



## OPTISHELL™ CAPSULES

Expanding the range of challenging fill formulations into softgels

**Innovative Technology** Catalent RP Scherer Softgel technology leads the industry with cutting-edge drug delivery innovations. Now—with OptiShell™ capsules—even more poorly soluble and poorly permeable molecules can access the bioavailability advantages of a softgel delivery technology.

<b>Shell Composition</b>	<b>Gelatin</b>	<b>Carrageenan</b> and modified starch
<b>Fill Temperatures</b>	<b>Lower</b> (up to 40°C)	<b>Higher</b> (up to 70°C)
<b>Fill Formulations</b>	<b>Solutions</b> and <b>suspensions</b>	<b>Semi-solid</b> and <b>highly-viscous</b> fills
<b>Excipients Range</b>	<b>Wide</b>	<b>Wider</b>
<b>pH Levels</b>	Slightly acidic to <b>neutral</b>	Slightly acidic to <b>alkaline</b>

**More Molecules to Market** With a non-gelatin polysaccharide shell, OptiShell™ capsules can accommodate higher melting point fill formulations and a wider pH range, expanding the capabilities of traditional gelatin capsules to include:

- Lipophilic, amphiphilic and hydrophilic formulations
- Microemulsion preconcentrates
- Semi-solid or highly-viscous liquids
- High levels of surfactants
- High drug concentrations and drug salts
- Excipients that may cross-link gelatin

Formula	Base Vehicle	Characteristics at Room Temperature	Drug Loading	Physical State of the Formulation		
				20°C	40°C	60°C
1	PEG 6000	hydrophilic, solid	35-43%	solid	solid	low viscosity fluid
2	Sucrose Acetate Isobutyrate	lipophilic, extremely viscous fluid	40-50%	extremely viscous fluid	extremely viscous fluid	viscous fluid



**Optimal Therapeutic Profile** Our unique, proprietary\* OptiShell™ capsules enable a wider range of target profiles, providing more solutions for your drug delivery challenges. For modified release of poorly soluble and poorly permeable drug compounds, soft capsules are now an option.

**EXTENDED RELEASE** Shell and semi-solid fill can be formulated to a specific profile to provide the optimal therapeutic value of the API.

**IMMEDIATE RELEASE** Ability to accommodate a wider range of permeation and solubility enhancers for optimal bioavailability and uptake.



**Expert Capabilities, Integrated Services** As the global leader in drug development solutions and advanced delivery technologies, we can help you bring your product to market faster with OptiShell™ technology.

**DEVELOPMENT SOLUTIONS & ADVANCED DELIVERY TECHNOLOGIES** We have a long track record of customizing successful programs with our deep formulation expertise and proprietary advanced technologies.

- Pre-formulation and feasibility studies
- Solubility screening of NCEs (new chemical entities)
- Fill formulation and shell development
- Small-scale lab encapsulation for early stability data and final formulation selection
- Extensive technical support in softgel capsule product development

**INTEGRATED SUPPLY SERVICES** Our global network of state-of-the-art cGMP, FDA, EMA and locally-accredited softgel facilities provide reliable supply from clinical phases to commercial manufacturing.

- Contingency planning and quality assurance
- Containment facilities for potent compounds and cytotoxic products
- FDA approved pilot plants
- An excellent regulatory compliance track record

**\*COMPOSITION PATENTS:**

US 6,582,727  
US 6,340,473

**PROCESS PATENT:**

US 6,884,060

**HIGH PH SYSTEMS**

**PATENTS:**

US 8,231,896  
US 8,377,470

Let us tailor an OptiShell™ capsule solution for your challenging molecule.

more products.  
better treatments.  
reliably supplied.™

**Discover more solutions at [www.catalent.com](http://www.catalent.com)**

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