

# Parteck® SLC Excipient

### **Enhancing drug solubility**

Drug solubility is a critical issue in formulation development, with more and more compounds at risk due to poor oral bioavailability. Parteck® SLC is an innovative mesoporous silica excipient that can unlock the power of amorphous solubility enhancement. This is possible due to the unique pore structure of Parteck® SLC: poorly soluble molecules can be adsorbed and confined in nanosized pores, where they are stabilized in the more soluble amorphous form (Figure 1-2). Furthermore, the high surface area of this product –  $500\,\mathrm{m}^2/\mathrm{g}$  – allows for optimal stabilization at high drug loads. The potential of Parteck® SLC has been demonstrated both in vitro and in vivo in several scientific publications (Figure 3).

Parteck® SLC is also supported by a robust and extensive regulatory and quality package, conforming to both the USP-NF and Ph. Eur. Our high quality raw materials and services will perform consistently and reliably at every stage and step, whether they're standard or custom tailored for you.

# Unparalleled amorphous stability

Parteck® SLC non-ordered mesopores are approximately 6 nm in diameter, which provides outstanding amorphous stability. When molecules are adsorbed and confined on this scale, molecular mobility is significantly hindered, and re-crystallization is prevented. This makes formulation with Parteck® SLC an ideal option for compounds with poor glass forming ability, which can be challenging to formulate with alternative polymer-based formulations, as has been described in literature (Figure 3 and Table 1).

## PARTECK® SLC PROVIDES:



Amorphous solubility advantage.

Increased oral bioavailability of poorly soluble compounds through supersaturated dissolution.



Unparalleled stability.

Adsorption and confinement to nanosized pores stabilize even the most challenging poor glass formers.



User-friendly particle size.

Allows easy handling in manufacturing.



High-end application support.

Extensive support from development to commercial-scale production.



Well-established safety profile.

Parteck® SLC is generally recognized as safe (GRAS) and complies with Ph. Eur. and USP.





API dissolved in organic solvent



Amorphous API loaded on Parteck® SLC



Improved API dissolution

**Crystalline API** 

### User-friendly particle size

With its user-friendly particle size and bulk density, Parteck® SLC allows for easy loading, tableting, and filling of capsules.

Since Parteck® SLC formulations enable consistently high API loads (up to 50%), final dosage forms are of a convenient size and weight. Finally, recent work has demonstrated the applicability of Parteck® SLC in continuous impregnation, loading, drying and tableting.

### **High-end application support**

Our expert support team helps you explore what Parteck® SLC offers – from early development up to production scale. For development studies, we are able to provide guidance and feasibility trials in our network of application labs across the globe. For production-scale loading, we have developed a validated commercial process for large-scale loading, more information is available on request.

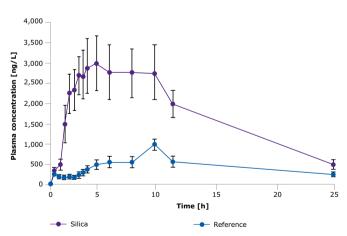


Fig. 3: In-vivo bioavailability.

PK study in fasted pigs indicates a significant bioavailability enhancement of fenofibrate through Parteck® SLC  $in\ vivo$ .

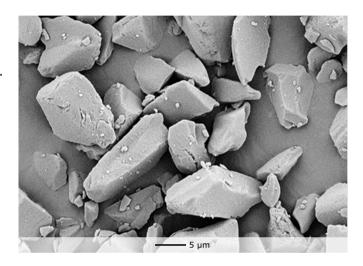


Fig. 2: SEM picture of Parteck® SLC particles.

Loading Content	30%	20%	15%	7.5%
Carbamazepine HME	X		_	_
Carbamazepine Parteck® SLC	V	V	_	_
Haloperidol HME	X	X	X	V
Haloperidol Parteck® SLC	V	V	V	V

Table 1: Stabilization of two poor glass formers with Parteck® SLC vs hot melt extrusion formulation.

Parteck® SLC consistently stabilizes high drug loads of poor glass formers whereas polymer-based formulations are less successful.

# Click. Explore. Learn more.

#### **PARTECK® PRODUCT PORTFOLIO**

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as suitability for direct compression or controlled release. For more information, visit:

EMDMillipore.com/parteck

### FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:

EMDMillipore.com/formulationapp

# Need Precipitation Inhibition?

Parteck® PLX 188 can prevent precipitation of supersaturated API.

### **Ordering information**

Cat. No.	Product	Pack size
1.20091.0300	Parteck® SLC 500 USP, Ph Eur	300 g
1.20091.1000	Parteck® SLC 500 USP, Ph Eur	1 kg
1.20091.9025	Parteck® SLC 500 USP, Ph Eur	25 kg

The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: **EMDMillipore.com** 

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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