

### Metered Dose Inhalers | Dry Powder Inhalers | Nebulisers Aqueous Droplet Inhalers | Nasal Products

Localised and systemic drug delivery via inhalation is a growing area of interest within the pharmaceutical industry, particularly for vaccine development. RSSL can support the development and validation of analytical methods for pharmaceutical and biopharmaceutical nasal drug products and inhaled drug delivery platforms. Inhaled and nasal drugs require stringent analytical testing to ensure that drug product is safe and effective.

RSSL can support you with the analytical testing including purity and contamination testing of drug components to ensure the drug product's safety, quality and efficacy is not compromised at any stage from manufacture to market release. The consistent dose delivery by inhaled/nasal drug delivery platforms presents a significant challenge. With more than 35 years of analytical excellence, RSSL has the expertise and experience to help you to bring your drug product to market.

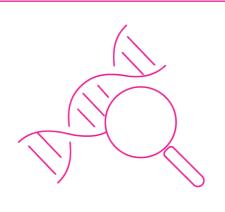


## Discover our range of innovative analytical solutions

RSSL is committed to making the world safer, healthier, and more sustainable by creating and implementing intelligent solutions.

We are also constantly expanding and evolving our expertise to support the development of therapeutics at the cutting-edge of the pharmaceutical industry.

With our extensive analytical testing facilities and equipment, our skilled teams can support your analytical requirements for both nasal drug products and inhaled drug delivery platforms.



#### Developing through collaboration

We can provide continuous support throughout inhalation drug product development, from research and development, through clinical phases and into manufacture and release to help ensure your product is safe and efficacious. Our services for chemical and biologic inhaled drug products include:

- Formulation development such as solubility studies, excipient compatibility studies, microbiological testing, extractable leachable testing, and sterility
- Particle characterisation
- · Analytical method development and validation
- Short- and long-term stability studies
- Risk assessment testing, including elemental impurities (ICH-Q3D) and residual solvents
- Pharmacopeial raw material testing and verification
- QC release testing of the finished products

#### Evaluation with expert knowledge

RSSL have the expertise and technology to support the development and evaluation of inhaled drug delivery platforms. This includes pressurised metered dose inhalers (pMDI) and dry-powder inhalers (DPI). When evaluating an inhaled drug delivery platform, there are two main factors that need to be considered to ensure that the correct dose is being delivered to the patient, and safety and efficacy are being maintained:

- Delivered Dose Uniformity (DDU)
- DDU relates to how much drug is delivered to the patient and how consistently it is delivered throughout the lifespan of the delivery device.
- Aerodynamic Particle Size Distribution (APSD)
  APSD considers where the drug is deposited in the lung and whether it is being delivered in a therapeutically effective manner.

RSSL can offer both DDU and APSD analyses using Next Generation (NGI) and Andersen Cascade Impactors (ACI). We also offer method comparison, as well as extractable and leachable testing of drug delivery systems.





# Your trusted analytical partner for inhalation drug products

At RSSL, we are dedicated to transforming lives through science, innovation, and collaboration. With 35 years of analytical experience, we are here to support the development of your inhaled drug and delivery platform, from early research through to manufacture and release.

We look forward to partnering with you.





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