

Licaps® Liquid-Filled Capsules

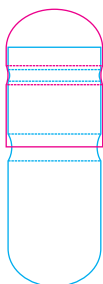
Licaps® two-piece capsules are an advanced dosage form offered in both gelatin and HPMC (hypromellose) for liquid, semi-solid, paste and multi-particulate applications. This unique and elegant dosage form has a proven track record for addressing complex formulation challenges and improving/re-positioning existing formulations.



The Perfected, “Fusion” Sealed Licaps Capsule

Capsugel's engineering advancements, spanning over a decade, in capsule sealing and filling of liquid hard shell capsules helps ensure consistent product quality and a robust, leak-proof seal without banding. To provide for customer preference and/or tailored design, banding capability is also available along with coating options.

- Innovative capsule design with well-defined seal zone optimizes mechanical strength
- High precision liquid dosing pump handles full range of liquid viscosities
- Optimized “Fusion” technology ensures leak-free seal
- Automated 100% on-line inspection system ensures final quality check



Secure Protection

- Leak-proof, airtight capsule
- Impermeable to moisture, oxygen and light
- Resists tampering

Proven Applications

Liquid-filled capsules address a broad array of formulation challenges, often incorporating a variety of pharmaceutical-approved lipids. Formulation flexibility is a hallmark of Licaps formulation and manufacturing technology.

Bioavailability	Multi-fold improvement in <i>in vivo</i> bioavailability demonstrated across a library of reference formulations
Dose Uniformity	Improvement in dose uniformity; optimal format for low dose APIs
High Potency	Safe handling of high potency API challenges
API Stability	Low melting point APIs; Improve API moisture, oxygen and/or light stability



Dosage Form Flexibility



Dual drug and/or dual release are utilized when incompatible actives need to be separated or when a dual release profile is desired. Available through our DUOCAP™ capsule-in-capsule technology, API loaded multi-particulates, or solid lipid pellet (SLP) encapsulated APIs can be dispersed in an immediate release liquid formulation.

Abuse deterrence options available utilizing our proprietary ABUSOLVE™ suite of formulation approaches.

Coating capability is in place for tailoring a Licaps formulation further, for either delayed or sustained release dissolution performance.

Billions of Commercial Units Produced Annually

Capsugel DFS has manufacturing sites in the U.S., Europe and Asia producing billions of softgel and liquid-fill hard shell capsule formulations annually for the pharmaceutical and health & nutrition market segments. Our FDA/MHRA inspected and accredited sites have specialized manufacturing capability in place for the safe production of high potency APIs and controlled substances. Coating, primary and secondary packaging options are also available.

Integrated Formulation Services

- Feasibility
- Formulation
- Scale-Up
- Clinical
- Commercial

DFS Technology Platforms

Capsugel DFS has two primary technology platforms, LIPIDEX® and Targeted Release, with which to develop optimized dosage forms, meeting single or multiple formulation challenges, fast. These technologies offer options and flexibility in tailoring formulations for new therapeutic products or improving/re-positioning existing products for pharmaceutical, health & nutrition customers.

The DFS LIPIDEX platform offers an unparalleled set of formulation options for lipid, liquid and semi-solid fills, with which to address bioavailability, high potency, low dosing, API stability and other challenges.

- **Licaps®** hard two-piece capsules in both gelatin and HPMC
- **SGcaps®** soft gelatin capsules
- **Solid lipid pellet** technology for capsule, sachet or suspension formulations

The DFS Targeted Release platform offers a wide range of oral delivery options for optimized site delivery, including the stomach, upper or lower intestinal tract, and/or colon. Targeted release options include timed release pellets in two-piece capsules, intrinsically enteric capsule technology, capsule-in-capsule technology (DUOCAP™) and specialized formulation capability for colonic delivery



(ENCODE®). Specialized capability is also available for the development of abuse-resistant formulations (ABUSOLVE™).

Highly-trained Product Development teams support the DFS Technology Platforms and are experts in lipid, liquid and semi-solid fill applications, analytical development and dosage form optimization. An established fast track program, aided by an expert system and a vast library of reference formulations, can speed your product from concept to clinic in less than 20 weeks.

Capsugel has also developed specialized liquid-filling/sealing technology and machinery for lab scale, clinical and commercial scale production. Manufacturing of finished dosage forms is available in the U.S., EU and Japan.

For more information on Licaps Liquid-filled Capsules and our comprehensive array of services and products for dosage form solutions contact us at DFSinquiry@capsugel.com.

Dosage Form Solutions

CAPSUGEL®