subject matter experts throughout your project. With vast experience in the inhalation sector, our team provides not only **top-tier analytical solutions** but also valuable **regulatory guidance** to navigate the complex landscape of OINDP development. Our comprehensive services are designed to **meet FDA/EMA GMP requirements**, supporting you through every step, from drug characterization to bioequivalence studies.

Biologics

Traditionally, biologics have been administered through parenteral injections. However, pulmonary delivery is emerging as a compelling non-invasive alternative. Solvias boasts a strong reputation among market-leading biopharmaceutical companies for its expertise in biologic characterization and quality control analysis. Take this opportunity to leverage our expertise in both biopharmaceuticals and OINDPs to accelerate your biologics journey to the market.

Bring **your innovation** to its destination

One-Stop Analytical Solution

Our services span from early-stage formulation analysis and device selection to full-scale analytical CMC programs, including stability, bioequivalence, and comparability studies, culminating in the pivotal commercial batch release.

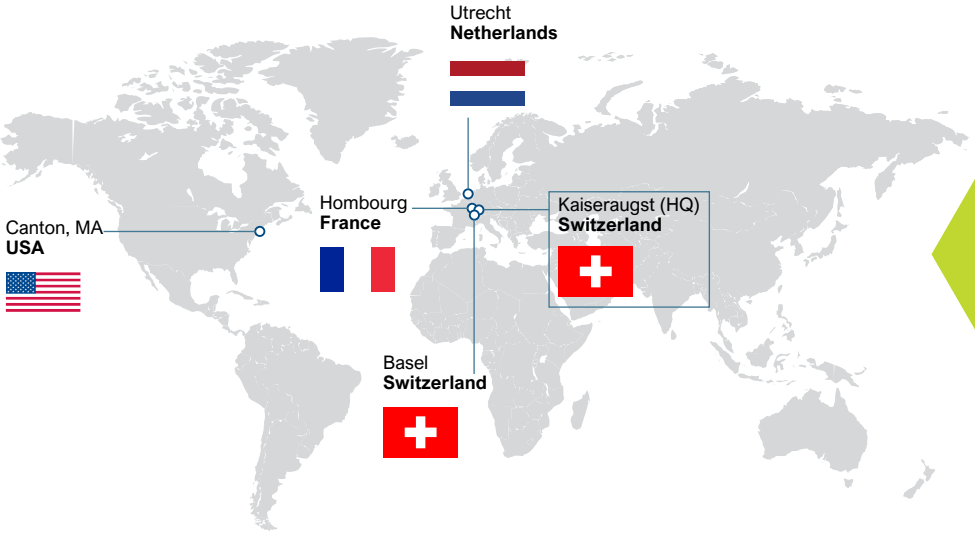
- ✓ Method development and optimization
- ✓ Method validation, qualification and transfer
- ✓ Drug substance properties and forced degradation studies, solubility determination
- ✓ Stability, release and QC testing
- ✓ *In vitro* bioequivalence tests for generic products
- ✓ In-use studies
- ✓ Drug product characterization studies
- ✓ Aerodynamic particle size distribution by cascade impactor
- ✓ Delivered dose uniformity
- ✓ Spray Pattern
- ✓ Plume Geometry
- ✓ Droplet size distribution

Beyond OINDP

Alongside our OINDP capabilities, we offer a wide array of analytical solutions for drug products and delivery devices, including solid state development, extractables & leachables analysis, and biopharmaceutical studies. Choose Solvias for comprehensive support and expertise in bringing your products to market with confidence.

Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



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