COPLEY

Experts in Nasal Spray, Nasal Aerosol and Nasal Powder Testing

Nasal drug product development is currently the focus of considerable research activity. Traditionally, nasal preparations have been used for the local administration of antihistamines, decongestants and steroids in order to alleviate cold or allergy symptoms and nasal congestion. A growing interest in nasal drug product development is largely fuelled by its wide-ranging potential for systemic and nose-to-brain drug delivery, vaccination, and drug repurposing.

When it comes to testing these medicines, multiple *in vitro* techniques can be usefully deployed for either new or generic product development. However, there is a growing need for better strategies to improve the sensitivity and clinical relevance of *in vitro* nasal drug product test methods to provide more insight for targeted systemic drug delivery and to demonstrate bioequivalence more rigorously.

Our nasal drug product testing solutions enable better, more informative testing in line with evolving market requirements.

Dose Uniformity Sampling Apparatus (DUSA)

For vertical (or near-vertical) nasal product actuation as recommended in Ph. Eur. 0676 and USP <601>

Delivered Dose Uniformity (DDU)

DDU testing is used to confirm that a consistent dose is delivered throughout the lifetime of the nasal drug product device. We offer two dose collection devices, depending on testing requirements.

Nasal Spray Dose Collector (NSDC) ***Patent Pending***

An optimised internal geometry eliminates splashback, drips and leakage and ensures complete dose capture every time, while the low internal volume and easy internal access aids drug recovery.

Aerodynamic Particle Size Distribution (APSD)

Nasal drug products typically generate particles with an MMAD >10-20µm to ensure nasal deposition and minimise deposition in the lungs.

However, they will also produce a proportion of drug in smaller particles/droplets (<10µm) which must be quantified as deposition of this respirable fraction beyond the nasal tract may be undesirable.

Aerodynamic particle sizing using a cascade impactor is a US FDA requirement and is recommended in USP <601> to complement other sizing techniques.

Glass Expansion Chamber

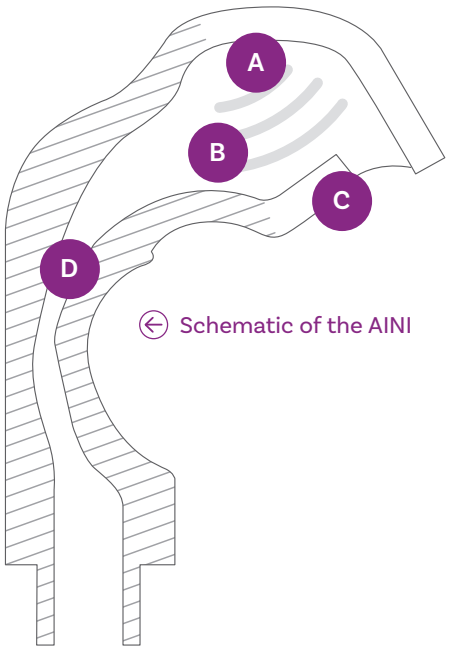
Used together with a cascade impactor (shown here with the Andersen Cascade Impactor ACI), the Glass Expansion Chamber maximises aerosolization of nasal drug products following actuation. Particles captured within the impactor are quantified to provide detail of the respirable fraction.

3 different chamber sizes are available.

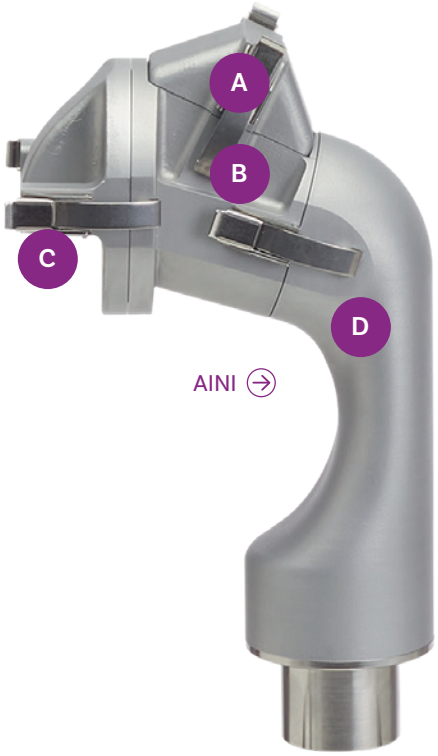
Alberta Idealised Nasal Inlet (AINI)

A Better Model of Nasal Regional Deposition

- **A** Olfactory region
- **B** Turbinates
- **C** Vestibule
- **D** Nasopharynx



Schematic of the AINI



AINI

Based on scans taken of multiple, diverse, realistic adult nasal geometries, the AINI was developed to enable representative testing of drug deposition within discrete regions of the nasal tract.

Improving the clinical relevance of routine *in vitro* tests, the AINI has separable parts allowing the chemical assay of location-specific drug deposition.

The AINI can be used with:

- an external filter to study regional deposition and representatively measure the respirable dose
- a cascade impactor for representative measurement of the APSD of the respirable dose and determine the amount of drug in small particles/droplets with a high degree of clinical realism.

Automated nasal device weighing via an integrated balance

Vertus® Plus with DUSA Interface Plate

For DDU testing

For APSD measurement

Automated Nasal Spray Testing

Automation not only eases the burden associated with routine analysis, but it also plays an important role in reducing variability and improving data integrity.

Our well-established, fully automated and flexible Vertus® shake, fire and flow control systems can be used for nasal spray testing to meet the need for highly consistent actuation, as required by USP <601>. The Vertus® Plus model also includes an integrated analytical balance for automated shot weight measurement.

At the same time, Vertus® enables researchers to systematically investigate the impact of patient-specific parameters such as shaking or actuation technique.

Compatible Vertus® Nasal Interfaces

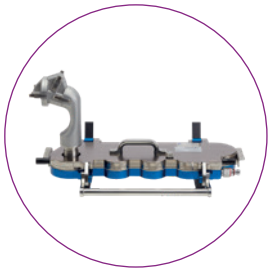
DUSA Interface Plate

Nasal Spray Dose Collector (NSDC)

Nasal Spray Waste Collector (NSWC)

NGI with Glass Expansion Chamber

ACI with Glass Expansion Chamber



NGI with Alberta Idealised Nasal Inlet (AINI)

ACI with Alberta Idealised Nasal Inlet (AINI)

Scan to access our online nasal product testing resources

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