SPI Pharma™
Formulating Success Through Innovation

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SPI Pharma has introduced two new products to the existing Crystalline Sorbitol line:
Sorbogem™ SD 250 and **Sorbogem™ SD 500**

Features:

- Very high compactibility
- Spherical particles for excellent flow
- Pleasant sweet taste
- High solubility
- Non-GMO
- Meets USP/NF andPh Eur monograph
- Produced under cGMP conditions

Sorbogem™ SD 250 and **Sorbogem™ SD 500** are spray dried sorbitol with spherical, uniform particles having excellent flow and superior tablet compactibility for direct compression applications. These characteristics combined with sorbitol's pleasant sweet taste and high solubility makes this the product of choice for directly compressible oral dose formulations.
S P I 's spray dried sorbitol is available in two partical size distributions, with SD 250 having a nominal particle size of 250 microns and SD 500 having a particle size in the 500 micron range.

Typical properties of Sorbogem SD:

	Nominal Particle Size	Bulk Density	Tapped Density
Sorbogem™ SD 250	250 µm	0.6 - 0.7 g/cc	0.70 g/cc
Sorbogem™ SD 500	500 µm	0.5 - 0.6 g/cc	0.60 g/cc

Excellent Compactibility:

The excellent compactibility of **Sorbogem™ SD** (see fig. 1) offers formulators the ability to achieve high tablet hardness at lower compression forces, thereby reducing wear on tableting equipment and tooling. This high compactibility also offers the formulator the ability to achieve higher active loading while maintaining the necessary tablet hardness.

Compactibility of Sorbogem SD 250 and SD 500:

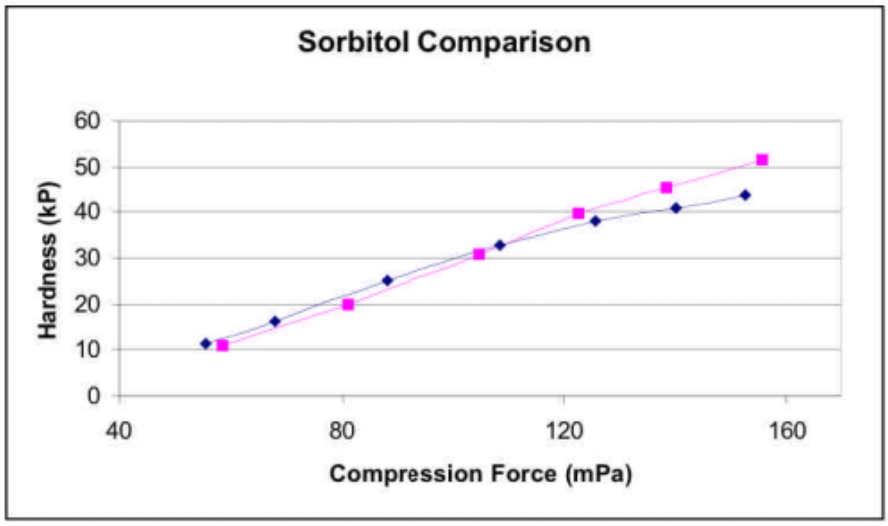

figure 1

Unique Particle Morphology:

Sorbogem™ SD has a particle morphology more conducive for tableting and formulating than traditional crystalline sorbitol products. It is this structure that gives it high compactibility and also provides the additional formulation benefits of being a good carrier. This unique porous structure (Figure 2) can carry actives or other excipients providing good content uniformity. Sorbogem™ SD is an excellent binder for high active loading formulas.

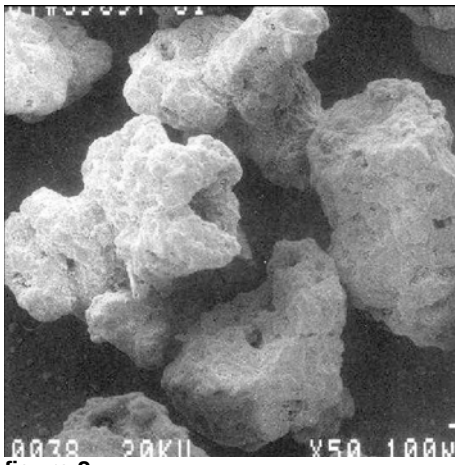

figure 2

Exceptionally smooth mouthfeel:

Sorbogem SD's particle structure compacts in a manner that leads to an exceptionally smooth mouthfeel over traditional crystalline sorbitol products.

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Introducing Lubripharm™ SSF

SPI Pharma introduces sodium stearyl fumarate (SSF) to its line of excipients. SSF is classified as a lubricant and is used in tablets to reduce diewall and interparticulate friction, anti-adherence to tableting equipment, and improve flowability.

The most widely used lubricant is magnesium stearate because of its cost effectiveness. However, in instances where magnesium stearate does not provide desired functionality, SSF is a popular alternative. Magnesium stearate can suffer in performance due to its hydrophobic nature. The hydrophobicity impacts disintegration time, dissolution, and tablet tensile strength. Magnesium ions can also promote drug degradation reactions such as ester hydrolysis and the Maillard reaction.

SSF does not reduce the tablet strength as much as magnesium stearate. SSF is less hydrophobic than magnesium stearate. In cases of over-blending, SSF does not affect the disintegration or dissolution. Two areas where SSF has proven highly useful are in orally disintegrating tablets (ODT) and effervescent tablets. Since SSF is not hydrophobic, tablet disintegration is significantly faster, which is crucial when developing ODTs. Likewise, for effervescent tablets, disintegration is important.

Magnesium stearate tends to slow disintegration and also leave a film in the drink of an effervescent system. Therefore, Lubripharm is complimentary to Pharmaburst and Effer-Soda 12 product lines from SPI Pharma.

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