



Specialized Dry Powder Inhalation Capsules

Designed to meet the unique challenges of pulmonary delivery

Dry powder inhalation (DPI) is a major drug delivery technology for the treatment of respiratory diseases as well as increasingly for systemic drug delivery. Providing a uniform dose in a portable, easy-to-use system, capsule-based DPI is a simple and cost-effective way to deliver medication via the pulmonary route. In collaboration with its customers, Capsugel's gelatin and hypromellose (HPMC) capsules are customized to provide optimal performance between the capsule/device and capsule/formulation to achieve the highest safety and efficacy of the drug product.

- Polymer science (gelatin, HPMC, HPMC without gelling agent)
- Customized weight tolerances, moisture content and lubricant levels
- Wide color range
- Printable

UNIQUELY DESIGNED FOR EACH APPLICATION

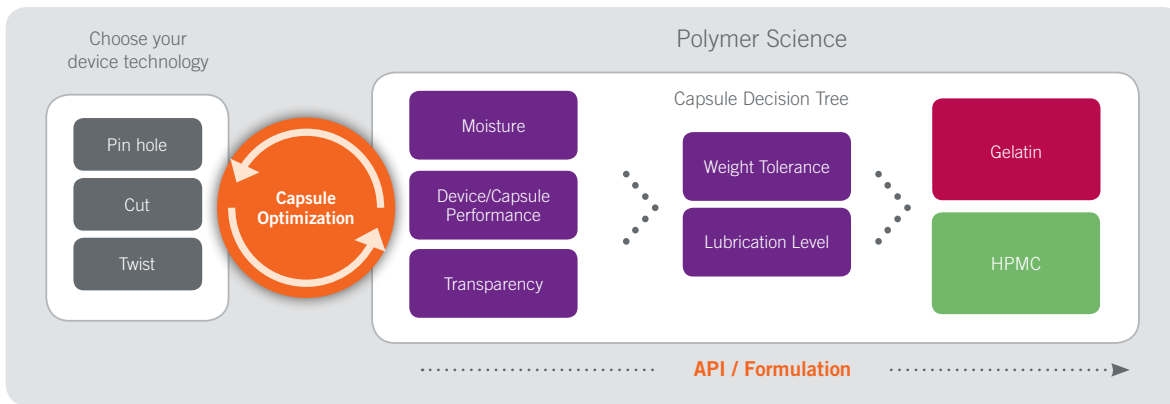
Capsugel partners with its customers to closely match specific requirements, and provides a wide range of customization services to support its DPI capsule portfolio.

To ensure optimal performance for the required device, Capsugel:

- Maintains compliance with global DPI regulatory guidelines through adherence to strict microbial limits
- Meets tight specifications for moisture content, lubrication levels, and weight tolerances to achieve desired stability and processability
- Minimizes powder adhesion for consistent dose delivery through inner surface modifications
- Provides a selection of capsules with optimal puncturing and cutting performance
- Differentiates your final product with a variety of branding and customization options
- Guarantees a secure supply chain up to the point of packaging to maintain integrity of capsule specifications, such as thermo-sealing and double layer aluminum bags



CAPSUGEL®



Experience in Customized Capsules



- 20+ years product development expertise in capsule-based inhaled drug delivery systems
- Unique know-how to adjust capsules' critical parameters to optimize performance in device

World-Class Quality



- Capsule process optimization to allow dose uniformity and reproducibility
- High performance machinability
- Consistency of quality/production process for customized capsules

Global Support



- Product compliance and certification support and documentation
- Global supply chain & security of supply
- Technical & regulatory support



Combined resources to deliver robust and effective inhalation drugs

Working alongside Bend Research, Capsugel optimizes every phase of development with the widest array of capsule solutions specifically designed for dry powder inhalation, including the Xcelodose® precision powder micro-dosing system.

FORMULATION DEVELOPMENT SERVICES

Bend Research, a division of Capsugel Dosage Form Solutions, provides unparalleled particle engineering capabilities for inhalation formulation design using spray dry (SD) technology. SD technology can achieve much tighter particle size distribution vs. conventional lactose blend technology resulting in improved pulmonary drug delivery and less drug wastage. Additionally, SD technology offers increased formulation flexibility in delivering either crystalline or

non-crystalline drugs, with no dependencies on lactose or aerosol compatibility, and no requirement for jet milling.

Capsugel's Xcelodose precision powder micro-dosing system has been engineered to provide accurate dosing in capsule fill applications.

To support DPI formulation development, Capsugel Dosage Form Solutions maintains a dedicated inhalation formulation manufacturing suite in Bend, OR (USA) that can accommodate small and large molecules to OEB 4-5 classification.

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