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.

MERCK

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.

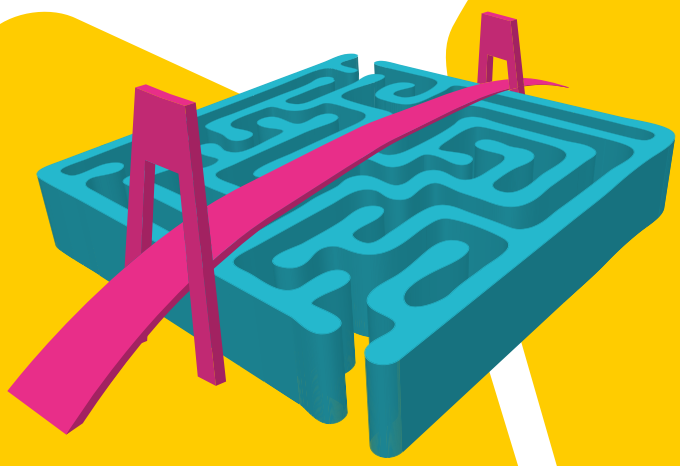
Fully synthetic origin leads to decreased variability in quality and performance, facilitating QbD and validation processes.

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: **MerckMillipore.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.

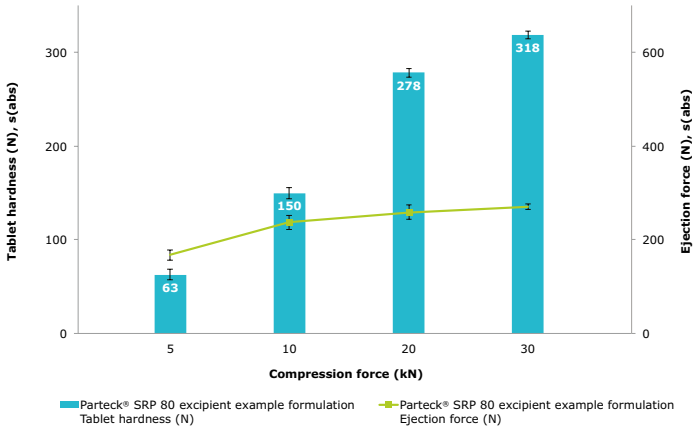


Fig. 1: Compressibility and ejection force.

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.

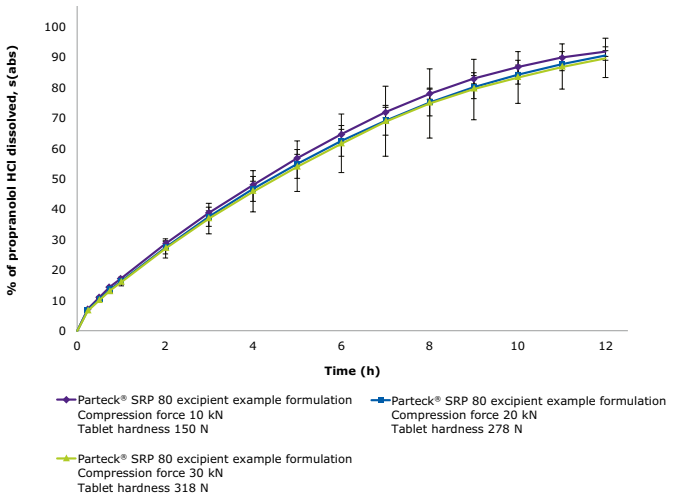
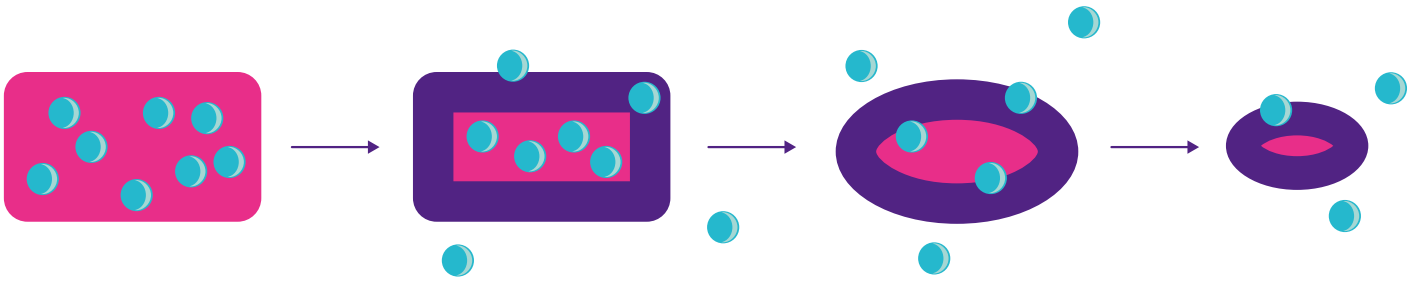


Fig. 2: Release profile.

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).

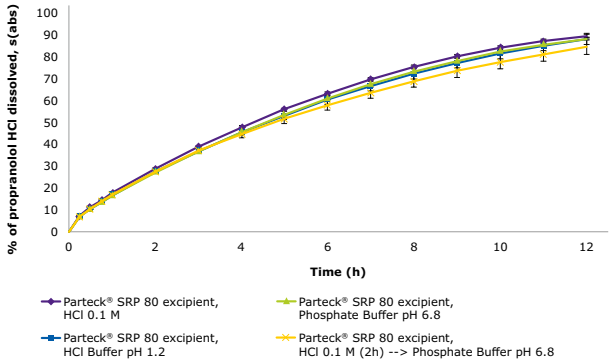


Fig. 3: No pH-dependent dose dumping.

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.

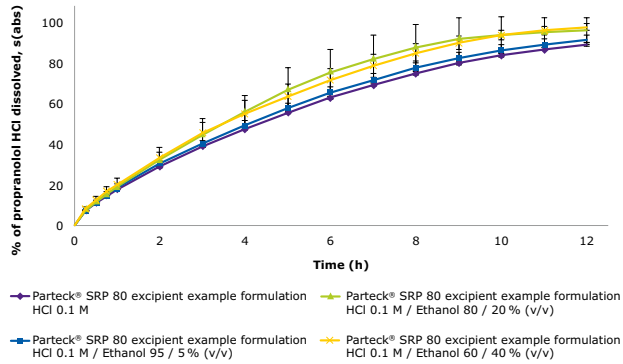


Fig. 4: No alcohol-induced dose dumping.

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:

MerckMillipore.com/parteck

FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:

MerckMillipore.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: **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.

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