TwinCaps®

A simple, disposable cost effective dry powder inhaler with high performance.

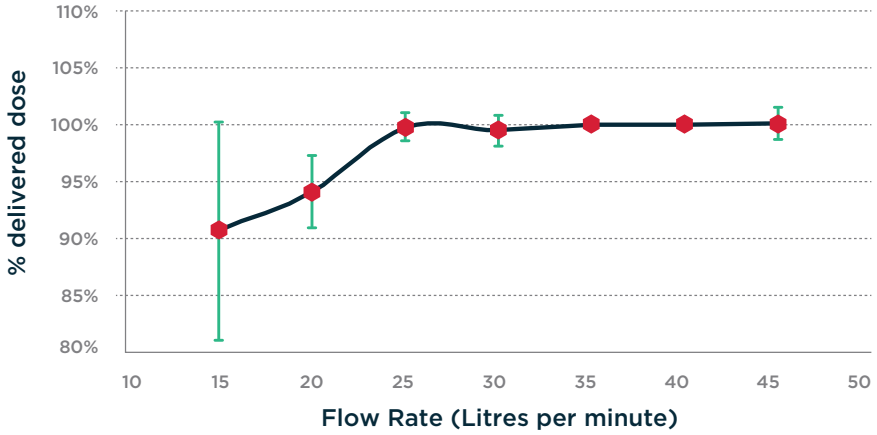
Hovione

The Challenge: In 2006, Hovione was asked to develop a disposable, pre-filled, low cost dry powder inhaler to deliver a large dose of drug.

The Solution: TwinCaps®, a two-component inhaler with a single step to inhalation, currently in Phase III clinical trials for an influenza drug.

TwinCaps® can deliver lactose-based or particle-engineered powders, and Hovione has effective experience in both types of formulations, from proof of concept, to optimization, robustness and compatibility tests, scale-up, method validation, stability studies and clinical supplies.

EFFECTIVE DELIVERY

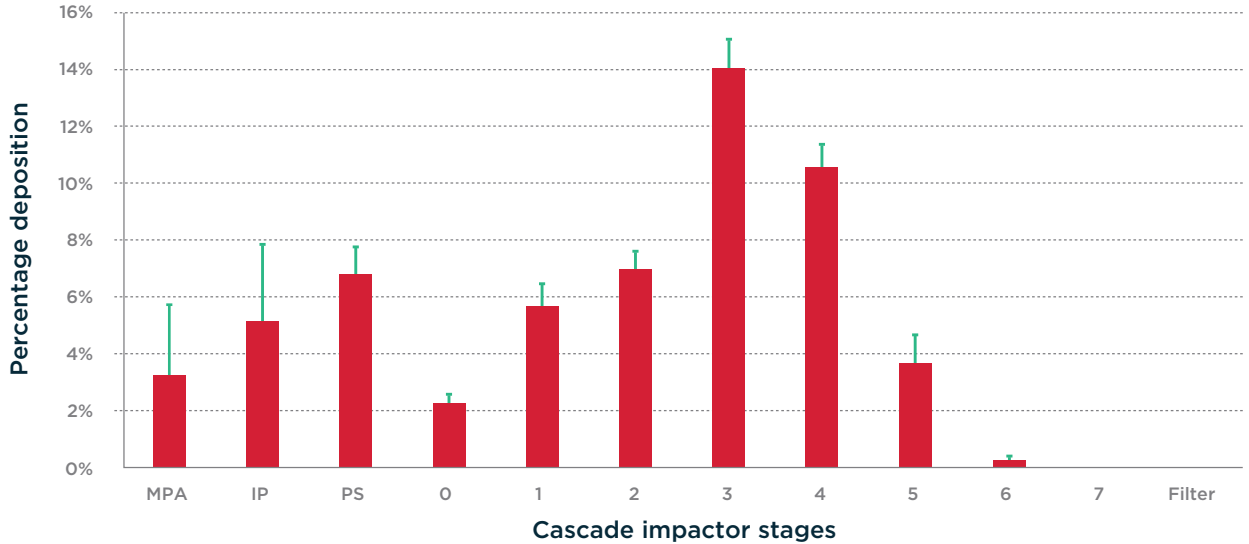


The minimum flow rate at which TwinCaps® has been shown to deliver 95% of the nominal dose is 20 litres per minute of airflow. Above 25 litres per minute, performance is unaffected (data formulation dependent).

Drug payloads range from the microgram range, employing lactose-based formulations, up to 80 mg of active using highly dispersible, engineered particles. With two dose compartments, nominal doses of up to 100 mg are possible.

EFFECTIVE DISPERSION

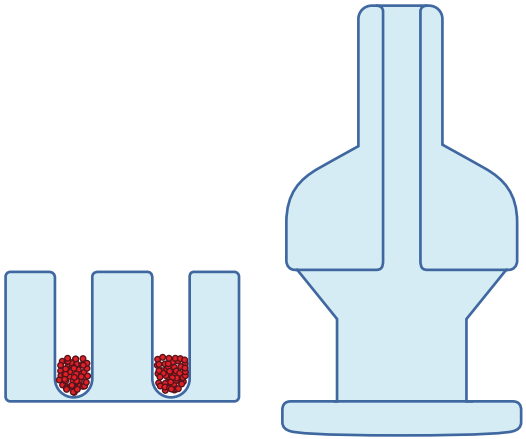
TwinCaps® uses a patented dispersion mechanism in which the dose compartment becomes a highly turbulent chamber, maximizing fine particle fractions. FPFs ranging from 25% to 70% have been obtained, at flow rates of 35 litres per minute (pressure drop 4 KPa).



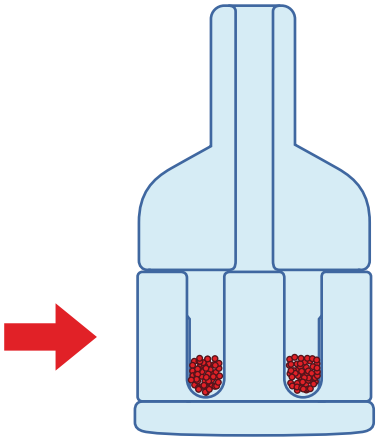
In the NGI test illustrated above, a reproducible, lung delivered dose of 58% was obtained. The percentage of drug deposited in stage 3 and below was 28% in relation to the label claim, and 58% in relation to the emitted dose, possibly implying retained drug in the inhaler is composed of larger particles.

SIMPLICITY IN OPERATION

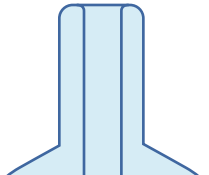
All that the patient has to do after removing the protective foil is to push the drug compartment to the side and inhale, push to the other side and inhale again.

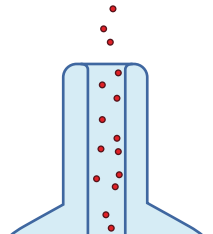


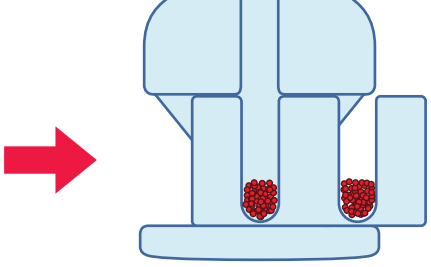
❶ Industrial filling. Two dose compartments are filled directly with drug powder...



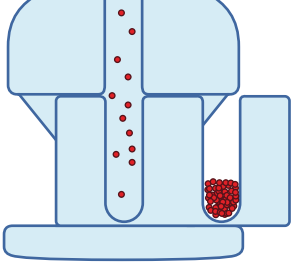
❷ ... and immediately closed by inserting them into the inhaler body.



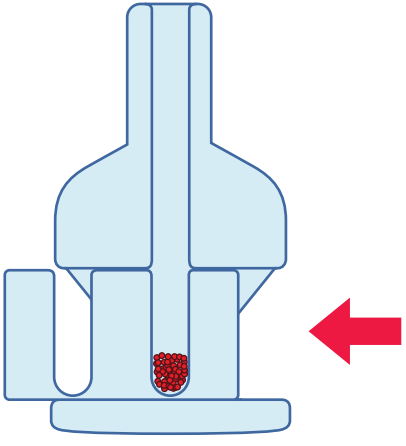




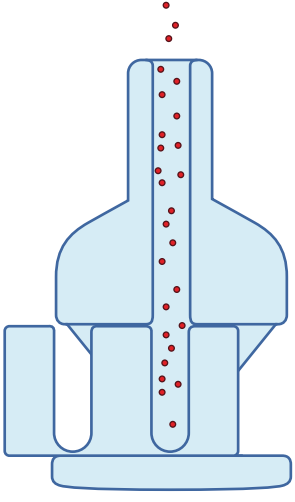
3 In use, the patient pushes the dose compartment sideways and aligns the first dose compartment with the mouthpiece.



4 With the inhaler ready for use, inhalation can take place.



5 For the second dose, the patient pushes the dose compartment in the other direction...



6 ... and inhales again.

All drawings actual size.

APPLICATIONS

TwinCaps® is presently in Phase III for the delivery of a long-acting neuraminidase inhibitor for the cure and prevention of influenza. This DPI is indicated for applications where a pre-filled, disposable, cost effective device is needed, with extreme ease of use. Examples include anti-virals and antibiotics for lung infection, oncological drugs, pulmonary hypertension drugs.

LICENSING AND SERVICES

TwinCaps® is available for licensing.

Hovione can provide all formulation development services as well as TwinCaps devices to GMP specifications. As an integrated inhalation products developer, Hovione possesses the most complete service offering, from API through particle design to formulation development and clinical supplies, for development, scale-up and industrial manufacturing, including full analytical support.

INTEGRATED INHALATION DRUG PRODUCT DEVELOPMENT

ALL YOUR NEEDS FROM A SINGLE COMPANY

Integrated Inhalation Services

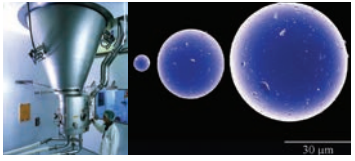
From APIs through Particle Design to Formulation development and clinical supplies.
The broadest range of inhalation development services.

cGMP Manufacturing

Inspected facilities located in Portugal, Macau and Taizhou (China), New Jersey (US) and Ireland.

API manufacturing

Process development, scale-up, validation and industrialization under cGMP manufacturing.



Particle Design

A wide range of technologies to design particles to specification maximizing lung deposition and stability.

Analytical Support

Methods development and validation for API, particles and drug product. ICH/FDA Stability studies and Microbiological Support.

Formulation

Powder formulations to maximize deposition performance or matching an existing product. For NCEs, NBEs or ANDAs.

DPI

Over 10 years' experience in developing and patenting powder inhalation devices, for specific indications.

Clinical supplies

Inhalation capsules and filled devices, including packaging, for Phases I-III.

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