SPRAY CHARACTERISATION TESTING

In this article, Ann Flodin, Vice President Inhalation Product Development and GM at Recipharm, introduces the company's SprayVIEW® measurement and automated actuation stations for the development and quality control of container closure and finished products.

SPRAYVIEW® MEASURING SYSTEMS BY PROVERIS

Recipharm has the expertise and specialised equipment to support the development of quality analytical techniques for the development of inhaled products, specifically nasal and oral sprays, and pressurised metered-dose inhalers (pMDIs). This includes the company's SprayVIEW® measurement and automated actuation stations, developed by Recipharm's expert development team. SprayVIEW® is a registered trademark of Proveris Scientific Corporation (Hudson, MA, US).

Inhalation products are extremely complex to develop and manufacture, and it is important to understand potential interactions between the formulation and the delivery device throughout the development stages.

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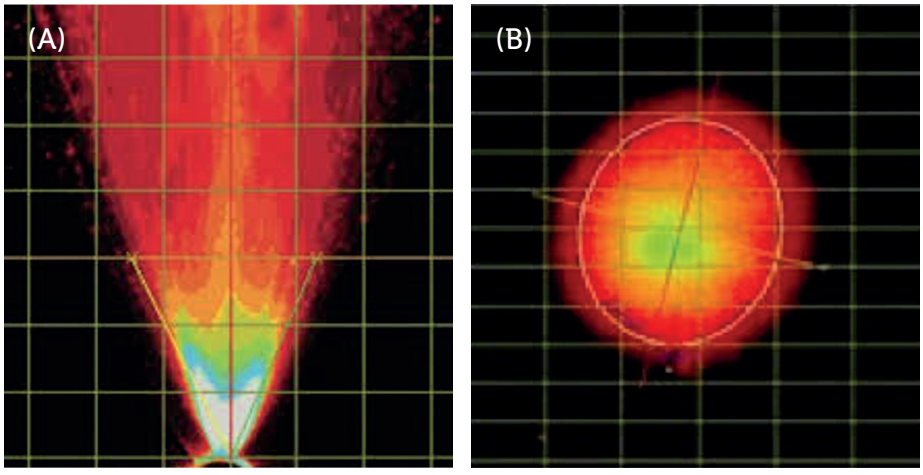

Figure 1: (A) Plume geometry and (B) spray pattern.

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Figure 2: Recipharm offers inhalation and nasal spray product development.

> "Recipharm carries out *in vitro* bioequivalence (IVBE) studies in generic inhalation and nasal spray product development, and uses its expertise to develop and validate SprayVIEW®-based methods for aerosol and nasal spray testing."

The acquisition of real-time images of aerosols or sprays emitted from a device, using a high-speed camera, enables subsequent analysis of the spray pattern and plume geometry, which represents the shape of the aerosol or spray.

Recipharm's automated MDx and NSx actuation stations allow for consistent actuation using parameters such as actuation velocity and acceleration, minimising intra- and inter-device variability. The NSx and MDx are automated test stations for actuating nasal spray products and pMDIs, respectively.

Actuation graphs, derived from data collected during spray pattern and plume geometry measurements, display the actuation profile to determine the force-to-actuate profile of the device.

SprayVIEW® measurement systems are not only valuable tools to guide drug product development, but can also be used to support quality control for container closure components (i.e. valves, pumps) and finished drug products.

As part of Recipharm's spray pattern and plume geometry test service, the company offers inhalation and nasal spray product development from initial formulation and process development to registration, commercial batch release and product characterisation. Recipharm carries out *in vitro* bioequivalence (IVBE) studies in generic inhalation and nasal spray product development, and uses its expertise to develop and validate SprayVIEW®-based methods for aerosol and nasal spray testing. The company also provides support with device-related changes during the product lifecycle (Figure 2).

WHY CHOOSE RECIPHARM INHALATION SOLUTIONS

Recipharm Inhalation Solutions™ provides a comprehensive, end-to-end service, which manages complexity and reduces risk for its customers. With its experience and track record, Recipharm is a leading contract development and manufacturing organisation (CDMO) in the inhalation field, with a long history of inhalation drug product and device development and manufacturing. Recipharm's depth of knowledge enables it to overcome the challenges associated with inhalation drug products and devices; by developing inhalation products with the device and commercial manufacture in mind, the company eliminates hurdles and reduces the time to market.

Recipharm has facilities in the US and EU dedicated to inhalation development and manufacturing, including a large pilot plant for clinical manufacture and small-scale manufacture. In addition, its services are supported by strong corporate health, safety, environment and cGMP quality systems to ensure the highest levels of compliance across worldwide markets.

ABOUT THE COMPANY

Recipharm is a CDMO, offering manufacturing for various dosage forms, production of clinical trial material and APIs, and pharmaceutical product development. Bespak by Recipharm delivers market-leading design development and manufacture of drug delivery devices, including orally inhaled and nasal technologies and autoinjectors, as well as development and manufacturing services. Recipharm has the competence and flexibility to take on challenging projects that require tailored processes. The company has the expertise to support project needs from development to full-scale manufacturing and life cycle management. Recipharm's end-to-end offering allows the company to help manage its customers' journeys from molecule to market, every step of the way.

ABOUT THE AUTHOR

Ann Flodin has 25 years of experience in the pharmaceutical CDMO industry and has held various leadership roles in Europe and in the US. Ms Flodin has extensive knowledge in product and process development and technology transfers across several different dosage forms, as well as vast experience in operational and strategic development. Ms Flodin currently leads Recipharm's product development business for orally inhaled and nasal drug products, and is a member of the management team for Recipharm's consolidated development business.