MilliporeSigma

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).

SAFC®

Pharma & Biopharma Raw Material Solutions

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 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 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.

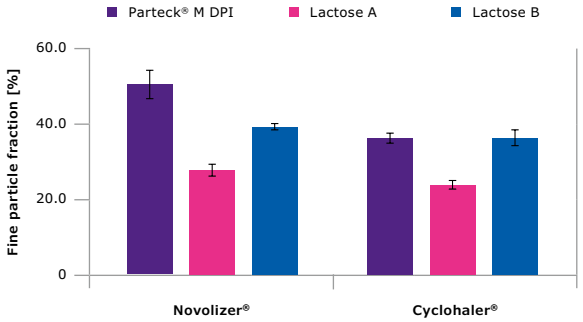
Enhanced patient tolerance

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 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 pharmacopeia. Meanwhile, Parteck® M DPI highlights a remarkable inertness that will not compromise the integrity of your API.

Budesonide:



Novolizer® by AstraZeneca AB, Sweden
Cyclohaler® by Pharmachemie B.V., Netherlands

Fig. 1: FPF measured with Next Generation Impactor with two commercial devices in comparison with two commercial carriers based on lactose.

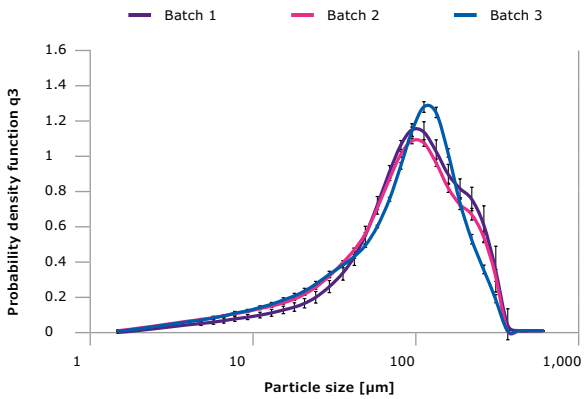


Fig. 2: Particle size distribution measured by laser diffraction.

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) (Figure 1) using our Parteck® M DPI 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 at approximately 0.01 % (LOD) is possible because of its very low hygroscopocity. 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. 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.

Flowability. Homogeneity. Particle size distribution.

Parteck® M DPI'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. Figure 3 shows an evenly distributed, stable blend of API and Parteck® M DPI as the selected carrier. Blends, such as the one pictured, support balanced adhesion forces for constant dosing.

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

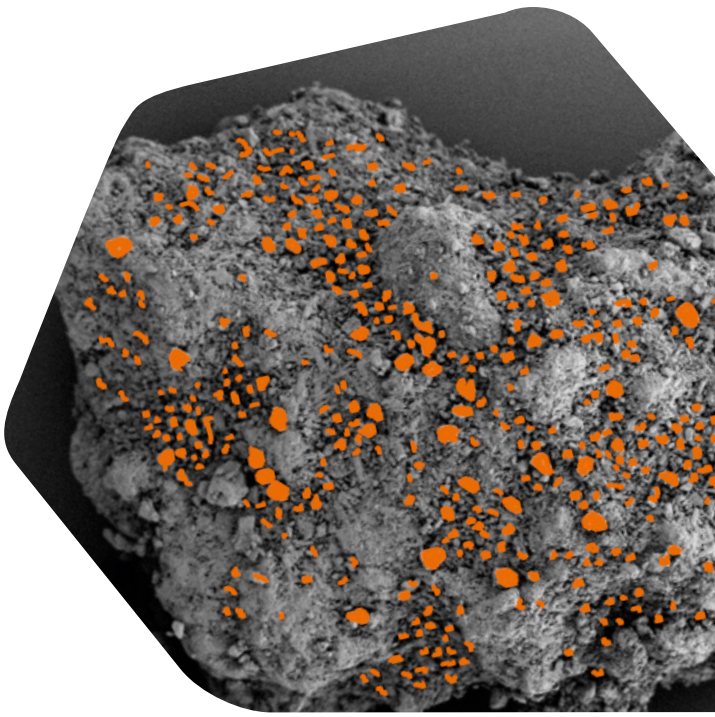
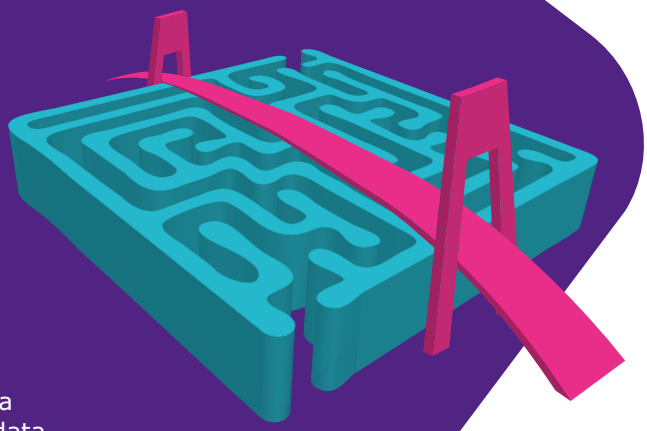


Fig. 3: Micronized model API (Budesonide) on Parteck® M DPI

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**

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

Parteck® M DPI EMPROVE® EXPERT Ph Eur, BP, JP, USP, E421

Cat. No.	Product	Pack size
1.03668.9025	double PE bag in Squarebox (PE drum, fibre free)	25 kg
1.03668.1000	2.5 L PE-bottle	1 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 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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