Capsugel Dosage Form Solutions offers soft gelatin capsule technology, as well as liquid-fill hard capsule technology, to bring a number of formulation and commercial benefits to both pharmaceutical and dietary supplement products.

The one-piece soft gelatin capsule features an easy-to-swallow shell consisting of plasticizers (glycerin, sorbitol, PEG) that meet all cGMP guidelines, FDA and MEA purity standards and feature a Certified QA system for traceability of raw materials. The tamper-resistant shell masks taste and smell in a broad range of unique shapes and colors.

A liquid matrix is utilized to improve the solubility of poorly water soluble compounds, address food effect and improve API stability. The tamper-resistant shell is available in a wide range of shapes and colors to meet branding, line extension and life cycle management objectives.

**Dosage Form Flexibility**

Meet your branding and/or life cycle management objectives with the flexibility of SGcaps® soft gelatin capsules.

- Encapsulation of liquids, semi-solids, suspension and solutions
- Wide array of sizes, shapes, colors and forms
- Oral, topical, ophthalmic and vaginal administration
- Use with or without preservatives

**Proven Applications**

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

- **Bioavailability**
  - Multi-fold improvement in *in vivo* 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

**Capsugel Ploermel – Specialized Capability for Difficult Compounds**

- High potency compounds, up to OEB5
- Global leadership in hormone soft gel production
- Center of excellence for pharma grade fish oils
- Multiple best-in-class manufacturing units and machines for pilot and commercial scale production
- Dedicated unit for H&N products and specialty applications
- In-line printing capability
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.

Integrated Product Development

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 soft gelatin capsule technology contact us at DFSinquiry@capsugel.com, visit capsugel.com, or reach a Capsugel representative directly at:

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