



## OPTISHELL™ TECHNOLOGY FOR THE OTC MARKET

## An innovative solution for encapsulation challenges

**Overcome** Expanding upon the utilization of traditional softgel solutions, OptiShell™ technology can handle more APIs with a shell matrix that is not reactive to gelatin cross-linking agents. The plant-derived shell enables filling temperatures significantly higher than conventional softgels.

Formula	Base Vehicle	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

**Improve** In addition to the elimination of shell odor and a more neutral shell color, the plant-derived shell of OptiShell™ technology helps solve complex solubility, permeability, and stability challenges that may improve the bioavailability of your product, helping you to deliver better treatments to the patients you serve.

## UNIQUE SHELL FORMULATION:

· modified starch

- · glycerol and/or sorbitol
- · carrageenan (extract of red seaweed)
- · purified water

· disodium phosphate

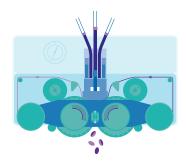
**Solve** OptiShell<sup>™</sup> technology expands the range of fill formulations of traditional gelatin capsules to include:

- · Hydrophilic
- · Lipophillic
- · Microemulsion preconcentrates
- · Semi-solids or highly viscous liquids
- · High levels of surfactants
- · High drug concentrations and drug salts









## Expert Encapsulation Solutions, Reliably Supplied

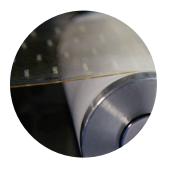
OptiShell™ technology, an innovative evolution in soft capsule drug delivery

**Development** Our formulation expertise makes Catalent's OptiShell™ capsules technology an optimized drug delivery technology with benefits beyond that of traditional tablet dosage forms:

- · Enhanced bioavailability
- · Improved absorption
- · Better permeability
- Excellent dose uniformity of highly potent,
  - low-dose compounds
- · Targeted delivery
- · Improved stability

**Delivery** OptiShell<sup>™</sup> technology offers expanded soft capsule benefits beyond traditional gelatin capsules.

- · Excellent stability with highly alkaline fills up to pH 12
- · Eliminates cross-linking of capsule shell for fills containing aldehyde or ketone groups
- Withstands elevated filling temperatures, up to 65°C without adversely affecting the capsule quality
- · Encapsulation of highly viscous and semi-solid systems
- · Elimination of shell odor
- · More neutral shell color



**Supply** We are the originators of the modern softgel manufacturing process with an integrated global network of state-of-the-art cGMP facilities that move your product from the clinic to the market with superior quality and reliability.

- · Containment facilities for potent compounds and cytotoxic products
- · FDA approved pilot plants that meet cGMP requirements
- · An excellent regulatory compliance track record

In addition to:



**Laboratory Encapsulation** Our expertise in producing small, laboratory-scale softgel batches provides you with the pre-clinical tools necessary for generating early drug product stability data, as well as, animal testing supplies.

**Softgel Printing** Our innovative in-line gel ribbon printing is a catalyst to help you differentiate your product in the global market place.

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