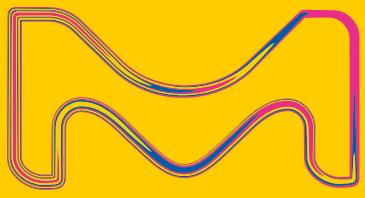

MilliporeSigma

Parteck® SLC Excipient

Drug substance, Meet drug product

A platform approach to manage particle and polymorph variation

Parteck® SLC can stabilize variable and unstable polymorphs and homogenize particle properties across diverse sets of APIs, unlocking lean and reproducible manufacturing processes.

SAFC®

Pharma & Biopharma Raw Material Solutions

Parteck® SLC Excipient

Polymorph Variation: An omnipresent risk in formulation development

Variation in crystal structure – polymorphism – is a critical issue in pharmaceutical development. The crystal structure of a drug is related to a wide range of important properties including, but not limited to: biopharmaceutical performance, processability, galenical properties, safety, intellectual property and regulatory filings. Therefore, if polymorph variation is encountered during a development regime, the compound is at increased risk of attrition. This problem becomes especially acute if the manufacturing route involves continuous processing, where particle properties are critical to understand process scale-up.

Parteck® SLC mesoporous silica is a solubility enhancement excipient, that stabilizes the amorphous form of a compound in nanosized pores. This stabilization has been shown to be reliable and consistent, providing the same solid-state profile with a range of APIs (Table 1). This unparalleled stabilization of the amorphous solid state can be leveraged to address unstable polymorphism in drug development. Parteck® SLC can be used as a platform technology in which any API can be loaded into the pores of the mesoporous silica, providing a consistent and reliable solid-state profile every single time.

PARTECK® SLC PROVIDES:

- **Unparalleled stabilization** of the amorphous solid state – every single time
- **Improved particle profile after loading,** with enhanced flowability
- **Homogenization of particle properties** for a broad range of APIs
- **Compatibility with continuous processes,** including impregnation, drying and tableting

	Solid-state	Drug Load (%)	LogP	MWt	pKa	BCS Class
Atenolol (ATN)		26	0.16	266	9.6 (basic)	III
Cinnarizine (CIN)		27	5.77	378	7.4 (basic)	II
Fenofibrate (FFB)		29	5.2	361	– (neutral)	II
Paracetamol (PAR)		29	0.91	151	9.5 (acidic)	I
Posaconazole (POS)	Amorphous	28	5.5	701	3.7 (basic)	II
Ibuprofen		30	3.97	207	5.3 (acidic)	II
Carbamazepine		29	2.77	236	– (neutral)	II
Haloperidol		30	4.3	376	8.3 (basic)	II
Indomethacin		28	4.27	358	4.5 (acidic)	II

Table 1: Stabilization of the amorphous form on Parteck® SLC particles is robust and reliable for a range of different APIs.
More data available on request.

Improved Galenical Properties

In the development of orally delivered dosage forms, powder flowability and compressibility are crucial factors to consider. In addition to reducing the risk of unstable polymorphism, we have demonstrated how Parteck® SLC excipient can be used to improve these two crucial properties for a range of APIs with diverse physicochemical properties. Furthermore, for APIs with already good powder behavior, the properties are retained after loading. Ultimately, loading of challenging APIs onto Parteck® SLC particles can unlock more efficient tableting processes such as direct compression or even continuous manufacturing (Figure 2).

Homogenized Particle Properties

APIs come in all shapes and sizes, which can provide challenges in developing lean and efficient manufacturing process. When APIs are loaded into the unique porous structure of Parteck® SLC, particle properties trend towards average values (Figure 3). Put simply, Parteck® SLC excipient "masks" the original particle properties of the API, and so reliable and templated formulation processes can be developed. With this approach, Parteck® SLC can be used as a platform excipient to load a multitude of APIs, with very distinct particle properties, while avoiding major changes in the manufacturing process. This is especially attractive in continuous manufacturing, where processes need to be defined and validated as early as possible.

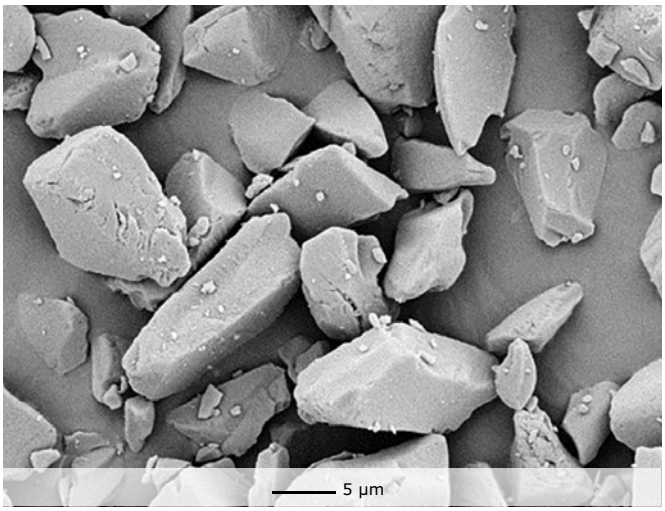

Fig. 1: SEM picture of Parteck® SLC particles.

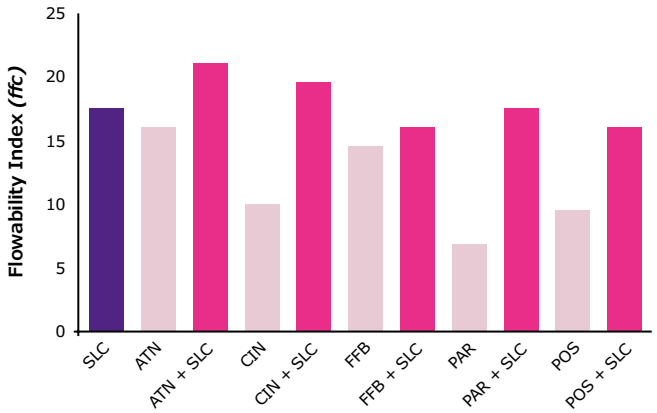

Fig. 2: A range of APIs were loaded onto Parteck SLC, with an improved particle flowability in all cases as demonstrated by an increasing ffc.

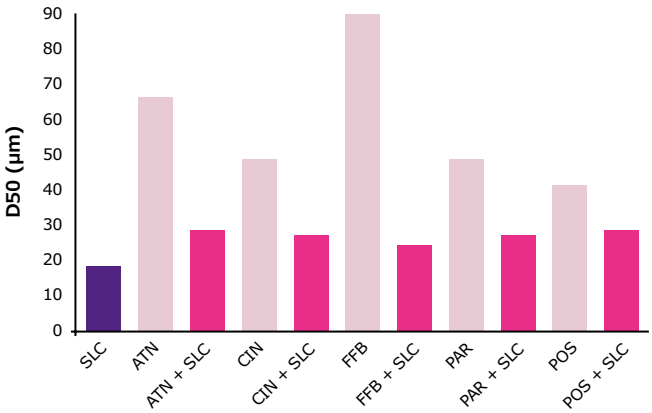

Fig. 3: Homogenization of particle size for a diverse set of APIs after loading onto Parteck® SLC

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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

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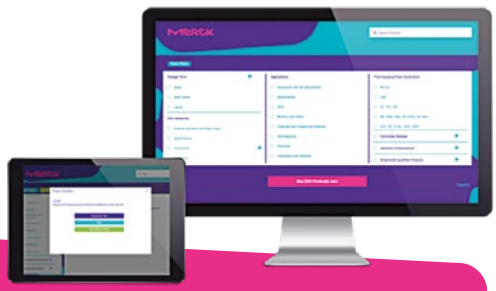
Parteck® Product Portfolio

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

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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**

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