



Inhalation formulations for nasal and pulmonary drug delivery continue to grow, driven by the prevalence of respiratory diseases, especially chronic obstructive pulmonary disease (COPD). Capsugel offers an inhalation drug delivery approach based on proven particle engineering through spray drying technology, as well as specially designed capsules for DPI drug applications.

Flexible Spray Drying Technology

Spray drying technology is broadly applicable for nasal and pulmonary delivery, and can be readily tailored to specific compounds and formulation approaches.

Enables compounds not compatible with other inhalation technologies, including large molecules

Can be modified for challenging drug forms, with the ability to target both crystalline and amorphous formulations

Is compatible with combination therapies

Requires minimal amounts of active pharmaceutical ingredient (API) for proof of concept (POC) and feasibility

Is easily scalable for rapid progression from feasibility to commercial equipment

Spray drying-based formulations have proven to provide greater flexibility and efficiency versus traditional lactose blend formulations.

Flexibility: fewer formulation dependencies

Not dependent on crystalline drugs

Not dependent on lactose compatibility

Not dependent on aerosol compatibility

Not dependent on jet milling

Industry Problem Statements and Solutions

Conventional formulation strategies typically encounter several challenges.

The physical properties of the API may be unsuitable for aerosolization

API characteristics may make it inappropriate for micronization

Process and scale-up are difficult

Content uniformity is difficult to achieve (particularly in combination therapies)

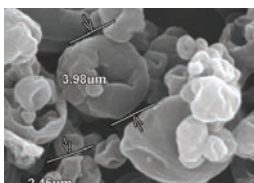
Progression of new chemical entities (NCEs) to dry-powder formulations is slow and can consume large quantities of the API-enabling technologies

Efficiency: more drug delivered, less waste

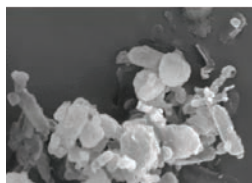
Tighter particle size distribution; 80-90% fine particle fraction (FPF) desired

Greater particle size uniformity to targeted 2.5 micron

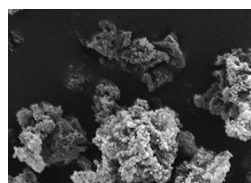
A number of particle engineering approaches, utilizing spray-drying and wet milling expertise, are available to address inhalation drug delivery challenges.



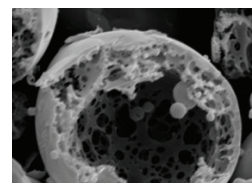
Dispersion



Crystalline API in Amorphous Matrix

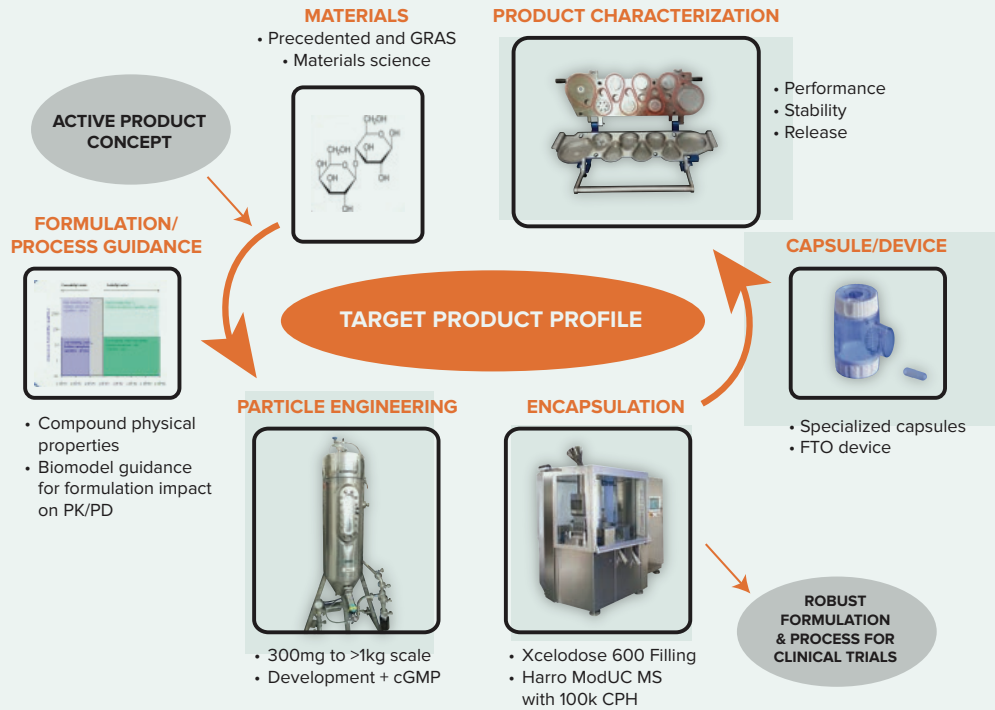


Nano-amorphous API Amorphous Matrix



Mixed Approaches

INHALATION PLATFORM – RAPID TO PHASE IIa



Inhalation Product Development

Capsugel offer a full range of services, from POC and formulation identification to powder manufacture for clinical studies, cGMP manufacturing and capsule filling optimized for inhalation drug development.

Specialized DPI Capsules Uniquely Designed for Each Application

Two-piece capsules are excellent containers to hold powder formulations for DPI applications. By treating the capsule as an excipient of the formulation itself, formulators can take advantage of the properties of various polymers to enhance and protect the formulation held inside. Similarly, understanding those properties can further minimize interaction between the capsule and the DPI device used.

Ready-to-use gelatin DPI-specific size 3 transparent capsules offer robust performance and machinability with wide regulatory acceptance. DPI capsules have specific inner surface properties that minimize powder adhesion to the inside wall of the capsule for consistent dose delivery to patients, and strict microbial limits that comply with all global DPI regulatory guidelines.

Capsules may be customized to meet individual performance criteria.

Enhanced flexibility at lower moisture levels for improved cutting/puncturing and retraction

Weight tolerance ranges for critical dosing of low-dose APIs

Optimized puncturing, retraction and closure specifications to maximize capsule closure integrity upon retraction

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Learn more about how Capsugel's Inhalation Drug Delivery solutions can improve your nasal, pulmonary and DPI development programs.