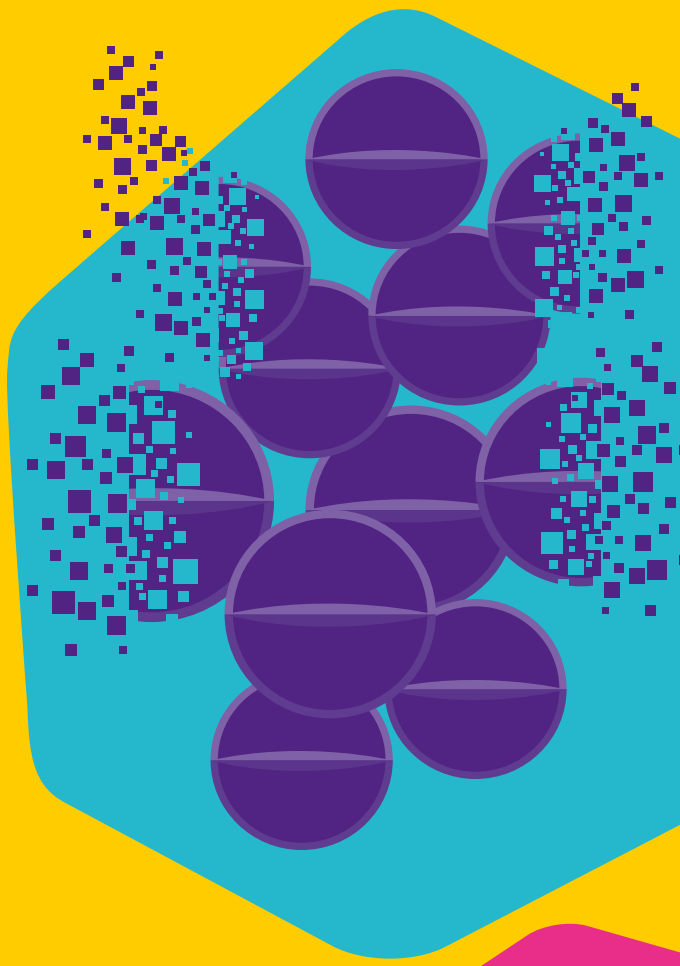
Parteck® PLX 188 Excipient

Accelerate dissolution

Enhance dissolution rate and lubrication with a single high performance excipient

Parteck® PLX provides consistent performance, improved dissolution rate and reliable lubrication – all at the same time.



SAFC®

Pharma & Biopharma Raw Material Solutions

Parteck® PLX 188 Excipient

Blend. Compress. Enhance.

Parteck® PLX 188 is a dissolution rate enhancing excipient, but it can do much more. With an optimized particle size, Parteck® PLX 188 is designed with the needs of modern manufacturing in mind – such as direct compression and continuous manufacturing – and ideally caters to the needs of solid dosage formulation.

Parteck® PLX 188 excipient is part of our Emprove® product range, which combines outstanding quality with comprehensive documentation and excellent service tailored to the pharmaceutical industry. The quality, consistency and compliance of our raw materials is fully documented and supported by a secure and robust supply chain.

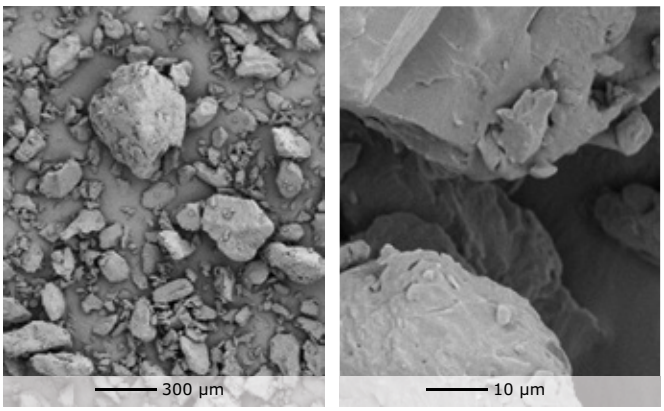


Fig. 1: SEMs of Parteck® PLX 188 excipient particles.

PARTECK® PLX 188 EXCIPIENT PROVIDES:

- Improved dissolution rates for poorly soluble DCS class 2a molecules
- Water soluble tablet lubrication
- Specified particle size distribution (D10, D50, D90) for constant performance
- Batch-to-batch consistency, for reliable results
- Regulatory support through compliance with PhEur and USP-NF and going beyond current requirements by specifiying formaldehyde content

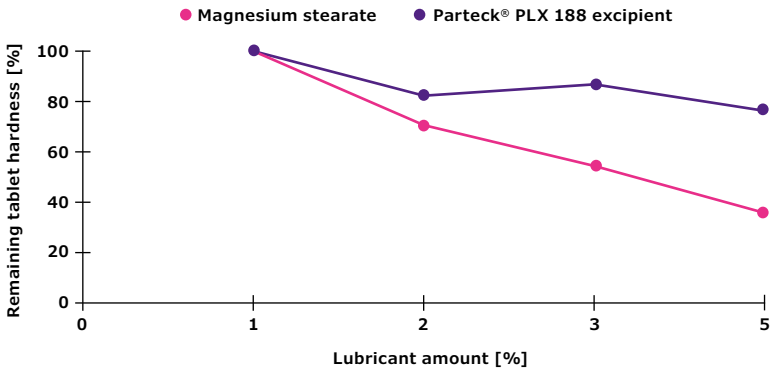


Figure 2: Remaining tablet hardness of 10 kN MCC tablets in % compared to tablets with 1 % lubricant

Water soluble lubrication

In some cases, traditional lubricants – such as high concentrations of magnesium stearate which can also lead to additional challenges in terms of tablet hardness – are not suitable for use with actives that exhibit low solubility and subsequent bioavailability. As they are hydrophobic by nature, they can retard disintegration and dissolution. This effect can even be exacerbated by overmixing and use of high concentrations of magnesium stearate. In such cases, Parteck® PLX 188 excipient may be a viable alternative, combining adequate Dissolution rate lubrication at tolerable concentrations with the added benefit of dissolution enhancement.

Dissolution rate enhancement

Dissolution rate is a key factor for bioavailability of active ingredients. Improving the dissolution rate increases speed and extent of absorption of the API from the gastrointestinal tract. If the dissolution rate is too low, an API may not reach its therapeutic concentration in the patient. This is especially relevant for molecules with dissolution rate limitations, so-called DCS 2a molecules.

Poloxamers are known to improve wettability and dissolution rate in pharmaceutical formulations and can therefore provide a simple solution to low bioavailability of DCS 2a compounds.

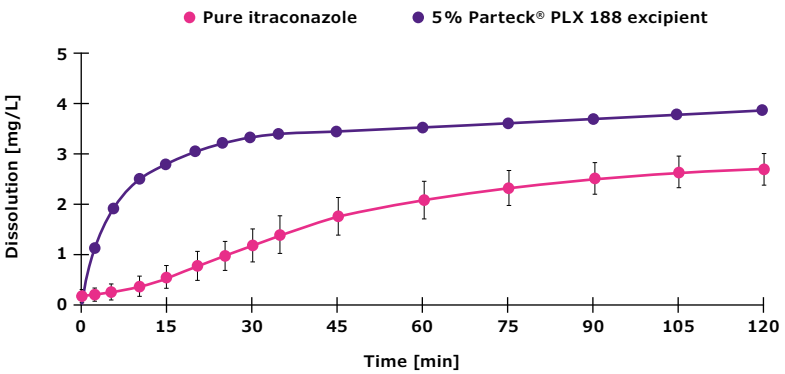


Figure 3: Dissolution performance of itraconazole tablets with 5% Parteck® PLX 188 excipient in comparison to pure itraconazole. Dissolution procedure: USP Apparatus 2 (Paddle), 1000 mL SGFsp pH 1.2, 75 rpm, 37 °C; n=3.

Click. Explore. Learn more.

PARTECK® PRODUCT PORTFOLIO

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

MerckMillipore.com/parteck

FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:

MerckMillipore.com/formulationapp

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. Our Emprove® Program helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To optimize your process, our Emprove® Program provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. The Emprove® Program is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:

MerckMillipore.com/emprove

Ordering information

Cat. No.	Product	Pack size	Packaging
1.08212.0001	Parteck® PLX 188 (Poloxamer 188) (stabilized with 70ppm BHT) EMPROVE® ESSENTIAL Ph Eur, NF	3 x 500 g	Sample Kit
1.08212.0500		500 g	PE wide-neck bottle
1.08212.5000		5 kg	PE wide-neck bottle
1.08212.9025		25 kg	PE bag in square PE 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: **MerckMillipore.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 **MerckMillipore.com**
To place an order or receive technical assistance, please visit **MerckMillipore.com/contactPS**

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