

COMBINATION INHALATION DEVICES



A WORLD-LEADING MANUFACTURER OF INHALATION DEVICES

Around 300 million people worldwide live with asthma¹ and 250 million with COPD². Many of these people rely on one of a range of inhalation device technologies to deliver lifesaving medication to their lungs. As a world-leading developer of drug delivery devices, Bepak by Recipharm has more than 60 years of experience as a trusted supplier of innovative dry powder inhalers, and valves and actuators for pressurised metered dose inhalers (pMDIs).

We have contributed to the design, development, and commercialisation of some of the world's leading inhalation devices. We are firmly established as one of the major pMDI valve suppliers worldwide. Our proprietary pMDI valves and actuators are critical components in several products approved by the US FDA.





pMDI VALVES

As the most technically complex element in a pMDI, the valve is critical to delivering a consistent and precise metered dose of medication to patients.

Developed to work with a wide range of formulations with low levels of extractables and leachables to ensure that they are both versatile and clean.

Robust and sterile manufacture to meet stringent regulatory requirements.

Reliable cGMP compliant commercial supply chain.

ACTUATORS

Optimised to work with our pMDI valves and are compatible with a wide range of canisters.

They are 100% airflow tested and supplied ready for immediate use in final packaging operations.

Uniquely customisable to meet the specific needs of your product.

Supplied with dust cap to keep the mouthpiece clean.



DRY POWDER INHALERS

We offer integrated drug, device and combination product development and manufacturing support for dry powder inhalers (DPIs).

Harnessing our 'Design for Manufacture' experience, we can optimise DPI product designs and manage the risks associated with scaling-up manufacturing capabilities.

DOSE COUNTING ACTUATOR

Reliably displays the remaining doses in the pMDI so end-users can see at a glance when they need to obtain a replacement device.



SOFT MIST NASAL SPRAY DEVICE

The NSPY™ device is an open nasal spray platform for application of medication to the nasal mucosa. It is a spraying adapter that can be connected via luer-lock to a disposable or pre-filled syringe.

It is a gentle spray with a long duration (1-2 seconds).

It reaches the whole nasal cavity because of the fine droplets.

Dose per spray: 100 µL. Fill dose: 200 µL (two sprays).

PRE-FILLED SYRINGE INHALER (PFSI)

The Soft Mist Inhaler (SMI) harnesses proprietary spray nozzle technology to deliver aerosols as a liquid solution.

Ideal for the delivery of both small and complex large molecules.

Specially designed to optimise lung deposition whilst minimising oropharyngeal deposition.



UNIDOSE® XTRA NASAL SPRAY DEVICES

Offers unique performance advantages through the use of IP protected technologies that control actuation and drug delivery.

Simple single unit dose so no priming is required.

Adjustable volume levels.

Customisable spray performance for specific formulation needs.

Ergonomic shape with ambidextrous profile.

PULMOSPRAY

Designed to substitute nebulisers in:

Clinical environment (e.g. COVID-19).

Products requiring reconstitution.

Single-dose treatments.

Clinical trials, investigational drug products.



FORMULATION DEVELOPMENT AND COMMERCIAL SUPPLY

Our dedicated team of specialists supports the development of the following inhaled dosage forms:

- ▶ Pressurised metered dose inhalers (pMDI)
- ▶ Dry powder inhalers (DPI)
- ▶ Soft mist inhalers
- ▶ Nebuliser solutions
- ▶ Unit dose and multi dose nasal sprays
- ▶ Nasal aerosols and powders

Our inhalation product development group has extensive experience in formulating suspensions, solutions, and dry powder blends. We offer:

- ▶ Dosage form selection
- ▶ Formulation selection and optimisation
- ▶ Aerosol characterisation
- ▶ Reverse engineering (e.g. Q1 and Q2 matching of generics)
- ▶ *In vitro* bioequivalence studies
- ▶ Commercial manufacturing capabilities for pMDI and nasal spray



Recipharm Inhalation Solutions™

Recipharm is a leading CDMO in the inhalation space, with a long history in inhalation drug product and device development and manufacturing. Recipharm offers an integrated service for inhalation drug products and devices from early stage development through to commercial manufacturing for pMDIs, DPIs and nasal sprays.

Delivering market leading design, development, and the manufacturing of drug delivery devices to the global pharmaceutical market, in conjunction with Bepak by Recipharm, the integrated CDMO can comprehensively cater for, inhaler, nasal and auto-injector projects, as well as providing access to a team of experts with decades of expertise that allows them to manage complexity and accelerate routes to market. These expertise form part of Recipharm's Inhalation Solutions™, an integrated service spanning early phase development to commercial manufacture.

As a global CDMO, Recipharm is at the forefront of global compliance requirements for inhalation products. For more information, please visit: recipharm.com

References: 1. <https://ginasthma.org/wp-content/uploads/2021/05/GINA-Pocket-Guide-2021-V2-WMS.pdf>. 2. <https://copd.net/statistics>

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.