

Sorbitol Special®

Soft Gel Plasticizers

www.spipharma.com



Improving Soft Gel Capsules



Sorbitol Special®

USP Monograph: Sorbitol-Sorbitan Solution
EP Monograph: Dehydrated Liquid Sorbitol

Sorbitol Special plasticizers are sorbitan-sorbitol based soft gel plasticizers. They enhance the capsule finish gloss for a premium appearance, help to prevent leakage, provide consistent pharmaceutical quality, and extend shelf life by maintaining a proper moisture balance within the capsule shell.

The design for a specific soft gelatin capsule formulation involves appropriate selection of the shell and fill composition. This is followed by optimization of the two to allow for efficient production of a chemically and physically stable product with the desired properties.

The formation of a soft capsule requires the use of a non-volatile plasticizer in addition to water to guarantee the mechanical stability. Sorbitol Special plasticizers are engineered to counter balance the stresses during processing and drying. SPI Pharma has the products and expertise to **make a difference** in your soft gel.



Enabling Manufacturing

Helps Improve Appearance of Soft Gel Capsules

In manufacturing soft gelatin capsules, SPI Pharma's grades of specialty plasticizers serve as a humectant and plasticizer for the capsule shell. They function to keep the shell soft and pliable, making it stable and easy to handle. These qualities result in a smooth, shiny, premium-finished appearance that is desirable to consumers.



Decreases Failure, Reducing Costs

Sorbitol Special plasticizers are not soluble in PEG. They will not leach into the PEG-based fills of the capsule unlike standard plasticizers such as glycerin that are soluble in PEG. Using Sorbitol Special can result in a more stable shell, reducing failures from leaking capsules and increasing quality and output.

Sorbitol Special can also inhibit blooming – white discoloration on the surface of the capsule. Left alone, PEG can react with gelatin plasticizers, allowing moisture to migrate away from the shell, causing the capsule to break down. Sorbitol Special plasticizers can help keep moisture well-adjusted to help prevent this failure.

Reduces Drying Time for Efficient Operations

For most fill types, Sorbitol Special plasticizers can be used independently or with a glycerin system to reduce drying time. Increased number of capsules at a faster speed, driving productivity and profit.



Excipients for Swallow Tablets



Taste Masked Actives



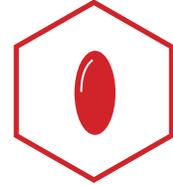
ODTs/ODPs



Effervescent Tablets



Vaccine Adjuvants



Soft Gel Capsules



Antacid & Laxative Ingredients



Chevable Tablets & Lozenges



Nutraceutical Applications

SPI Pharma offers a wide range of specialty plasticizers for the soft gelatin capsule market. The Sorbitol Special manufacturing process and products conform to the IPEC/PQG "Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients."

✉ salesinfo@spipharma.com

🌐 www.spipharma.com

in SPI Pharma

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