



PHARMACEUTICS KNOW-HOW™

SOFT GELS



Approximately 40% of approved drugs and nearly 90% of development pipeline drugs consist of poorly soluble molecules¹ (BCS Class II or Class IV), which poses a challenge for the development of orally bioavailable dosage forms. Soft gelatin capsules are a proven solution for such challenging molecules as they effectively increase the solubility and permeability of drugs. Soft gelatin dosage forms have several advantages, including:

- Delivery of non-aqueous solution/suspensions and/or self-micro-emulsifying systems to enhance solubility and oral bioavailability²
- Easy to swallow, making it attractive for pediatric and geriatric populations
- Delivery of very low doses of API with precision and accuracy
- Masking of taste and odor
- Protection against oxygen and light for oxygen and photosensitive APIs
- Readily dissolve in vivo, providing faster onset of action
- Can be manufactured in various colors for elegant appearance
- Manufacturing process minimizes dust generation which helps in safety of production personnel
- Ease of scalability

Pii provides a wide array of services including:

- Solubility and gel-fill compatibility studies
- Development of soft gel fill and shell formulations
- Manufacture of small scale feasibility batches for formulation, process and stability profile optimization
- Manufacture of small clinical to commercial-scale batches of hormones, cytotoxics, highly potent drugs and controlled substances (Schedule I–V)

1. Loftsson T, Brewster ME. Pharmaceutical applications of cyclodextrins: basic science and product development. *J Pharm Pharmacol.* 2010;62:1607–1621

2. Kalepu S, Manthina M, Padavala V. Oral lipid-based drug delivery systems—an overview. *Acta Pharm Sin B.* 2013;3:361–372

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Pii provides customized and flexible solutions, across several dosage forms and has experience with a broad range of compounds. For over twenty-five years Pii has been supporting its pharmaceutical partners with extensive technical capabilities, know-how, and the highest level of customer service. With more than 400 development programs completed, Pii's scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities and knowledge-base, allow us to work with potent compounds and hormones, develop complex dosage forms, and support varied manufacturing processes.

CAPABILITIES

- Sterile (vials, syringes, lyophilized)
- Injectables (including viscous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Topicals
- Potent compounds, hormones, cytotoxics
- Solid dispersions (HME and spray drying)
- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro & Nanotechnologies

SERVICES

- Preformulation Testing
- Dosage Form Development
- Analytical Development & Testing
- CTM Manufacturing
- Commercial Manufacturing
- Aseptic Filling
- Clinical Packaging and Distribution
- Regulatory Support



FORMULATION
KNOW-HOW



PROCESS AND
MANUFACTURING
KNOW-HOW



COMMERCIAL
KNOW-HOW



QUALITY
KNOW-HOW



PROJECT
MANAGEMENT
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REGULATORY
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