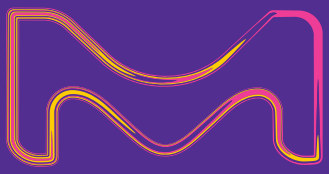
SAFC®
Pharma/Biopharma Raw Materials



PARTECK® EXCIPIENTS

INTELLIGENT FORMULATION MADE EASY.

Portfolio of functional excipients for oral solid dosage

MilliporeSigma

Parteck® Excipients

Intelligent formulation made easy.

Designing solid dosage requires a fine balance. The active ingredient, bioavailability enhancement, release kinetics, a specific dosage, packaging, shelf life – each of these deserves careful consideration. Selecting the right excipient is key for a successful formulation. Since we know that every solid dosage form has its own challenges, we have developed an entire brand family of excipients for you: Parteck®.

Parteck® excipients are distinguished by outstanding individual functionalities and a unique particle structure. When you choose Parteck® excipients, you'll find that your solid dosage forms are easier to design. You'll also have MilliporeSigma's stringent quality control and full regulatory support at your fingertips.

Overview of Parteck® functionalities

Enhanced solubility

Functional excipients that boost the efficacy of your final drug product by enhancing API solubility

Optimized drug delivery

Functional excipients that influence the release kinetics of your formulation

Flexible tableting

Functional excipients for different tableting technologies that achieve high tablet hardness at low compression forces, short disintegration times, and tailored API dosages due to unique particle surface

High-quality products for formulation.

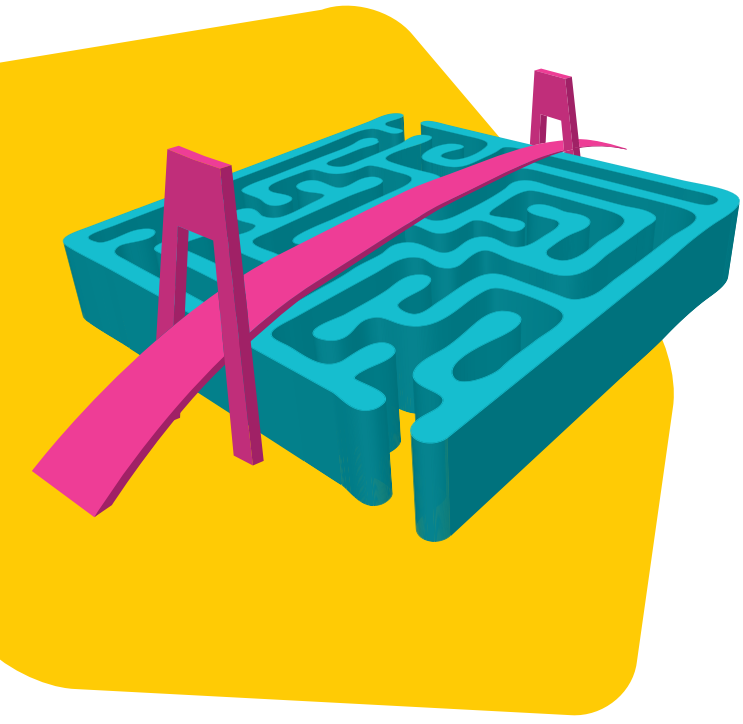
Parteck® excipients are manufactured to MilliporeSigma's world-class standards. When you choose Parteck®, you're choosing reliable batch-to-batch consistency and production. Flowability, compressibility, and surface area of our excipients are just a few characteristics we focus on to help you to achieve better content uniformity and reproducibility of your final drug product.

Cost-efficient formulation.

We have optimized the flow behavior to make Parteck® excipients easier to blend and handle throughout the process. High performance, even at low compression forces, places less strain on your equipment, leading to an extended service life. And since Parteck® excipients are easy to formulate, they help streamlining your development processes. Additionally, you can take advantage of our full Emprove® documentation to expedite your approval preparation.

Simplified formulation.

Since we are dedicated to optimized tableting, you can benefit from products particularly suitable for different tableting technologies such as direct compression and wet granulation. If you need to enhance your API solubility, we also have two innovative products just for that purpose: polyvinyl alcohol for hot melt extrusion as well as a silica drug carrier. To address the challenges of oral drug delivery, products from our portfolio help to influence the release kinetics of your formulation, either by prolonging API release times over the course of several hours or reducing the disintegration time to accelerate API release, at low or high doses.



THE EMPROVE® PROGRAM

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

The Emprove® Program simplifies your processes by:

- Expediting approval preparation and extending compliance
- Facilitating qualification processes
- Supporting risk assessment, management and mitigation
- Increasing supply chain transparency
- Saving you time and money

Our Parteck® excipients are supported by the Emprove® Program.

Find out more at:
EMDMillipore.com/emprove

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® MXP

MIX. MELT. PERFORM.

Enhance API solubility. Achieve stable, high drug loads.

Parteck® MXP is a new excipient for hot melt extrusion to increase solubility and allow for stable and high drug loads for a broad range of APIs.

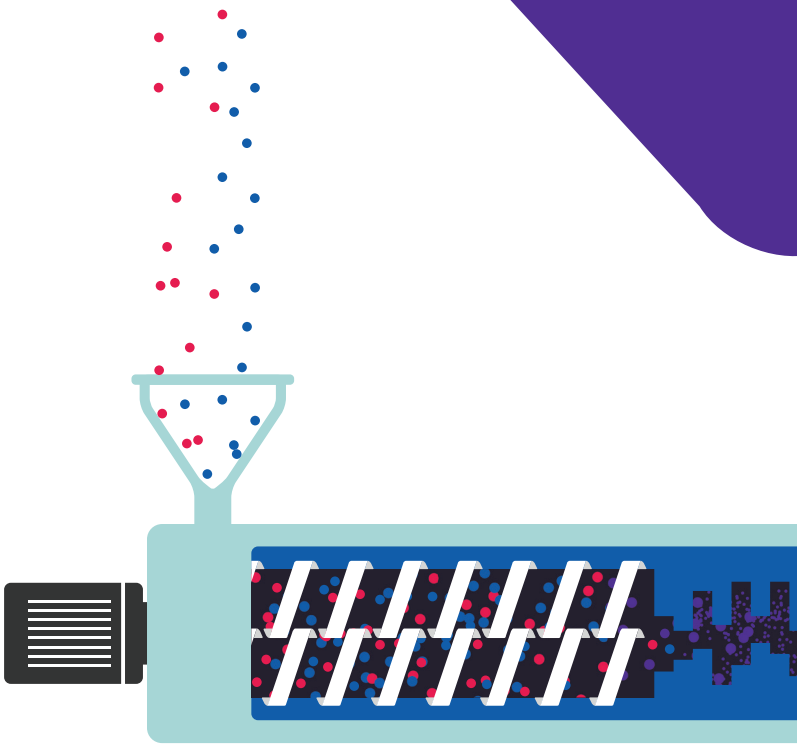
MilliporeSigma

Parteck® MXP

The hot melt extrusion difference.

Poor solubility of APIs is a critical challenge in drug development. One formulation technique to increase solubility and, consequently, improve bioavailability of drugs is hot melt extrusion (HME). With this technique the API is dispersed, often down to the molecular level, into a polymer matrix to form an amorphous solid dispersion. It is a solvent-free process that is applicable to a broad range of poorly soluble APIs, making it suitable for various solid dosage formulations.

Our new Parteck® MXP is specifically designed for application in HME. The polyvinyl alcohol-based excipient enhances the solubility of a wide range of APIs with low solubility. The polymer used in Parteck® MXP has a long safety record related to its usage in drugs and is generally recognized as safe (GRAS) by the U.S. Food and Drug Administration. Parteck® MXP complies with United States Pharmacopeia (USP), European Pharmacopeia (Ph Eur), and Japanese Pharmacopeia for excipient (JPE) monographs.



PARTECK® MXP PROVIDES:

Enhanced solubility.

100 % (eight of eight) model APIs assessed for Parteck® MXP indicate significant solubility increases.

Stable, high drug load.

75 % (six of eight) assessed model APIs achieve a 30 % minimum drug load that is stable under various conditions.

High thermostability and broad API range.

Maintains stability at temperatures above 200 °C, making it well-suited to broaden the API application range for hot melt extrusion.

Flexible release kinetics.

A variety of final oral dosage forms demonstrate immediate or sustained release formulations using the same extrudates.

Ease of use.

For all assessed APIs, physical blends and extrudates of the API and polymer were homogeneous.

Fast dissolution. High solubility. Long stability.

Using a fixed API load of 30 %, a dissolution of extrudated Parteck® MXP and other polymers for HME was assessed in a performance study of itraconazole extrudates. Parteck® MXP demonstrated a faster dissolution time and a higher maximal solubility value when compared to marketed polymers under the same conditions (Figure 1).

Long-term stability of extrudates at a higher API load can be a major concern for the stability of the drug product. Milled itraconazole:Parteck® MXP extrudates were stored under various conditions for six months. Stability was assessed using HPLC (API chemical stability), DSC (assessment of recrystallization from amorphous state), and repeat dissolution. As seen in Figure 2, the extrudate was stable under all conditions.

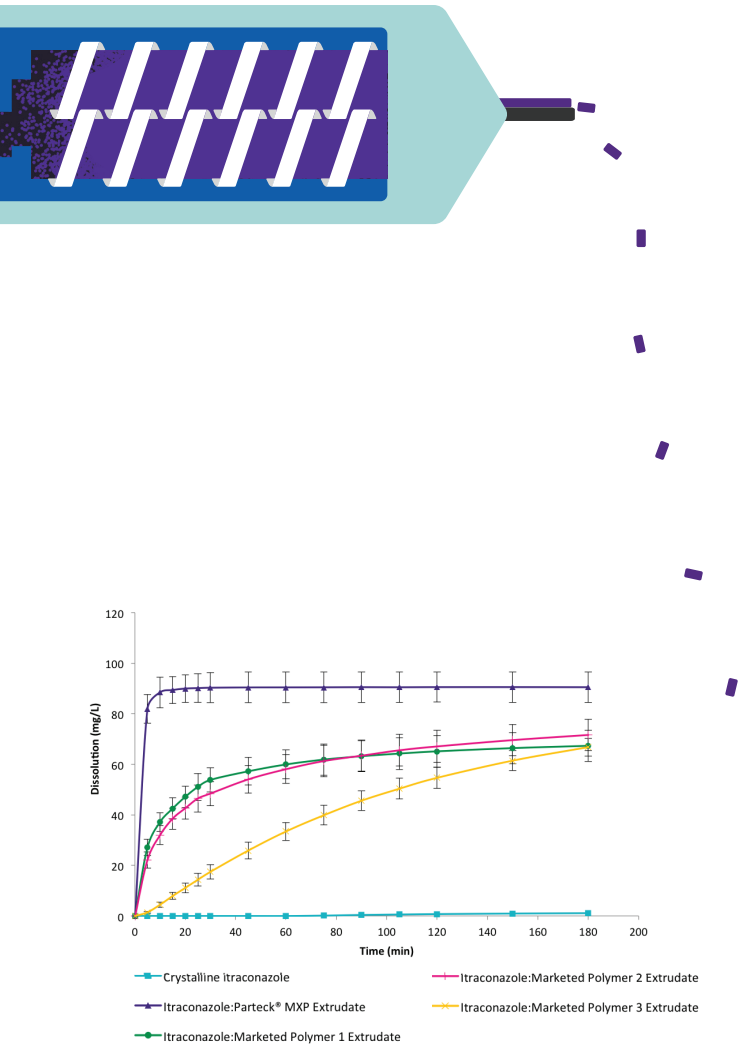


Fig. 1: Dissolution performance of itraconazole extrudates (milled).

Conditions: FDA-recommended conditions for itraconazole, 900 mL SGF, 37 °C, 100 rpm, 100 mg itraconazole, 30 % drug load, N=3

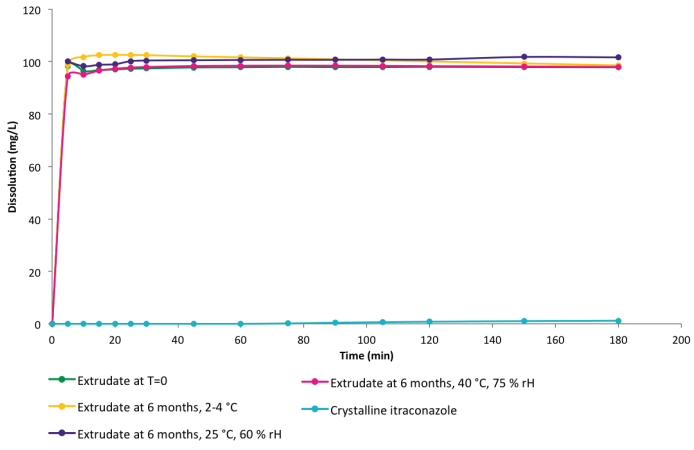


Fig. 2: Repeat dissolution performance of itraconazole:Parteck® MXP extrudates (milled).

Conditions: FDA-recommended conditions for itraconazole, 900 mL SGF, 37 °C, 100 rpm, 100 mg itraconazole, 30 % drug load, N=3

Enhanced solubility. High API load. Broad range of APIs.

For the APIs assessed in our studies, using Parteck® MXP significantly enhanced solubility with no detectable degradation of the API.

Parteck® MXP has excellent thermocapacity which can lead to increased solubilization of the API. Due to its high degradation temperature, extrusion above 200 °C shows no degradation of the polymer thereby making it applicable to APIs across a wide range of melting temperatures (T_m). Parteck® MXP can achieve a minimum API load of 30 % in the majority of APIs that were tested.

API	T_m of API (°C)	Loading (%)	Solubility Enhancement (max.)
Ibuprofen*	78	min. 30	2-fold
Cinnarizine	118 – 122	< 20	10-fold
Indomethacin	151	min. 30	3-fold
Ketoconazole	146	min. 30	17-fold
Naproxen	152	min. 30	4-fold
Atorvastatin	159 – 160	min. 30	154-fold
Itraconazole	166.5	min. 30	80-fold
Telmisartan*	260	min. 15	35-fold

Table 1. Case studies of eight model APIs from BCS class II.

Dissolution studies were performed using recommended conditions from the FDA.
*Plasticizer is required to make the extrusion feasible or easier.

Flexible release kinetics. Variety of dosage forms.

Once the challenges of solubility enhancement have been overcome, difficulties in the final oral formulation can arise. These may vary based on the intended final release kinetics, final dosage form, and inherent properties of the polymer itself (e. g., poor aqueous solubility).

Using the same extrudate, Parteck® MXP can be easily formulated into a variety of final oral dosage forms with immediate or sustained release kinetics, without the need to fine-tune the polymer.

Furthermore, the different dosage forms assessed in our studies have little (< 15 %) to no additional excipients added to optimize the formulation and feature a high API load. Tablets (direct-shaped or compressed) are very strong (> 200 N) and are resistant to alcohol, thus leading to reduced dose dumping and side effects.

Click. Explore. Learn more.

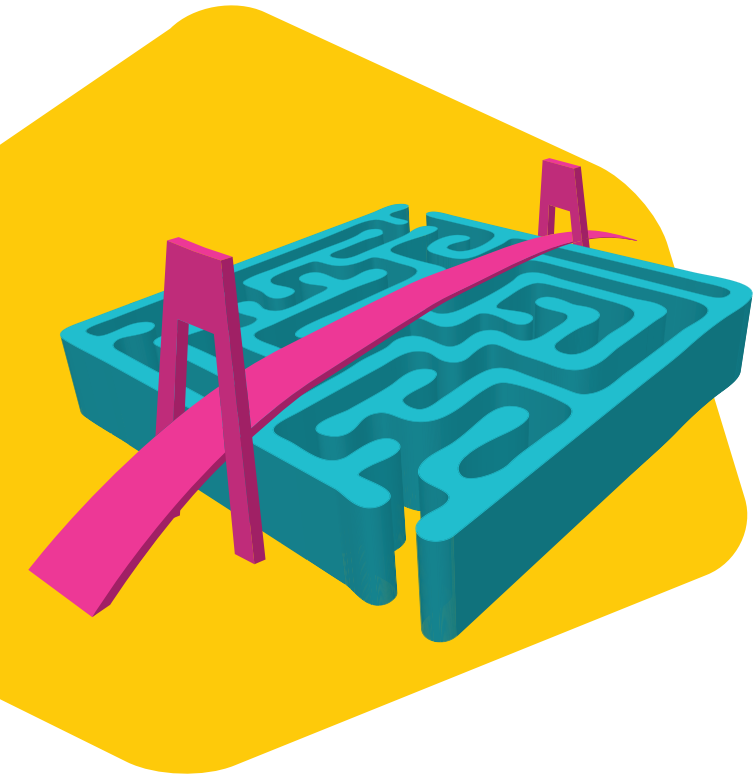
There is more to learn about Parteck® MXP.
Discover the performance and technical details in our interactive tool.

www.emdmillipore.com/parteckmxp

Ordering information

Parteck® MXP is available in 1 kg and 25 kg pack sizes.

Cat. No.	Product	Pack size
1.41464.1000	Parteck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur, JPE, USP	1 kg
1.41464.9025	Parteck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur, JPE, USP	25 kg



THE EMPROVE® PROGRAM

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive.

In order to facilitate and accelerate this process, we developed our Emprove® program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at: **www.emdmillipore.com/emprove**

THE PARTECK® PRODUCT FAMILY

Intelligent formulation made easy.

Parteck® offers a broad range of superior excipients created specifically for solid dosage forms. The Parteck® excipient portfolio features unique particle properties and outstanding individual functionalities such as solubility enhancement or controlled release, among others. Formulators benefit from excellent tableting behavior and simplified formulation design.

For more information about our Parteck® range, visit **www.emdmillipore.com/parteck**

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: www.emdmillipore.com

We provide information and advice to our customers on application 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.

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
290 Concord Road
Billerica, MA 01821, U.S.A.

Phone: +1-800-645-5476
Email: pcs.salessupport@emdmillipore.com

www.emdmillipore.com

w305917

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® M DPI EXCIPIENT

TAKE A DEEP BREATH

Enhance API delivery to the lungs.

Parteck® M DPI is a mannitol-based versatile alternative carrier option for your dry powder inhalation applications (DPI).

MilliporeSigma

Parteck® M DPI Excipient

Upgrade your carrier performance.

Engineered from mannitol, Parteck® M DPI particles are designed to improve the flow and release characteristics of active pharmaceutical ingredients (APIs) in drugs delivered via dry, inhaled powders.

PARTECK® M DPI EXCIPIENT PROVIDES:

Superior chemical, physical and biological stability.

The materials' low water content and hygroscopicity reduces the risk of hydrolysis to your API, promotes reliable flow characteristics and helps to minimize bioburden.

Compatibility with a wide range of APIs.

Physiologically inert, Parteck® M DPI excipient helps to prevent complications that arise from the Maillard reaction, which occurs when APIs that contain primary or secondary amine groups interact with reducing sugars.

Ease of use.

Its bulk and flow properties are well-suited for optimal blend homogeneity, API delivery to the lungs, and constant dose uniformity.

Enhanced patient tolerance.

It is a viable alternative for patients with lactose intolerance and is of non-animal origin.

No reducing sugars, no incompatibility issues.

Our Parteck® M DPI excipient is engineered to limit impurities down to 0.05%, as granted by the CoA specification. Reducing sugars are a major threat to the stability of small-molecule APIs with primary amine groups, biomolecules and peptides. Lactose is one such reducing sugar. Mannitol, another non-reducing sugar alternative, still contains trace levels of reducing sugar impurities of up to 0.20% according to pharmacopoeia. Meanwhile, Parteck® M DPI excipient highlights a remarkable inertness that will not compromise the integrity of your API.

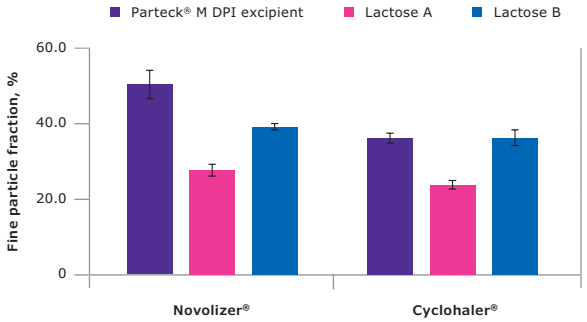


Fig. 1: FPF measured with Next Generation Impactor with two commercial devices in comparison with two commercial carriers based on lactose, using budesonide as model API.

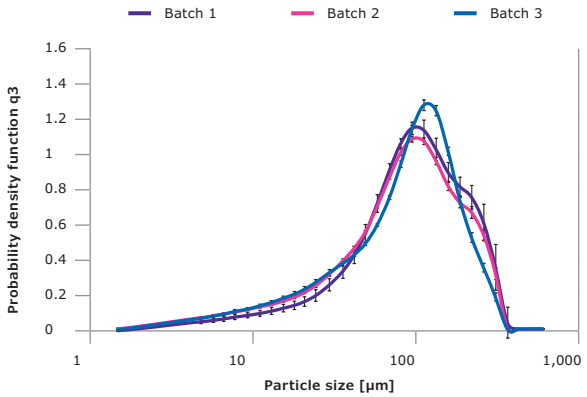


Fig. 2: Particle size distribution measured by laser diffraction.

Exceptional API delivery. A trusted carrier co-pilot.

Ultimately, getting your API to reach the lungs is the main objective. An aerodynamic characterization of fine particle fraction (FPF) (Fig. 1) using our Parteck® M DPI excipient indicates that there is an enhancement of API deposited in the lungs. Therefore, your treatment has a better chance of having the desirable outcome upon each inhalation.

Superior stability with a 3-year shelf life.

Reduced moisture content is advantageous for API stability during storage. The very low water content of Parteck® M DPI excipient at approximately 0.01 % (LOD) is possible because of its very low hygroscopicity. Having a decreased all-around moisture content helps to protect API-carrier interactions and promotes better stability of your formulation with a 3-year shelf life.

Flowability. Homogeneity. Particle-size distribution.

Parteck® M DPI excipient's fine-tuned constant flow over the shelf life of your drug product is attributed to its bulk properties:

i. Angle of repose: 30–32°
ii. Bulk density: 160–200 mL/100 g
iii. Tapped density: 130–170 mL/100 g
iv. Hausner index: 1.17–1.23

The carrier particles also exhibit a noteworthy structured surface area that is greater than 2.5 m^2/g. This highly specific and large surface area provides exceptional homogeneity with micronized APIs. Fig. 3 shows an evenly distributed, stable blend of API and Parteck® M DPI excipient as the selected carrier. Blends, such as the one pictured, support balanced adhesion forces for constant dosing.

Furthermore, Fig. 2 demonstrates how Parteck® M DPI excipient – from three batches – maintains a mean particle size of 200 µm, beneficial for the reproducibility of the dose.

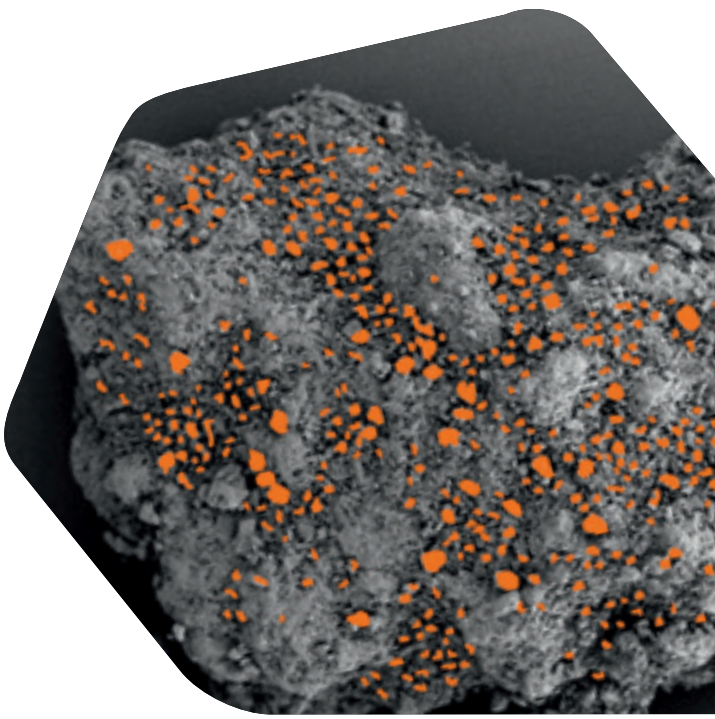
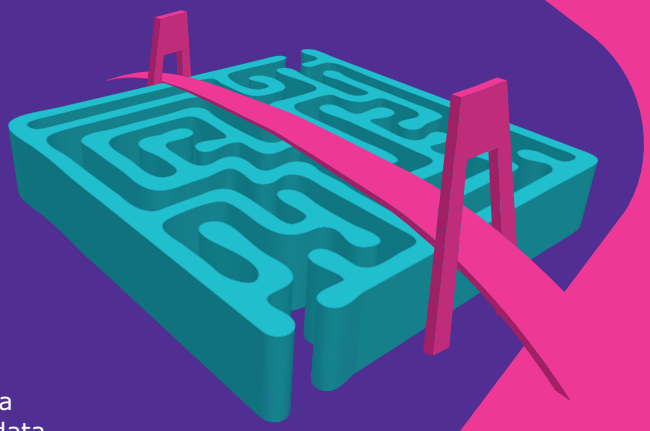


Fig. 3: Micronized model API (Budesonide) on Parteck® M DPI excipient

THE EMPROVE® PROGRAM

Your fast track through regulatory challenges.



Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive.

In order to facilitate and accelerate this process, we developed our Emprove® program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at: **EMDMillipore.com/emprove**

Need lubrication?

Parteck® LUB MST offers a magnesium stearate with a CoA-specified BET surface and a PSD for reliable batch-to-batch consistency. Enhance your sensitive application of inhalation with constant performance using our range of Parteck® LUB, which also includes calcium stearate and stearic acid.

Ordering information

Cat. No.	Product	Pack size
1.03668.9025	Parteck® M DPI EMPROVE® EXPERT Ph Eur, BP, JP, USP, E421	25 kg Double PE bag in Squarebox (PE drum, fibre free)
1.03668.1000	Parteck® M DPI EMPROVE® EXPERT Ph Eur, BP, JP, USP, E421	1 kg 2.5 L PE bottle

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, from the website: **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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1345EN
11/2017

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® SRP 80 EXCIPIENT

TAKE CONTROL OF SUSTAINED DRUG RELEASE

Achieve consistent API release. Reduce risk of dose dumping.

Parteck® SRP 80 is a polyvinyl alcohol-based excipient that provides consistent, sustained drug delivery over long release periods.

MilliporeSigma

Parteck® SRP 80 Excipient

Top performance for your solid dose formulations.

Patient compliance is essential for therapeutic success, which is one of the reasons why solid oral formulations are one of the most well-established dosage forms in the world. In many cases, long-acting API efficacy is required. That's why Parteck® SRP 80 excipient has been specifically designed for superior reliability and consistency in sustained-release solid oral formulations.

Parteck® SRP 80, our new functional excipient based on polyvinyl alcohol (PVA), provides consistent, sustained drug delivery over long release periods.

Its matrix diffusion technology helps increase the efficacy of your compound, while reducing side effects and the risk of dose dumping. Patient convenience and compliance can be increased as well, due to reduced dose frequency.

Well suited for direct compression processes, Parteck® SRP 80 excipient can help accelerate your formulation work – from simplified feasibility and development to rapid and cost-efficient manufacturing.

PARTECK® SRP 80 EXCIPIENT PROVIDES:

Consistent API release over several hours.

Allows for a constant release behavior over a broad range of compression forces and tablet hardnesses.

Reliable product performance.

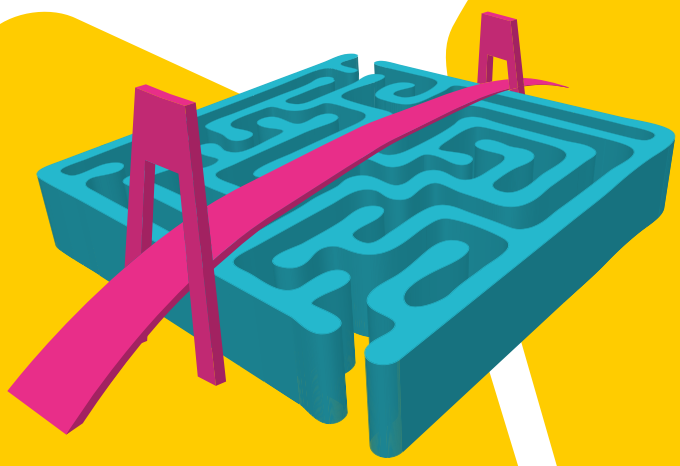
Fully synthetic origin leads to decreased variability in quality and performance, facilitating QbD and validation processes.

Convenient, cost-efficient manufacturing.

Suitable for direct compression processes, featuring both high compressibility and low ejection forces.

Reduced risk of dose dumping.

Thanks to reliable alcohol resistance and constant API release over a broad pH range, dose dumping potential is significantly reduced.



THE EMPROVE® PROGRAM

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and bio-pharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive.

In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at: **EMDMillipore.com/emprove**

Ordering information

Cat. No.	Product	Pack size
1.41439.1000	Parteck® SRP 80 (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur, JPE, USP	1 kg PE bottle with screw cap
1.41439.9025	Parteck® SRP 80 (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur, JPE, USP	25 kg carton box

Excellent compressibility. High dilution. Reliable dissolution.

Thanks to its optimized particle size and properties, Parteck® SRP 80 excipient shows high compressibility and low ejection forces over a vast range of compression forces (Fig. 1), leading to excellent galenical properties of the tablets as well as high dilution potential combined with reliable *in-vitro* drug dissolution.

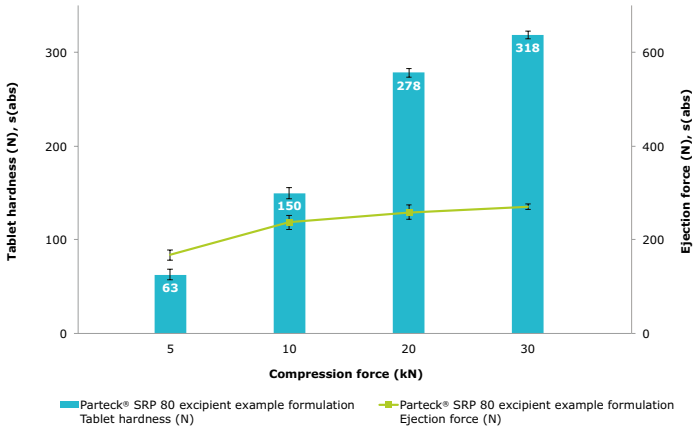


Fig. 1: Compressibility and ejection force.

Tablet hardness and ejection force were measured with n=20.

Consistent API release. Robust manufacturing process. Reliable patient compliance.

Matrix tablets with Parteck® SRP 80 excipient show a consistent API release over long time periods, typically between 8 to 12 hours, over a broad range of compression forces and independent of the resulting tablet hardness (Fig. 2). This leads to a robust manufacturing process, reliable performance and patient compliance through reproducible efficacy of given dose.

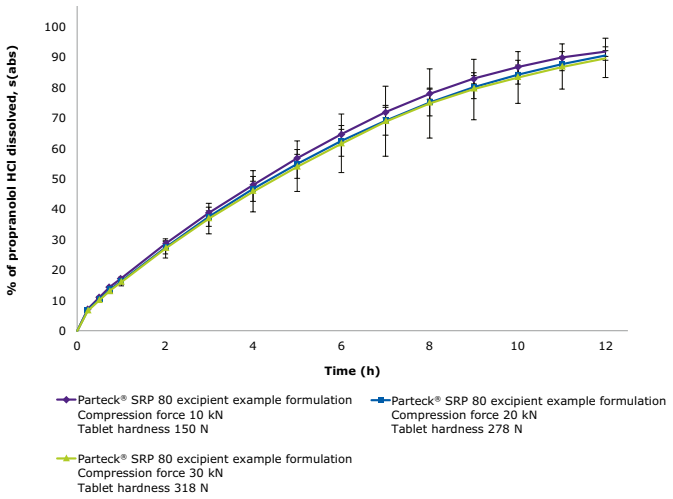
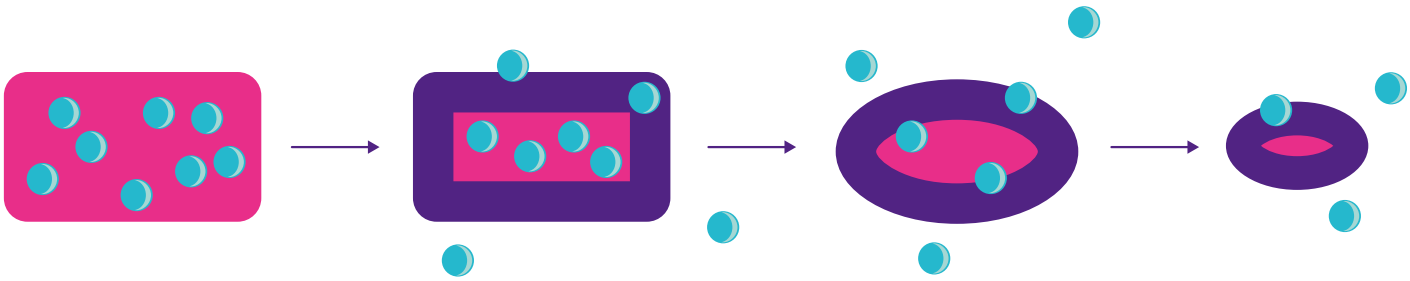


Fig. 2: Release profile.

Dissolution procedure: USP Apparatus 2 (Paddle Apparatus), 900 mL phosphate buffer pH 6.8, 50 rpm, 37 °C, detection wavelength 214 nm; n=3.

Sustained-release formulations: matrix systems



Swelling and diffusion

Diffusion and dissolution/erosion

No pH- or alcohol-induced dose dumping.

Parteck® SRP 80 excipient matrices are unsusceptible to API dose dumping, be it through pH shifts, such as food effect or gastrointestinal transit, or in the presence of alcohol. The constant *in-vitro* release behavior is shown in different dissolution media over a broad pH range (Fig. 3). There is no *in-vitro* dose dumping effect visible over the 12-hour release time even in a 40 % (v/v) alcohol release medium (Fig. 4).

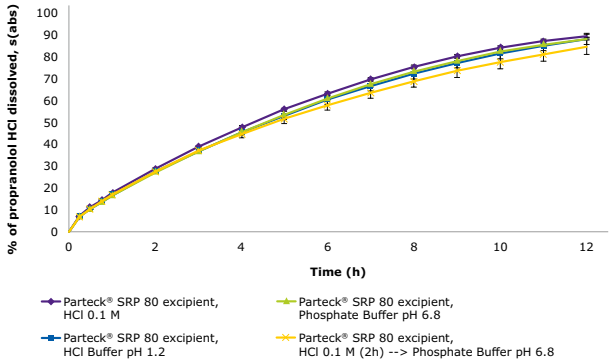


Fig. 3: No pH-dependent dose dumping.

Dissolution procedure: USP Apparatus 2 (Paddle Apparatus), 900/1000 mL medium, 50 rpm, 37 °C, detection wavelength 214 nm; n=3. Samples used: tablets compressed at 20 kN.

High performance. Consistent performance.

Because of its synthetic origin, Parteck® SRP 80 excipient does not exhibit the unpredictable raw material variations that can affect the performance of natural or semi-natural polymers. QbD and validation processes are greatly simplified with Parteck® SRP 80 excipient.

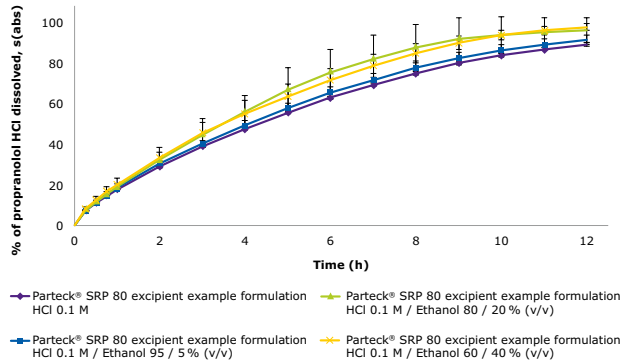


Fig. 4: No alcohol-induced dose dumping.

Dissolution procedure: USP Apparatus 2 (Paddle Apparatus), 900 mL HCl/Ethanol medium, 50 rpm, 37 °C, detection wavelength 214 nm; n=3. Samples used: tablets compressed at 20 kN.

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

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

EMDMillipore.com/parteck

FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:

EMDMillipore.com/formulationapp

Need lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

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 hird 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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1206EN
w305915
10/2017

SAFC®
Pharma/Biopharma Raw Materials

PARTECK® SLC EXCIPIENT

CARRY YOUR API TO TOP PERFORMANCE

Enhance API solubility.
Achieve stable, high drug loads.

Parteck® SLC excipient is an innovative silica drug carrier that enhances drug solubility thanks to its unique surface structure. This allows for significantly increased dissolution of your API.

MilliporeSigma

Parteck® SLC Excipient

Enhancing drug solubility.

The solubility of your API is critical. To help you improve your formulation, we've created an innovative material with a unique surface structure that provides significantly increased dissolution of your API, but without increasing regulatory requirements. Featuring a unique pore structure, Parteck® SLC excipient enables you to load oral solid dosage forms with your amorphously distributed API to the highest levels, dramatically increasing API solubility.

By using Parteck® SLC excipient as a new formulation tool, you are able to reformulate many drug molecules. As more and more drug patents expire, the reformulation of drugs can greatly enhance your life cycle management. Parteck® SLC excipient is our solution to achieve maximum load for maximum release, leading to increased bioavailability of your API.

Superior dissolution performance.

Parteck® SLC excipient's disordered mesopores (~ 6 nm) create a large and easily accessible surface area of approx. 500 m²/g, enabling high API load. The API is deposited within the particle structures in its amorphous form, leading to increased dissolution rate and solubility through supersaturation. Multiple studies have proven superior performance both *in vitro* and *in vivo* (Fig. 2 and 3).

PARTECK® SLC EXCIPIENT PROVIDES:

Superior dissolution performance.

Leads to increased dissolution rate and solubility through supersaturation.

User-friendly particle size.

Allows easy handling in manufacturing.

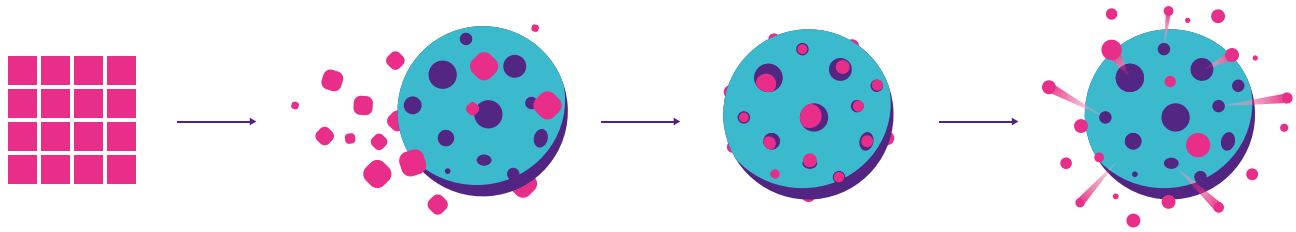
High-end application support.

We offer in-depth technical counseling, supported by dedicated Application Centers.

Multi-compendial compliance.

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

Drug carrier: mode of action



Crystalline API

API dissolved in organic solvent

Amorphous API loaded on Parteck® SLC excipient

Improved API dissolution

User-friendly particle size.

With its user-friendly particle size (5–20 µm) and bulk density (0.32 g/mL), Parteck® SLC excipient allows for easy loading, tableting, or creation of capsules. API-loaded Parteck® SLC can easily be further formulated with established excipients, producing stable and fast-acting tablets. Since it achieves a considerably high API load, final tablets result in a convenient size and weight. The dissolution performance is not impacted by the compression to the final tablet.

High-end application support.

Our expert support team helps you explore what Parteck® SLC excipient offers – from early development up to production scale. We also offer feasibility studies concerning loading and *in-vitro* dissolution as well as a product starter kit which includes a step-by-step loading guidance.

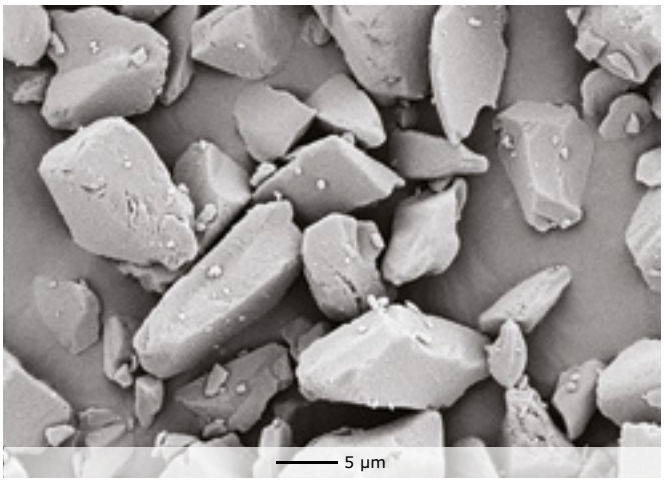


Fig. 1: REM picture of Parteck® SLC excipient particles.

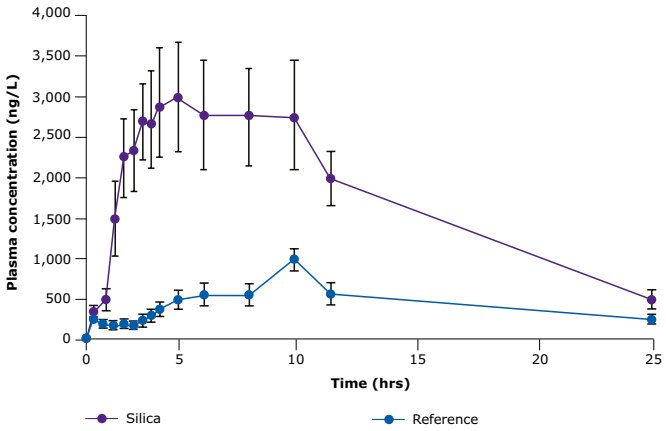


Fig. 2: *In-vivo* bioavailability.

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

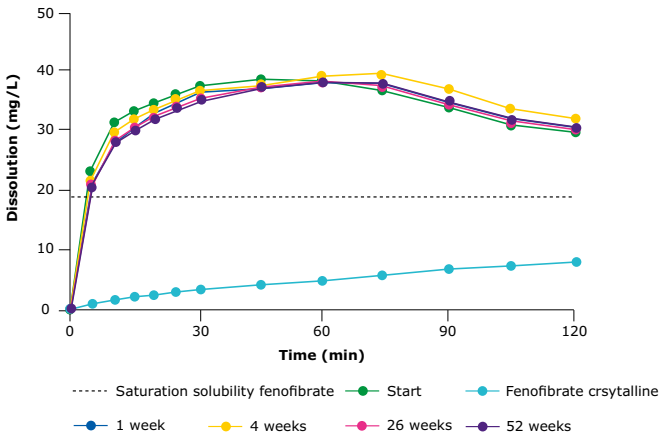


Fig. 3: Dissolution performance of tablets after storage (25 °C/60 % r.H.).

Fenofibrate loaded on Parteck® SLC excipient shows stable dissolution performance over 52 weeks. 38 mg API – 750 mL SGFsp + 0.1 % SDS – 75 rpm, n=3.

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 lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

Ordering information

Cat. No.	Product	Pack size
1.20091.0001	Parteck® SLC 500 USP, Ph Eur	300 g Starter kit
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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No.: MS_FL1205EN
w303941
11/2017

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® SI EXCIPIENT

SOFT TO THE TONGUE

Combining good compressibility with a great mouth feel for your oral dosage formulation.

Parteck® SI is a superior excipient consisting of directly compressible sorbitol, supporting excellent flowability and a great mouth feel.

MilliporeSigma

Parteck® SI Excipient

Pleasantness in all its facets.

When formulating oral dosage forms, matching patients' needs is key. While taste and mouth feel may be judged as subjective, they are crucial to patient compliance when it comes to lozenges, chewables, and similar dosage forms. Parteck® SI excipient is a directly compressible sorbitol, which combines excellent tableting behavior with a pleasant mouth feel and taste. It comes in a variety of particle sizes and qualities to meet the needs of the most diverse applications. The particle structure consists of very loosely packed, interwoven filamentary crystals that point in all directions. Unique to Parteck® SI excipient, these needle-like crystals form the cornerstone of its distinctive physical properties (Fig. 1), allowing you to combine many ingredients into a robust tablet formulation.

PARTECK® SI EXCIPIENT PROVIDES:

- Excellent compressibility
- High dilution and adsorption capacity
- Pleasant mouth feel
- Good flowability

Pleasant mouth feel.

Patients judge a formulation on the grounds of its palatability: its physical appearance in the mouth and the dissolution properties are just as important as its taste. A formula's cooling effect adds a more pleasant appeal while insoluble particles will lead to rejection. Parteck® SI excipient has shown superior properties in this regard, as it prevents clumping and dissolves smoothly, creating a cooling effect on the patients' palates (Fig. 2).

Excellent compression and high dilution potential.

To succeed on the market, most oral dosage forms need to have a highly compressible diluent. Compared to other commercial, crystallized sorbitols, our spray-dried Parteck® SI excipient demonstrates superior compression properties, which minimize the wear and tear on your machines while delivering the tablet hardness you want. Also, Parteck® SI excipient works with active ingredients that have little or no compressibility of their own (Fig. 3).

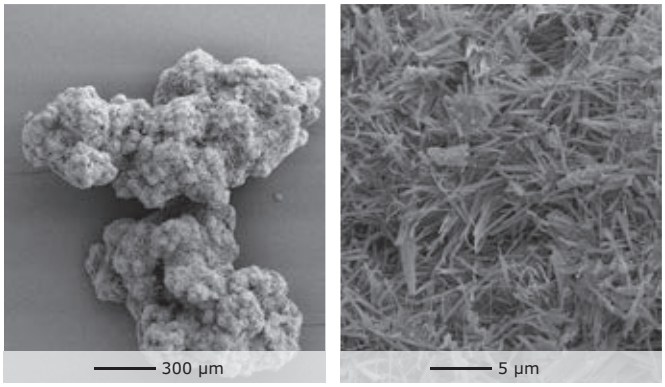
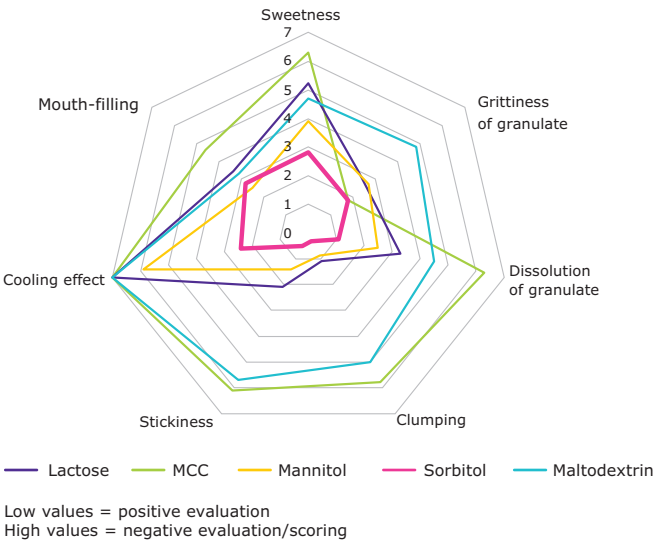


Fig. 1: SEM of Parteck® SI excipient: 50 x (left) and 2500 x (right).



Low values = positive evaluation
High values = negative evaluation/scoring

Fig. 2: Multivariate data analysis of palatability parameters, comparison of 5 typical tablet binders.

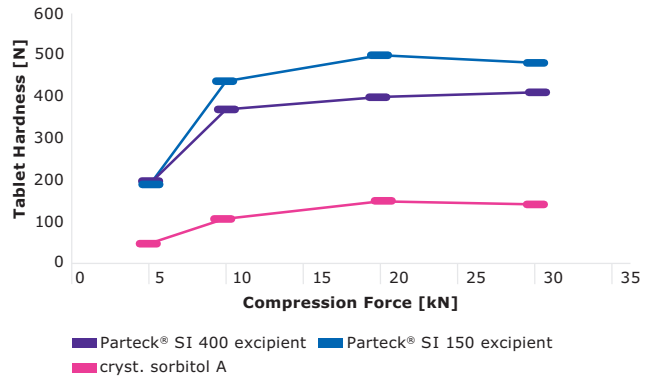


Fig. 3: Parteck® SI excipient: Compression profile.

Placebo formula with 1 % magnesium stearate. Parteck® SI excipient is spray-dried sorbitol, while cryst. sorbitol A is commercially available crystallized sorbitol.

High adsorption capacity.

Our Parteck® SI excipient has an outstanding ability to form ordered mixtures with other solid substances – the preferred choice for micronized active ingredients. Its unique structure traps the active ingredient in the filaments and forms stable clusters. As a result, you'll see more homogenous powder blends, improved content uniformity and less dust during manufacture.

Good flowability and stable formulas.

Thanks to its good flow behavior and exceptional compressibility, our Parteck® SI excipient helps your production to run even more smoothly and efficiently. That's why it is an ideal fit for sugar-free chewables, effervescent tablets, and lozenges. Tablets manufactured with Parteck® SI excipient also show a reduced water uptake compared to tablets produced with standard sorbitol. The amount of reducing sugars in the excipient itself is far lower than what is allowed according to pharmacopoeias, resulting in even more stable formulas.

The Emprove® Program.

Ensuring the compliance of your pharma and bio-pharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as solubility enhancement 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 lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

Ordering information

Cat. No.	Product	Pack size
1.03583.9028	Parteck® SI 150 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF, JSFA, E420	25 kg
1.15079.9028	Parteck® SI 200 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur, BP, NF, E420	25 kg
1.03140.9028	Parteck® SI 400 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur, BP, JSFA, NF, E420	25 kg
1.11597.9028	Parteck® SI 400 LEX EMPROVE® ESSENTIAL Ph Eur, BP, NF, JP	25 kg
1.03557.9028	Parteck® SI 450 (Sorbitol) EMPROVE® ESSENTIAL NF, FCC, JSFA	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, from the website: **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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1200EN
w303958
10/2017

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® ODT EXCIPIENT

RIGHT HERE RIGHT NOW

Combining rapid disintegration with exceptional strength for your ODT formulation.

Parteck® ODT is an excipient allowing for a simplified production of orally disintegrating tablets.

MilliporeSigma

Parteck® ODT Excipient

Convenience for the patient. And for you.

Many patients prefer the convenience and speed of orally disintegrating tablets (ODTs). By providing fast-acting medication, ODTs allow you to add value to existing compounds and extend your product life cycles. Our Parteck® ODT excipient is directly compressible and contains two ingredients: spray-granulated D-Mannitol and croscarmellose sodium – both comply with the main pharmacopoeias. The excipient facilitates the production of robust, pleasant-tasting tablets that rapidly disintegrate and dissolve across a broad range of hardnesses and compression forces. Parteck® ODT excipient is easy on your budget, easy on your equipment, and easy to formulate and handle, while meeting the highest standards in production reliability and product quality.

PARTECK® ODT EXCIPIENT PROVIDES:

- Rapid disintegration with pleasant taste and mouth feel for patient compliance
- Fast dissolution for rapid relief
- Cost-effective development and production thanks to direct compressibility
- Exceptionally hard tablets leading to simplified formulation work and handling
- High dilution potential – allows up to 50 % active ingredients in DC formulations

Rapid disintegration.

Whether you need soft or hard tablets, high or low compaction – the choice is yours with Parteck® ODT excipient. It enables you to produce tablets that “melt” quickly and smoothly across a wide range of different production parameters, such as tablet hardnesses (Fig. 3). Thanks to its unique filamentous particle structure (Fig. 1) which remains even throughout compression and its greatly increased surface area, Parteck® ODT excipient supports high levels of safety and flexibility for your ODT development and production.

Fast dissolution.

While other ODTs may disintegrate fast, too, they do not necessarily release the active ingredient immediately (Fig. 4). However, to help your formulation succeed, with Parteck® ODT excipient your active ingredients are released quickly and taste pleasant, too – for the convenience of patients.

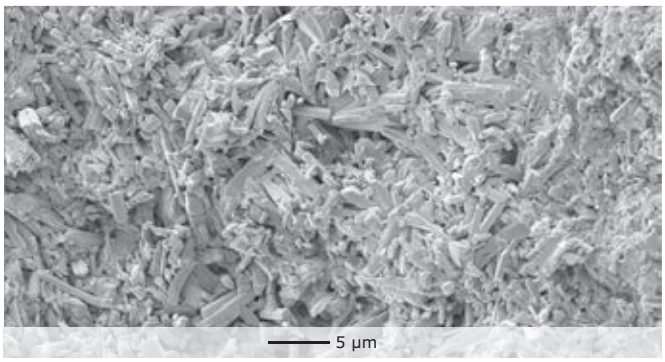


Fig. 1: Morphology of Parteck® ODT excipient powder (magnification 2000x).

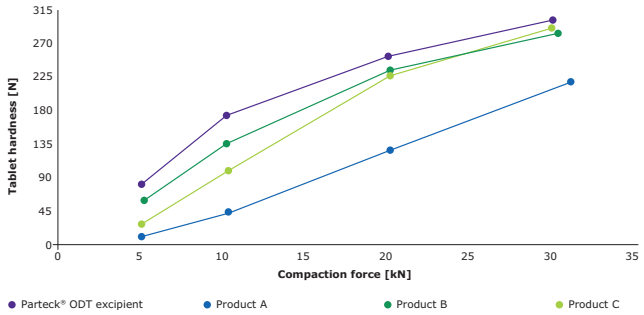


Fig. 2: Compression profile of placebos with Parteck® ODT excipient vs. competitors.

1 % Mg stearate, Korsch EK 0 DMS, 500 mg tablets, diameter 11 mm, flat, facetted, tablet hardness by ERWEKA TBH 30 MD

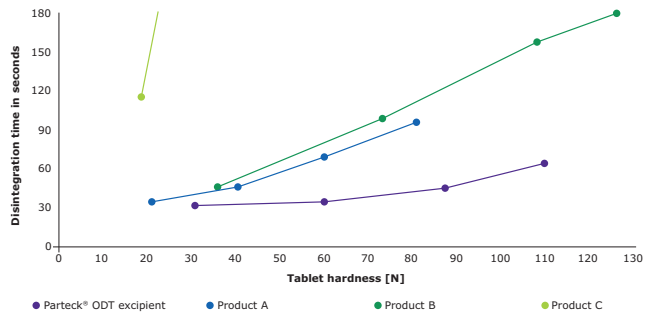


Fig. 3: Disintegration profile of API formulation with Parteck® ODT excipient vs. competitors.

200 mg ibuprofen + 1 % SiO_2 + 1 % Mg stearate, Korsch EK 0 DMS, 500 mg tablets, diameter 11 mm, flat, facetted, USP disintegration in water at 37 °C

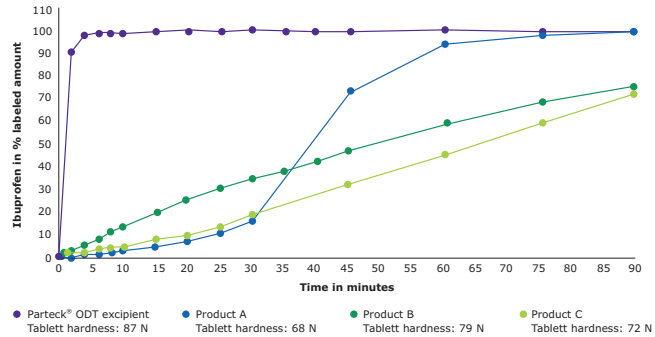


Fig. 4: *In-vitro* dissolution profile of API formulation with Parteck® ODT excipient vs. competitors.

200 mg ibuprofen + 1 % SiO_2 + 1 % Mg stearate (500 mg final weight) (Procedure: USP apparatus 2, 900 mL phosphate buffer, pH 7.2, 37 °C, 50 rpm, 221 nm)

General formulation with Parteck® excipients	
Active Ingredient (non DC)	0 – 50 %
100490 Parteck® ODT excipient	Ad 100 %
100663 Parteck® LUB excipient	1 – 1.5 %
100895 Sucralose	0.5 – 1.5 %
Flavor	0.5 %

Table 1: The exemplary formulation above should give good results for a variety of drugs. Our application laboratory will gladly assist you with specific formulation challenges.

Directly compressible.

As Parteck® ODT excipient is designed for direct compression, it helps you produce tablets more cost-effectively. With its unique surface structure (Fig. 1), it also minimizes wear and tear on your equipment and leads to robust tablets with extremely low friability. Thanks to the high compressibility (Fig. 2) of Parteck® ODT excipient, active ingredients can account for up to 50 % of your formulation.

The Emprove® Program.

Ensuring the compliance of your pharma and bio-pharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as solubility enhancement 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 lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

Ordering information

Cat. No.	Product	Pack size
1.00490.1000	Parteck® ODT EMPROVE® ESSENTIAL	1 kg PE bottle with screw cap
1.00490.9025	Parteck® ODT EMPROVE® ESSENTIAL	25 kg PE carton box

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, from the website: **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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1201EN
w303956
10/2017

SAFC®

Pharma/Biopharma Raw Materials

PARTECK® M EXCIPIENT

KEEP YOUR FORMULATION SAFE

API stability combined with rapid disintegration.

Parteck® M is a directly compressible excipient that combines stability with rapid disintegration for your solid dosage form.

MilliporeSigma

Parteck® M Excipient

Less pressure. For quick action.

Achieving a stable and reliable outcome in tablet manufacturing often calls for intense processing and the use of high forces. As one of our functional excipients, Parteck® M excipient achieves excellent compressibility while keeping the API stable throughout your manufacturing process and beyond. Based on directly compressible mannitol, it does not require further processing or high forces. Parteck® M excipient enables a rapid disintegration and quick release regardless of the dosage, giving your high- or low-dosed active ingredients a speed-up.

Accommodating plenty of dosage forms, Parteck® M excipient is available in two grades:

- Parteck® M 100 excipient
- Parteck® M 200 excipient

PARTECK® M EXCIPIENT PROVIDES:

- High compactibility thanks to unique particle properties
- Uniform doses with homogenous distribution
- High dilution potential
- Rapid disintegration
- Excellent API stability thanks to low levels of hygroscopicity, reducing sugar content, and compression forces

Uniform doses with homogenous distribution.

Thanks to its large surface area and unique particle structure, Parteck® M excipient helps active ingredients adsorb strongly to it, while also preventing segregation during processing. Even in low-dose formulas, in which dose uniformity and mix homogeneity take priority, Parteck® M excipient serves as an ideal diluent. You can also expect smooth and easy development and production with Parteck® M excipient, as good flowability and chemical stability make it easy to handle.

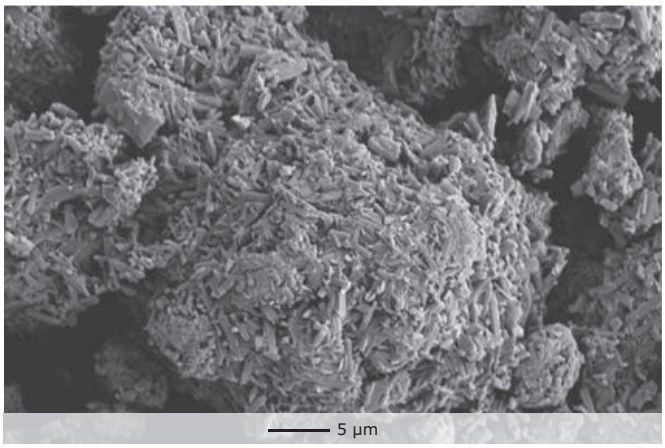


Fig. 1: SEM of Parteck® M excipient: Highly structured surface area.

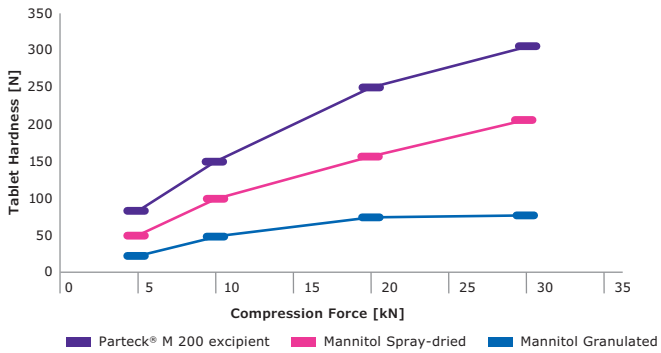


Fig. 2: Parteck® M excipient: Compression profile.

Placebo formula using 1% magnesium stearate. Granulated and spray-dried mannitol are commercially available mannitol grades for direct compression.

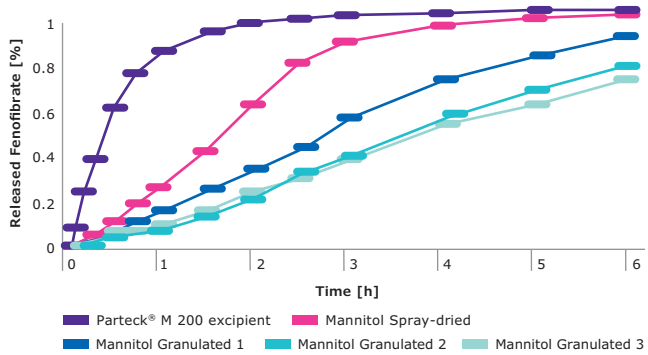


Fig. 3: Disintegration and dissolution profile.

Formulas consisting of 20% (100 mg) micronized fenofibrate, 1% Aerosil®, 1.5% magnesium stearate, and 77.5% DC-mannitol.

High compactability.

Created with directly compressible mannitol, Parteck® M excipient features an open and filamentary particle structure, allowing you to compact tablets at low forces and hence minimize the wear and tear on your equipment (Fig. 1 and Fig. 2). Parteck® M excipient is also free-flowing, which helps to keep a stable and high-throughput process.

High dilution potential.

Parteck® M excipient is specifically designed as a diluent for tableting active ingredients that do not really lend themselves to compression. With Parteck® M excipient you can include up to 60% of non-directly compressible actives in your formulas, in order to reduce tablet sizes where high loads of active pharmaceutical ingredients are concerned.

Rapid disintegration and dissolution.

With its unique particle structure and greatly increased surface area, Parteck® M excipient helps even very hard tablets to both disintegrate and dissolve – faster and more easily (Fig. 3).

The Emprove® Program.

Ensuring the compliance of your pharma and bio-pharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as solubility enhancement 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 lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

Ordering information

Cat. No.	Product	Pack size
1.00494.2500	Parteck® M 100 EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E421	2.5 kg PE bottle
1.00494.9025	Parteck® M 100 EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E421	25 kg carton box
1.00419.2500	Parteck® M 200 EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E421	2.5 kg PE bottle
1.00419.9025	Parteck® M 200 EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E421	25 kg carton box
1.00419.9050	Parteck® M 200 EMPROVE® ESSENTIAL Ph Eur, BP, JP, USP, E421	50 kg carton box

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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No.: MS_FL1202EN
w303953
10/2017

SAFC®
Pharma/Biopharma Raw Materials

PARTECK® LUB EXCIPIENT

A SMOOTH OPERATION

Achieve consistent lubrication performance.

Parteck® LUB is a range of vegetable-origin stearates featuring excellent batch-to-batch consistency for reliable lubrication.

MilliporeSigma

Parteck® LUB Excipient

Reliability in every sense.

When it comes to tablet production there is nothing more important than a smooth production process – in particular choosing the right lubricant. Parteck® LUB, a product line of our most effective excipients for lubrication, demonstrates excellent batch-to-batch consistency and helps you to achieve a reliable workflow in your tablet manufacture.

Parteck® LUB products are available in three vegetable-origin variants:

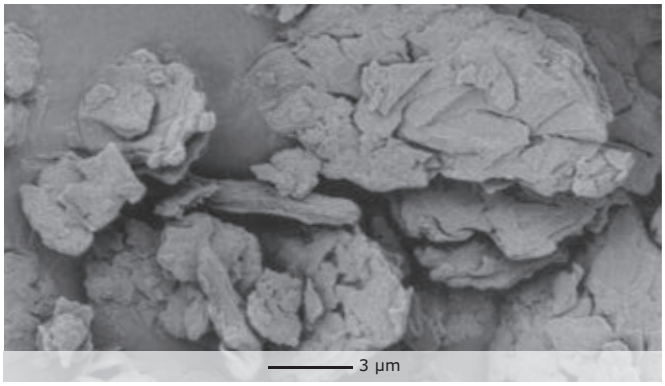
- Parteck® LUB MST (magnesium stearate)
- Parteck® LUB CST (calcium stearate)
- Parteck® LUB STA (stearic acid)

PARTECK® LUB EXCIPIENT PROVIDES:

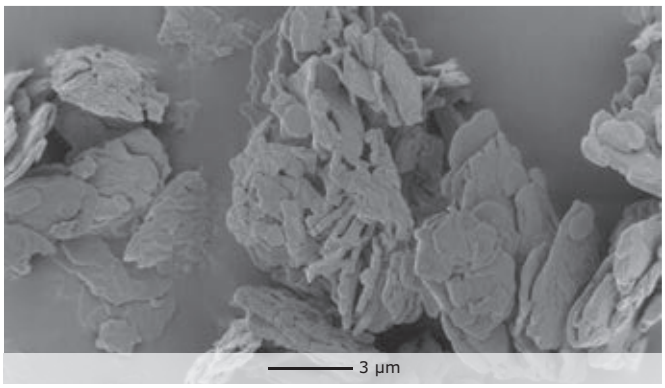
High batch-to-batch consistency

Reliable performance thanks to specified particle size and surface area

Vegetable origin and regulatory documentation for minimal qualification and registration efforts



SEM of Parteck® LUB MST



SEM of Parteck® LUB CST

	Parteck® LUB MST	Parteck® LUB CST	Parteck® LUB STA
d10	≥ 1 µm	≥ 0.8 mm	≥ 5 µm
d50	~ 5 µm	~ 4 µm	~ 35 µm
d90	≤ 20 µm	≤ 20 µm	≤ 200 µm
BET	5–12 m²/g	4–8 m²/g	0.90–1.40 m²/g

Table 1: Particle size and BET of Parteck® LUB excipient.

Excellent batch-to-batch consistency.

To demonstrate the galenical suitability of an excipient, the lubrication effect hinges on two crucial parameters: particle size and specific surface area. We set tight limits on both. The production processes are designed to allow for consistent quality with every batch, keeping your manufacturing running smoothly.

Specified parameters.

We certify specific details on particle size ranges and the BET surface area for all Parteck® LUB excipients. These parameters are essential in developing a stable formula for the lubricating film, enabling a reliable tableting behavior.

Vegetable origin.

As a result of the BSE/TSE crisis, many pharmacopoeias call for additional manufacturing stages to inactivate pathogens in stearates. Good news: As they are made from vegetable raw materials, our Parteck® LUB excipient keeps your regulatory work to a minimum.

The Emprove® Program.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as solubility enhancement 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

Ordering information

Cat. No.	Product	Pack size
1.00663.9020	Parteck® LUB MST (magnesium stearate) EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF, FCC	20 kg
1.00664.9020	Parteck® LUB CST (calcium stearate) EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF, FCC	20 kg
1.00661.9020	Parteck® LUB STA (stearic acid) EMPROVE® ESSENTIAL Ph Eur, BP, JP, NF	20 kg

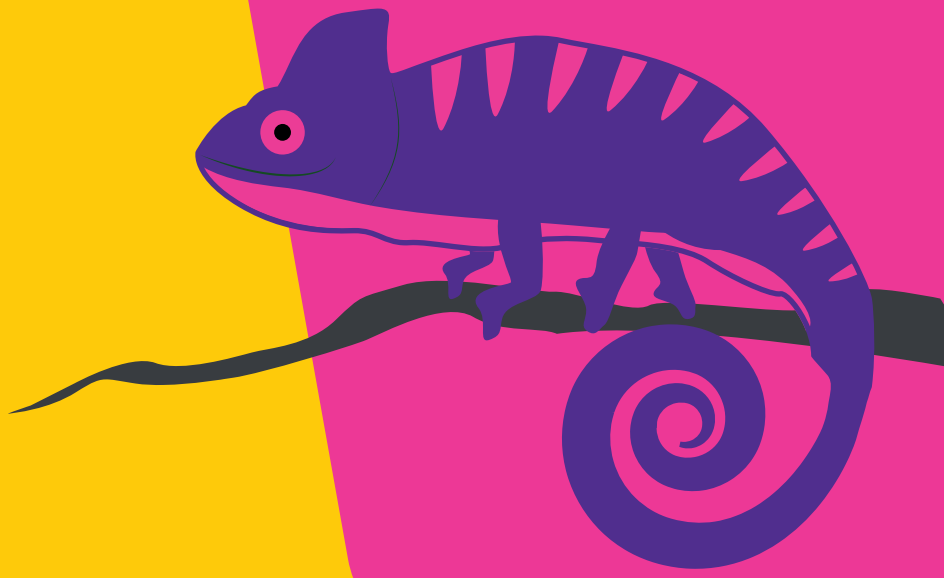
The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: **EMDMillipore.com**

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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1198EN
W303955
10/2017

SAFC®
Pharma/Biopharma Raw Materials



PARTECK® DELTA M EXCIPIENT

ADAPT TO SUCCEED

Meeting your formulation challenges with exceptional disintegration and binding capacity.

Parteck® Delta M is a convertible mannitol specifically designed to handle wet granulation.

MilliporeSigma

Parteck® Delta M Excipient

Adapting abilities.

Especially during wet granulation, it is challenging to find an excipient that will keep excellent binding and compaction properties. Our Parteck® Delta M excipient features a unique mannitol with delta-polymorphic crystals, which makes it extremely adaptable. While it is monographed as a standard mannitol, this exceptional excipient changes its structure and converts into a beta-polymorph when it comes into touch with water. This creates an increased surface area and a porous structure, which leads to the ability to produce exceptionally hard tablets with fast disintegration.

PARTECK® DELTA M EXCIPIENT PROVIDES:

- Large surface area after granulation thanks to unique delta-polymorphic crystals
- Excellent binding properties
- Accelerated disintegration
- Non-hygroscopicity and exceptionally low content of reducing sugars

Large surface area after granulation.

Parteck® Delta M excipient is the only mannitol on the market which is a delta-polymorph (Fig. 1). During wet granulation it converts into a beta-polymorph, which increases the mannitol's surface area by a factor of ten compared to commercially available beta-mannitol. The beta-polymorph that results is highly porous and has excellent binding and tableting properties (Fig. 2).

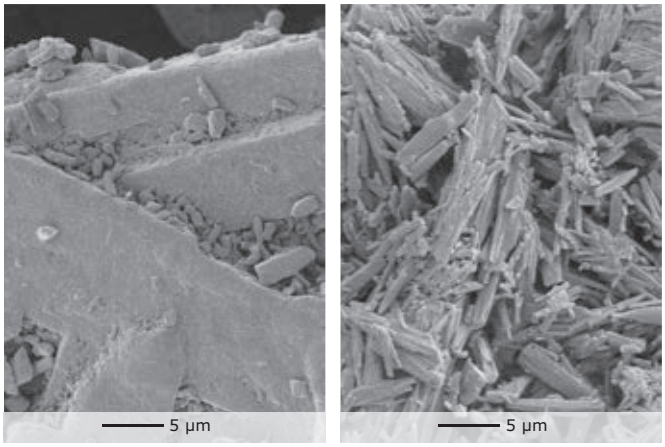


Fig. 1: Unique delta-polymorphic crystals: before/after wet granulation.

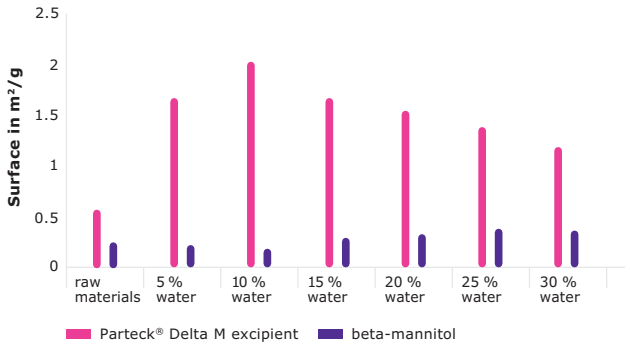


Fig. 2: BET surface – granules of delta- vs. beta-mannitol produced by wet granulation.

Mannitol was granulated with water and dried in a fluidized bed. Granules larger than 1,000 µm were removed by sieving before the BET surface was measured. Granulation of Parteck® Delta M excipient with about 10–20 % water achieved the maximum increase in surface area, whereas the granulation of beta-mannitol led to no increase in surface area.

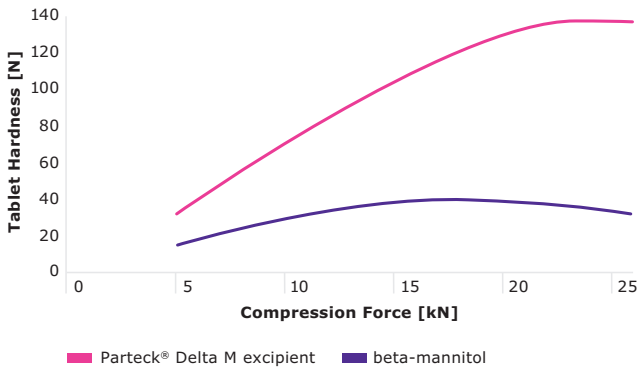


Fig. 3: Compression profiles Parteck® Delta M excipient and beta-mannitol.

Granulated with 15 % water, the material was mixed for 5 minutes with 1.5 % magnesium and compressed on a single punch press at different compression forces. Press: Korsch EKO DMS; punch: 11mm, flat and facetted. Tablet weight: 400 mg.

Excellent binding properties.

Thanks to a tenfold increase in surface area during wet granulation compared to standard beta-mannitol, Parteck® Delta M excipient allows you to manufacture tablets that are significantly harder than tablets with standard beta-mannitol. By compressing tablets at lower forces like this, you reduce wear and tear on your equipment, thus extending its service life. Moreover, you can successfully compress challenging formulas with active ingredients that do not compress well at all (Fig. 3).

Accelerated disintegration.

Simplified formulations and rapidly disintegrating tablets are two of the essential aims in the tablet manufacturing. With Parteck® Delta M excipient and its highly porous structure they become standard – without forcing you to compromise on inertness, non-hygroscopicity and binding properties.

The Emprove® Program.

Ensuring the compliance of your pharma and bio-pharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization – all designed to help you speed your way through the regulatory maze.

Find out more at:
EMDMillipore.com/emprove

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as solubility enhancement 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 lubrication?

Parteck® LUB is a range of stearates for consistent lubrication performance.

Ordering information

Cat. No.	Product	Pack size
1.12635.1000	Parteck® Delta M EMPROVE® ESSENTIAL Ph Eur, BP, USP, JP, E 421	1 kg PE bottle with screw cap
1.12635.9025	Parteck® Delta M EMPROVE® ESSENTIAL Ph Eur, BP, USP, JP, E421	25 kg carton box

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, from the website: **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 hird 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.

For additional information, please visit **EMDMillipore.com**
To place an order or receive technical assistance, please visit **EMDMillipore.com/contactPS**

Lit. No. MS_FL1199EN
W303960
10/2017

Click. Explore. Learn more.

For more information about our Parteck® range, visit:
EMDMillipore.com/parteck

Find the right product for specific applications with our Formulation Product Finder App at:
EMDMillipore.com/formulationapp

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 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.

For additional information, please visit EMDMillipore.com
To place an order or receive technical assistance, please visit EMDMillipore.com/contactPS

MilliporeSigma
290 Concord Road
Billerica, MA 01821

w303951
08/2017