

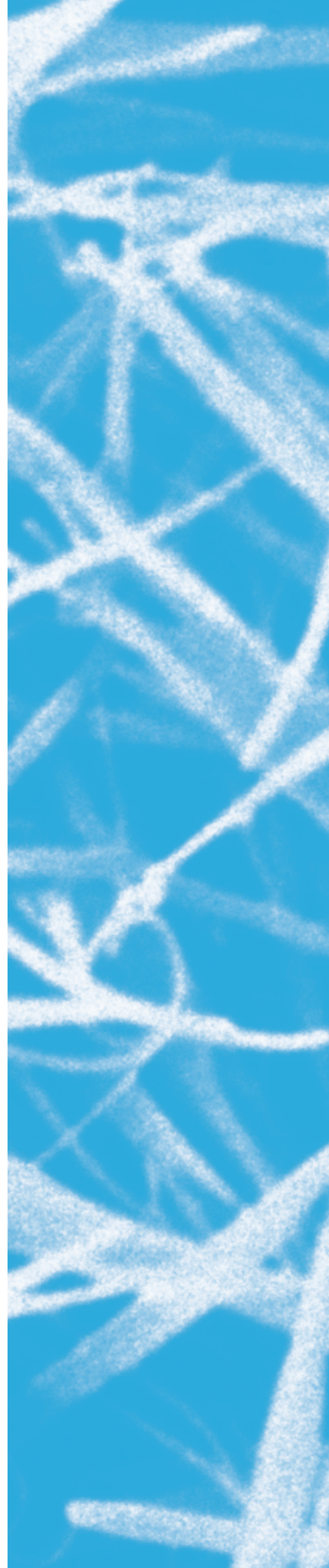


Functional Particle Engineering™  
...For Optimal Performance

Parteck® SI



Advancing Your Life Sciences –  
From Discovery to Launch



Pardeck® SI 150

Pardeck® SI 200

Pardeck® SI 400

Pardeck® SI 400 LEX

Pardeck® SI 450

- Unique, functional Sorbitol particles
- Excellent compressibility
- High adsorption capacity
- High dilution potential
- Low hygroscopicity of Pardeck® SI tablets
- Free flowing
- Variety of grades available
- EMPROVE® products

*General Characteristics  
of Sorbitol*

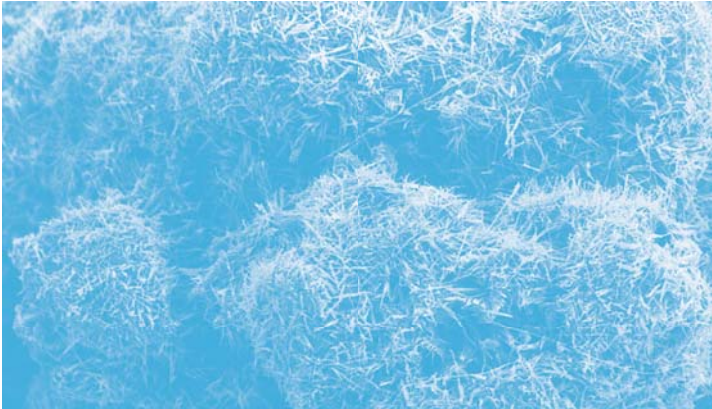
- Non cariogenic
- Pleasant tasting
- High solubility
- Compatible with amines
- Vegetable derived
- No BSE/TSE risk

**Pardeck® SI**, a superior directly compressible Sorbitol (SI=Sorbitol Instant) is offered in a variety of particle size distributions and qualities designed to meet requirements of the pharmaceutical industry.

**Pardeck®** is the trade name for a range of products under our Functional Particle Engineering concept which allows us to offer specialty excipients with outstanding functionalities especially for the design of solid dosage forms.

## Pardeck® SI: A Unique Particle Structure

The particle structure of Pardeck® SI consists of very loosely packed, randomly orientated, interwoven filamentary crystals. These needle-like crystals, unique to Pardeck® SI, give rise to its distinctive physical properties. As a truly directly compressible material, Pardeck® SI offers a number of benefits to the pharmaceutical formulator.

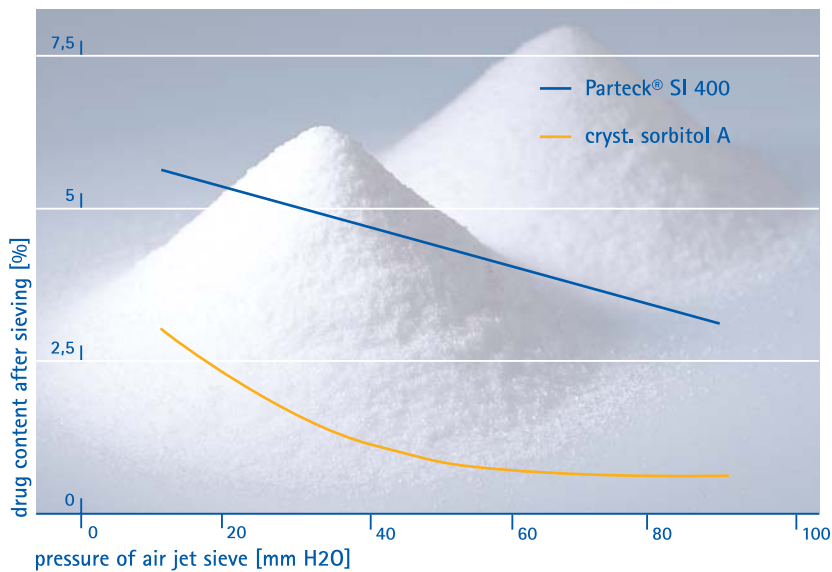


SEM of Pardeck® SI (4000 x)



SEM of Pardeck® SI (200 x)

## Ampicilline mixture with Pardeck® SI



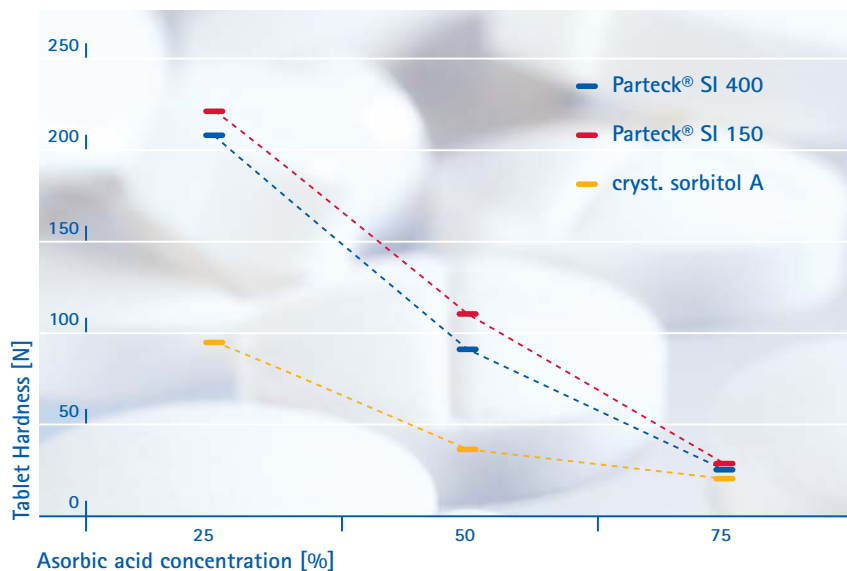
*Effect of the operating pressure of an Alpine air jet sieve on the content of Ampicillin trihydrate left in the mixture after sieving a standard 20 % mixture of either Pardeck® SI or standard crystalline sorbitol.*

## High adsorption capacity

Parateck® SI has the outstanding ability to form ordered mixtures with other solid substances. The unique rough, porous surface area available for adsorption of Parateck® SI (~ 1m<sup>2</sup>/g), allows the active to become entrapped within the filamentous matrix. The high potential for Parateck® SI's electrostatic attraction improves the overall stability of the resultant adsorbate. This phenomenon helps to increase the homogeneity of powder blends, to avoid dust development during manufacturing and to achieve high level of content uniformity. Parateck® SI can be also used as excellent diluent for low dose preparations.

The adsorption capacity and stability of resultant mixtures were tested when mixtures of Ampicillin trihydrate (20 %) with Parateck® SI or crystalline sorbitol (80 %) were sieved using air jet sieve (pressure 100mm H<sub>2</sub>O). The sieved Ampicillin mixture with Parateck® SI contained over 6 % Ampicillin, whereas the concentration of the active in the crystalline sorbitol was below 1 %.

## Vitamin C tablets with Parateck® SI



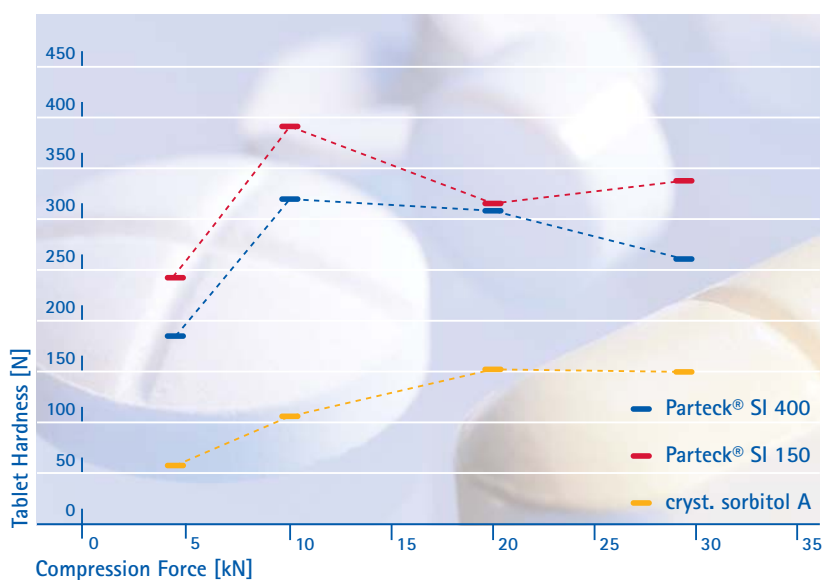
*Method: 25-75 % cryst. ascorbic, 1 % magnesium stearate and 24-74 % test material were mixed and compressed on an Korsch EKO DMS single punch tablet press (punch: flat, faceted, 11 mm; tablet weight 500 mg). Parateck® SI is spray-dried sorbitol, cryst. sorbitol A is commercially available crystalline sorbitol.*

## High dilution potential

The inherent DC properties of Parateck® SI, even with actives that have little or no compressibility of their own, means the formulator does not have to compromise quality (tablet hardness). This is because of Parateck® SI's open internal structure and high capacity to form ordered mixtures. A good example of Parateck® SI's high dilution capacity is seen when it is compressed in combination with increasing amounts of asorbic acid.



### Parateck® SI Compression profile



Method: 99 % test material and 1 % magnesium stearate were mixed and compressed on an Korsch EKO DMS (rpm:54, punch: flat, faceted, 11 mm; tablet weight 500 mg). Parateck SI is spray-dried sorbitol, cryst. sorbitol A is commercially available crystalline sorbitol.

### Excellent compressibility

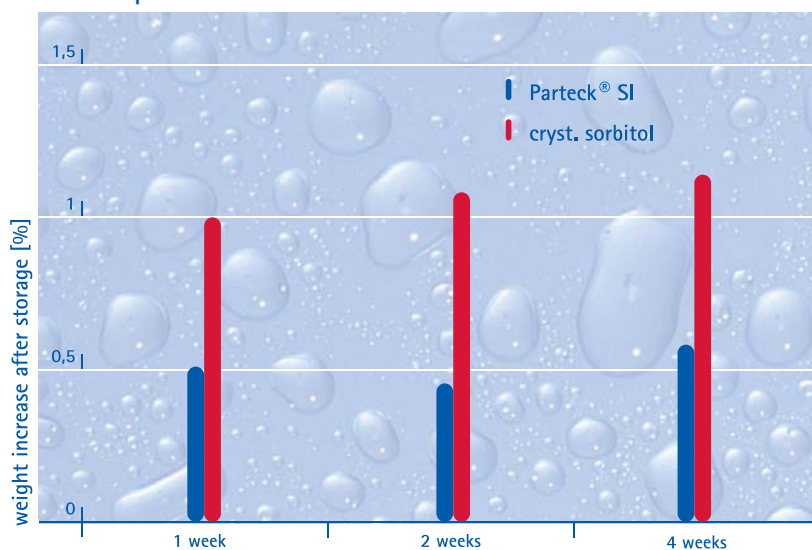
For lozenges and chewable tablets the high compressibility of diluent is of the utmost importance. When compared to standard, commercially available crystalline sorbitol, Parateck® SI exhibits superior compression properties. This excellent compressibility profile allows the formulator to reduce the stress on the tableting machine and tools by operating at lower pressures for a given tablet hardness.

## Low hygroscopicity of ParTECK® SI tablets

Crystalline Sorbitol is known to be slightly hygroscopic hence potential problems with production and stability of tablets. However, in case of ParTECK® SI - after compression - a hard and smooth film is formed on the surface of the tablet, which reduces the ability of moisture to penetrate into the core.

Tablets made of ParTECK® SI stored at 65 % relative humidity and room temperature for four weeks, showed a weight increase of 0.8 % versus 1.3 % for the tablets containing crystalline sorbitol.

### Water uptake of ParTECK® SI tablets



*Method: tablet diameter 11mm, weight 360 mg. Tablets were stored at room temperature at 65 % relative humidity for 1, 2 and 4 weeks. Initial moisture content of ParTECK® SI and cryst. sorbitol 0,5%.*

## Main applications

The superior direct compression characteristics, its excellent mouthfeel, pleasant taste, good flow and high solubility make ParTECK® SI the excipient of first choice for sugar free chewables, effervescent tablets and lozenges. ParTECK® SI is particularly suitable for formulations where low dose active preparations are required. This includes sublingual and buccal tablets where mouthfeel is important. In addition, the unique ability of ParTECK® SI particles to form stable ordered mixtures has been widely studied and applied extensively in the area of reconstitution syrups and suspensions.



## The choice is yours – Variety of grades available

We recommend the use of Parateck® SI 400 for most applications. However, over time, we have developed several special grades of Parateck® SI with particle size distribution and quality requirements designed to meet our customers' specific applications. More detailed information on grades and particle size is available on request.

Most Parateck® SI qualities comply with the Sorbitol monographs of Ph. Eur., BP and NF

## EMPROVE® product

With EMPROVE®, the new top brand in pharmaceutical manufacturing, Merck provides a combined package of product and support services and is thus meeting the ever-growing demands placed on raw material quality.

Also, we are in the process of developing intelligent support services, most notably in value-added areas such as documentation, customizing and packaging.

The documentation service alone allows you to benefit in three different ways:

EMPROVE® provides convenience and time saving in quality assurance  
EMPROVE® reduces costs and simplifies processes in Regulatory Affairs and Quality Assurance departments  
EMPROVE® increases product safety in Production departments

For more information on EMPROVE® please visit:  
[www.emprove.merck.de](http://www.emprove.merck.de)

## Ordering Information

103583 Parateck® SI 150  
115079 Parateck® SI 200  
103140 Parateck® SI 400  
111597 Parateck® SI 400 LEX  
103557 Parateck® SI 450

The currently valid specification can be retrieved from:  
[www.chemdat.info](http://www.chemdat.info).

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