

Pardeck® Delta M Excipient

Adapt to succeed

Meeting your formulation challenges
with exceptional disintegration
and binding capacity.

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

The life science business
of Merck KGaA,
Darmstadt, Germany
operates as MilliporeSigma
in the U.S. and Canada.

SAFC®

Pharma & Biopharma Raw
Material Solutions

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 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 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 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).

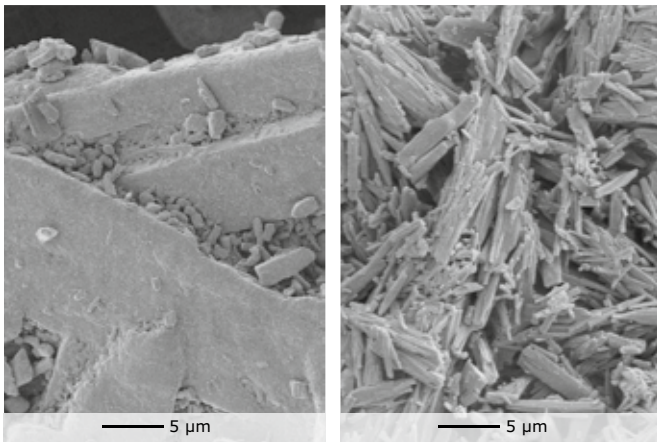


Fig. 1: Unique delta-polymorphic crystals: before/after wet granulation.

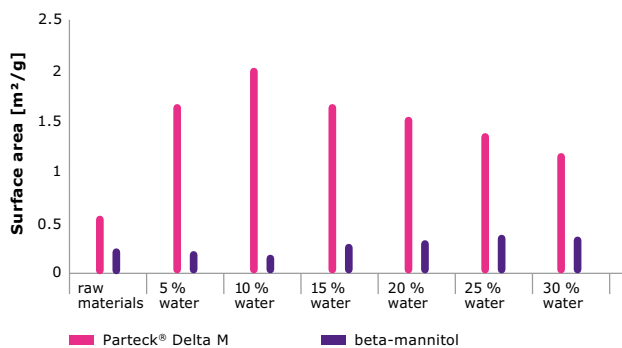


Fig. 2: BET surface – granules of delta- vs. beta-mannitol produced by wet granulation.

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 Parateck® Delta M 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.

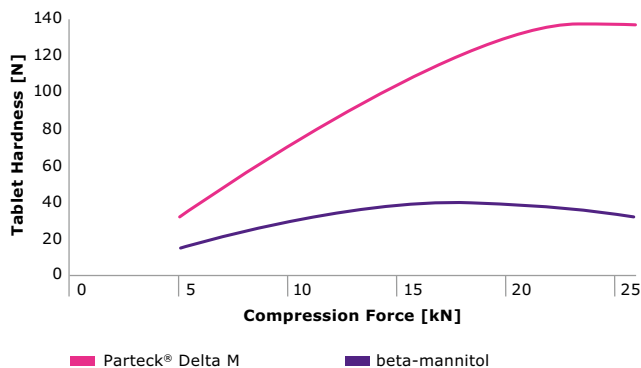


Fig. 3: Compression profiles Parateck® Delta M and beta-mannitol.

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 faceted. Tablet weight: 400 mg.

Excellent binding properties.

Thanks to a tenfold increase in surface area during wet granulation compared to standard beta-mannitol, Parateck® Delta M 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 Parateck® Delta M 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. Our knowledgeable team of technical and quality experts will share best practices and help guide you to a compliant solution that meets your performance goals.

Find out more at:
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Ordering information

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

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