



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:

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

· disodium phosphate

· modified starch

Solve OptiShell[™] technology expands the range of fill formulations of traditional gelatin capsules to include:

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

DELIVERY







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
- Excellent dose uniformity of highly potent,
- · Targeted delivery

- Improved absorptionBetter permeability
- low-dose compounds

· Improved stability

Delivery OptiShell[™] technology offers expanded soft capsule benefits beyond

traditional gelatin capsules.

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

- $\cdot\,$ Containment facilities for potent compounds and cytotoxic products
- $\cdot\,$ 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.



more products.

better treatments.

reliably supplied.[™]

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