CAPSUGEL®

Capsule-in-Capsule Delivery System

Dosage Form Solutions

Capsugel Dosage Form Solutions offers a patented capsule-incapsule delivery system that is ideally suited for combination or dual release products. This single oral dosage delivery system, which involves inserting a smaller pre-filled capsule into a larger liquid-filled capsule, offers numerous therapeutic possibilities and a broad range of formulation and design options. Other dual release or fixed dose combination systems are also available including bi- and tri-layer matrices and fluid-bed layered multiparticulates.



A Range of Possibilities

Capsule-in-capsule technology allows our product development team to better achieve release profiles that precisely meet a client's target product profile.

Options include:

- Combination and dual release products
- Immediate, extended, pulsed and delayed release options



The inner capsule of this unique delivery system can contain liquid, semi-solids, powder or pellets, while the outer capsule can be either

a liquid or semi-solid formulation. Capsugel's expertise in developing a single dosage unit with such varied uses allows clients to combine incompatible APIs, deliver compounds to two different regions of the GI tract, and the ability to add enteric coatings in order to meet targeted release profiles that even include delivery to the colon.



Success Story: TravelGuard® Probiotic

TravelGuard® is a probiotic product that utilizes capsule-incapsule technology in order to deliver live bacteria and plant oils in a single dosage unit without damaging the efficacy of each compound.

INNER CAPSULE

Compound	Probiotic strains: Lactobacillus Acidophilus and Bifidobacterium Bifidum
Form	Powder in suspension
Capsule Size	Size 1
Capsule Coating	Enteric coated
Capsule Type	Gelatin or HPMC shell
Release Profile	Delayed release of probiotics into small intestine
Benefit	Protects product potency and early activation of freeze-dried live organisms

OUTER CAPSULE

Compound	Anti-microbial oils
Form	Semi-solid gel
Capsule Size	Size 0
Capsule Coating	None
Capsule Type	Gelatin or HPMC shell
Release Profile	Immediate release of anti-microbial oils into stomach
Benefit	Separates incompatible anti-microbial oils from probiotics





CAPSUGEL®

Billions of Commercial Units Produced Annually

Capsugel's Dosage Form Solutions solves customers' most pressing product development challenges, including bioavailability enhancement, modified release, abuse deterrence, biotherapeutic processing, and inhalation formulation. We have manufacturing sites approved by global regulatory agencies in the U.S., Europe and Asia producing

billions of liquid-fill hard capsules and soft gels annually for the pharmaceutical and health & nutrition market segments. Drug product intermediates are produced at commercial scale at our Bend, OR (USA) facility using spray-dry dispersion and other proprietary technologies.

Product

• Claims & IP

Robust & Well Understood

Integrated Product Development

Active Pharma/ Nutritional Ingredient

Target Product Profile

Commercial Goals

Design

Rapid Advancement Process™

Tech Selection Methodology

Technology Breadth

Develop

Formulation Capabilities

Clinical Manufacture

• Scale-up

- - Facilities & Equipment
 - Global Footprint

Manufacture

- Quality & Supply Chain

Capsugel Dosage Form Solutions utilizes an integrated product development approach ensuring that our clients can rely on one partner from design to commercial scale production of innovative drug product intermediates and finished dosage forms. High quality science and engineering is core to our offering at every stage of the product development cycle and has enabled the successful advancement of hundreds of

compounds. Specialized rapid advancement & technology selection methodologies allow our product development teams to advance compounds to clinic in 4-6 months. Co-located product development and manufacturing sites further ensure accelerated speed-to-market as well as reduced product development risk and cost.

Technology Platforms

Capsugel Dosage Form Solutions utilizes a premier breadth of technologies, used alone or in combination, to address key formulation challenges and meet target product profiles. Specialized development and manufacturing capability is in place to handle highly potent, controlled substance, hormonal and oncology compounds.

Bioavailability Enhancement

Spray-dried dispersions • Hot-melt extrusion • Lipid/liquid-based formulations • Nano-crystal technology • Salt forms • Particle size reduction/micronization

Modified & Targeted Release

Multiparticulate approaches • Matrix & osmotic technology • Intrinsically enteric capsule technology • Colonic delivery • Pulsatile release/dual release & fixed dose combinations

Specialized Applications

Lipid multiparticulate technology • Inhalation formulations • Abuse deterrent technology • Taste-masking • High potency APIs

For more information on our capsule-in-capsule delivery or other technologies for achieved dual release or fixed dose combinations, contact us at DFSinguiry@capsugel.com, visit capsugel.com, or reach a Capsugel representative directly at:

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