Nebulized Drug Delivery

TEST SERVICES

Accelerate your Product Launch with Proveris Laboratories' Nebulized Drug Testing Services

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Nebulizers are essential in pulmonary medicine, delivering medication in aerosol form directly to the lungs. A drastic rise in development of inhaled biologics and advances in technology such as vibrating mesh nebulizers are driving novel nebulized therapies. Nebulized therapies are also particularly beneficial for patients, such as children, the elderly and the physically impaired, who struggle with traditional inhalers. This development is complex because a successful nebulized drug involves optimizing the formulation and nebulizer device combination to ensure the drug reaches the lungs effectively. Proveris Laboratories has the experience and expertise to navigate strict regulatory testing requirements essential to successful nebulized product development.

Nebulizers / Formulation Screening Studies Knowledge Needed to Make Informed Decisions

Whether you want to evaluate how your formulation performs in various nebulizers or to evaluate different breathing profiles, Proveris Laboratories can help. Using demographically relevant realistic breathing profiles, nebulizer studies with Proveris Laboratories provide you with a complete understanding of product performance as it will be used by the patient. Thorough screening of device formulation combinations using human realistic breathing not only helps you comply with regulations but also reduces the risk of late-stage failures by simulating human usage.

Once the formulation and nebulizer are chosen, numerous tests are required for NDA or ANDA submissions. Proveris Laboratories can assist with these, including dose determination for delivery rate and total API delivered, as well as droplet size distribution.

Dose Determination

In dose determination experiments, accurately quantifying the drug substance collected is critical.

Variability in dose delivery can impact therapeutic efficacy and regulatory approval.

Filter spike and recovery experiments validate this by spiking a known concentration of the active drug substance onto filters and quantifying the extracted drug substance.

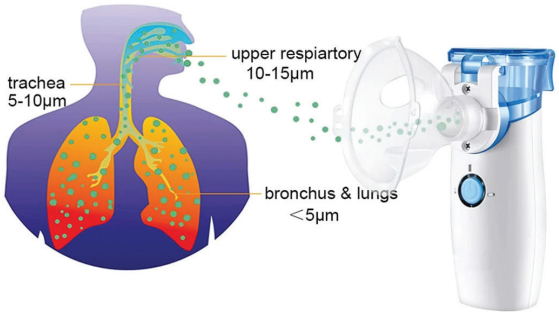
This ensures the accuracy and repeatability of the quantification process, enabling researchers to make informed decisions and advance nebulized drug therapy development.

Dry Substance Delivery Rate and Total Dry Substance Delivered

Following USP <1601> guidelines, Delivery Rate and Total Drug Substance Delivery needs to be determined using either a volumetric flow rate, or a breathing simulator. Any nebulizer that is breath actuated or breath assisted would be best evaluated with a breathing simulator and the appropriate breathing profiles. With the breath actuated or breath assisted nebulizers, total drug substance delivered is dependents on the inhalation flow rate.

The drug substances is extracted using a validated extraction procedure after a specified time (often 1 minute) to determine the Delivery Rate, and then by extracting filter(s) across the total nebulization process to determine the Total Drug Substance Delivered. Quantitation is typically done by HPLC analysis.

This method ensures adherence to standardized procedures and accurate assessment of Drug Substance delivery parameters, facilitating a robust evaluation of nebulized drug therapies.

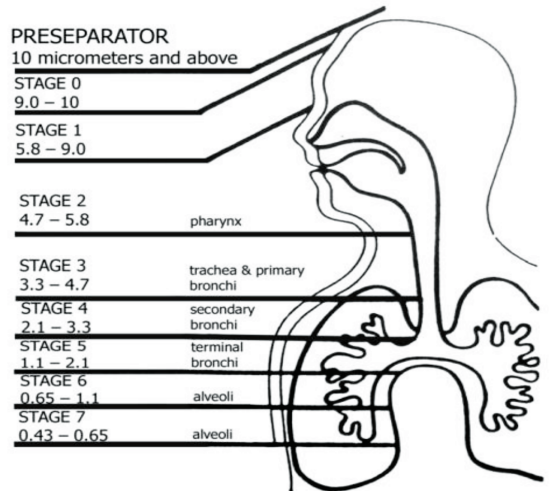


Particle Size Distribution Testing

The safety and effectiveness of nebulized drugs depends on consistent particle size. Deposition in the lungs is directly impacted by particle size. Proveris Laboratories adheres to Aerodynamic Particle Size Distribution (APSD) testing requirements outlined in FDA guidance's documents and U.S. Pharmacopeia chapter <1601>. Optimizing the particle size distribution is essential; particles that are too large may not reach the lower airways, reducing efficacy.

Method development is critical in particle size distribution, to assure the next generation impactor is not being overloaded by too large of a sample size, this can be managed by determining an effective sampling period to not cause overloading, and to match with the analytical sensitivity of the method. By accurately measuring and controlling particle size distribution, drug delivery is optimized, which maximizes therapeutic benefits, and minimizes potential side effects.

The APSD testing can be paired with Droplet Size Distribution testing offered at Proveris Laboratories that can bring additional insights into particle size.



Benefits of Working with Proveris Laboratories

- **Screening of Nebulizers** rapid ability to evaluate different nebulizer types and vendors to determine optimum performance
- **Screening of Formulations** even small formulaiton changes can have an impact on how the forumlations nebulizes and performs
- **Screening of Different Breathing Profiles** helps to model how different patient conditions are impacted by the nebulizer/formulation.
- **Comprehensive *in vitro* development and regulatory testing.**

A Trusted Partner for Over 25 Years

To expedite the development of nebulized drug products, Proveris Laboratories' experienced team provides comprehensive nebulized API testing services tailored for both novel and generic drug development. By leveraging Human-Realistic Breathing, developers gain invaluable insights into understanding how their nebulized formulations interact with human-realistic respiratory dynamics across all patient populations, adults, children, infants and neonates.

This systematic approach facilitates the development of more efficient and tailored therapies and can also be used to screen different formulation and nebulizer combinations. This ultimately enhances patient outcomes and quality of care.

Once the development process is complete, Proveris Laboratories is then able to help with the submission data for an NDA or ANDA submission.

Let Proveris Laboratories serve as an experienced strategic partner and an additional resource to advance the drug development and submission process forward for nebulized drug products. By integrating advanced technologies and expert support, pharmaceutical companies can navigate the complexities of inhaled drug development and bring innovative treatments to market.

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