



Liquid-fill hard capsule (LFHC) technology provides an advanced dosage form offered in both gelatin and HPMC (hypromellose) for liquid, semi-solid, paste and multiparticulate applications. This unique, flexible and elegant dosage form has a proven track record for addressing complex formulation challenges and improving or re-positioning existing formulations. LFHC provides secure protection to drug compounds through leak-proof, airtight encapsulation which is impermeable to moisture, oxygen and light.

### Proven Applications

Liquid-filled capsules address a broad array of formulation challenges, often incorporating a variety of pharmaceutically approved lipid and non-lipid excipients. Formulation flexibility is a hallmark of our liquid-fill hard capsule formulation and manufacturing technology.

### Two Sealing Options

Capsugel's engineering advancements in capsule sealing and filling of liquid hard-shell capsules, spanning more than 25 years, helps ensure consistent product quality and a robust, leak-proof seal using either of our two sealing technologies.

#### Capsule banding.

A visible band of gelatin or HPMC is applied around the join between the capsule, sealing the caps to the body. This method is particularly useful for brand identification (band coloring), dose identification or tamper evidence. And when a capsule requires the application of a functional coat, banding provides a smoother surface at the cap/body interface for successful coat adhesion.

#### “Fusion” Capsule Sealing Technology

Capsugel's proprietary Liquid Encapsulation Micro Spray or “Fusion” technology applies a fine micro-spray of sealing solution around the join between the body and the cap, so that the contacting surfaces of the cap and the body are effectively fused together.

#### Bioavailability

Multi-fold improvement in in vivo bioavailability demonstrated across a library of reference formulations

#### Dose Uniformity

Optimal dose format for low dose uniformity

#### High Potency

Safe handling of high-potency API challenges

#### API Stability

Low-melting-point APIs; improvement in API moisture, oxygen and/or light stability

#### Clinical Development Tool

A simple manufacturing process and shortened development cycle for CTM and scale-up

#### Combination Products

Dual capsule systems using LFHC technology are used for formulations where incompatible actives need to be separated or when a dual release profile is desired

#### Colonic Delivery

Specially coated LFHC provide inherent advantages for drug delivery to the colon.

#### Abuse Deterrence

Abuse deterrence formulations using LFHC can incorporate a range of excipients specifically to the compound and typical routes of abuse.

# Liquid-Fill Hard Capsule Technology



## Center of Excellence for LFHC Development & Manufacturing

Our LFHC Center of Excellence in Edinburgh, Scotland (UK) serves a global market with integrated product design, development and manufacturing of pharmaceutical products. The facility is the largest dedicated pharmaceutical liquid and semi-solid production site using LFHC technology in the world. Capsugel Edinburgh has an extensive track record in designing optimized lipid, semi-solid and liquid formulations, and advancing compounds from feasibility through clinic to commercialization.

The Edinburgh site is US FDA and MHRA accredited, and has controlled substance licenses as well as dedicated high-containment and isolation capability. The product development team at Edinburgh also draws on the network of Capsugel product development sites in Europe and the United States, sharing best practices in identifying optimal technologies and approaches for formulation challenges. A full range of pre-formulation and feasibility studies, including solubility screening for new chemical entities, is conducted for client compounds. Dedicated development suites are used for small-scale lab encapsulation for feasibility assessments, stability data and final formulation selection.

### Product Design Expertise

Lipid/solvent/co-solvent formulations

Liquid/semi-solid products

Colonic delivery using LFHC and specialized coatings

Dual delivery with specialized capsule-in-capsule technology

Abuse deterrent formulations

### Focus on Challenging Compounds

Poorly soluble compounds

Potent and highly potent compounds

Cytotoxics, antibiotics, peptides

**Learn more about how Capsugel's Liquid-Fill Hard Capsule Technology can help you address complex formulation challenges.**

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### Manufacturing Track Record

Over 25 years of experience in product development and manufacturing

FDA and MHRA accredited

### Versatile Capabilities

Integrated product development and commercial manufacturing on-site

Specialized isolation capabilities for potent and highly potent compounds

Multiple production lines with capacity >100MM LFHC units/year

Pilot and commercial manufacturing

Non-GMP and GMP capabilities

Feasibility, stability and clinical batches

In-line printing capabilities

Primary and secondary packaging

We maintain additional LFHC Centers of Excellence for pharmaceutical applications in France (Colmar and Ploermel). Dedicated LFHC design, development and manufacturing facilities for consumer health & nutritional applications are located in – in Greenwood, South Carolina (USA) and Sagamihara, Japan.