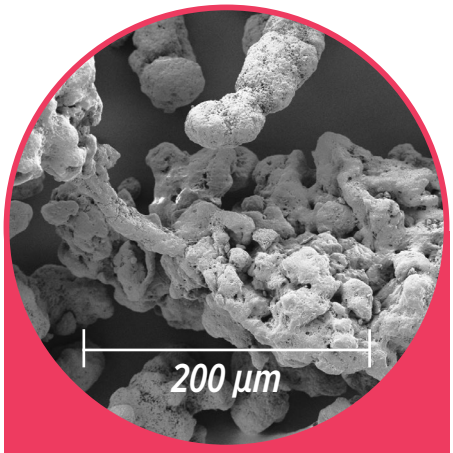
Welcome to a new era! MEGGLE's first lactose-free co-processed excipient: Reta M®

MEGGLE has been known as one of the key lactose excipient manufactures and pioneer of co-processed excipients for decades. In 2009 MEGGLE introduced RetaLac® a combination of lactose monohydrate and hypromellose, tailored specifically to sustained drug release formulation, which can be easily produced by direct compression.

Now MEGGLE is proud to introduce its first lactose-free excipient: **Reta M®.** It's comprising 50 % Mannitol and 50 % hypromellose (K4M) and easily enables sustained drug formulation through direct compression.



Reta M®

lactose-free

Product description

Reta M® is the first hypromellose/mannitol-based, co-processed excipient specifically designed for DC and dry granulation of modified release formulations. To minimize development time, API dissolution prediction as a function of tablet geometry is possible. This is aided by **Reta M®'s** dramatic improvement in wettability compared to HPMC alone or in traditional wet granulations and simple admixtures.

Application

- Tableting – Direct Compression, also for multi unit and mini tablets
- Tableting – Roller Compaction
- Preparation of aqueous HPMC-formulations (thickener)
- Spheronization, Extrusion

Benefits

- All-in-one excipient which enables manufacture of sustained drug release (time release) tablets by direct compression
- Prolonged drug release up to 13 hours
- High loading capability up to 50 % drug load
- Pharmacopoeial quality
- Lactose-free

Reta M®
Impressing functional performance. Outstanding compactibility. Well-founded expertise.

Powder characterization

Reta M®'s PSD and bulk density (400 g/l) are right in the range of providing free flow, good blending capabilities and compaction behavior. Its powder flow ranks as "Fair-aid not needed".

Co-processing two or more excipients generally improves the resulting excipient's **compactibility** over its physical ad-mixture. This effect can also be seen for **Reta M®**. It shows a quite linear increase of tablet hardness as function of employed compaction pressure, which allows for reliable and better-to-predict product performance.

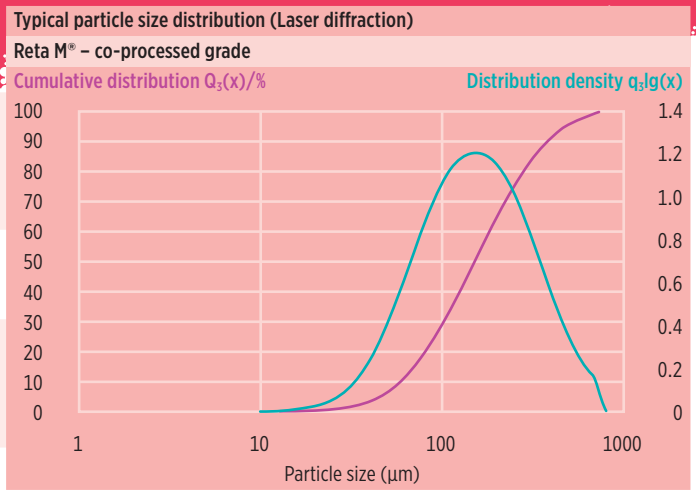
Sustained release

Reta M® works with a variety of APIs and food supplements. To demonstrate **Reta M®** performance, vitamine C has been chosen as active molecule, whose sustained release has been widely accepted to be beneficial to its subsequent user. Employing **Reta M®** as excipient in order to manufacture tablets via direct compression has led to prolonged release of vitamine C over the course of 13 hours.

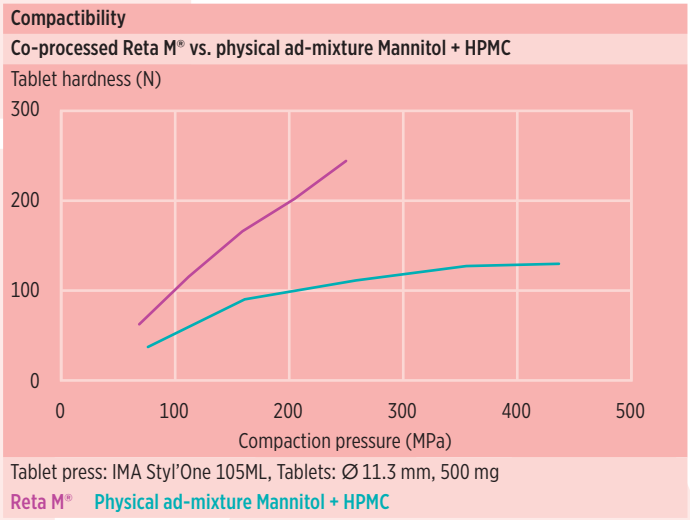
Packaging, storage, shelf-life

Reta M® comes in a 15 kg carton box, while pharma-compliant PE-EVOH-PE inliner is being used as primary packaging with a shelf life of 24 month.

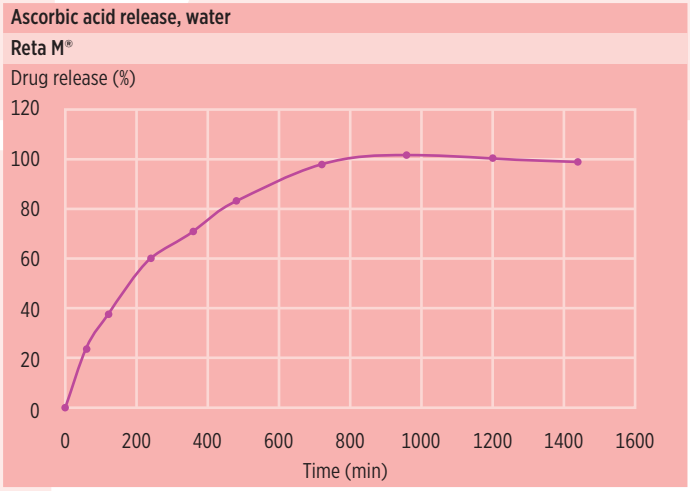
MEGGLE's first lactose-free product Reta M®: Co-processed excipient enabling sustained release formulation through direct compression.



Typical culmulative PSD and distribution density of MEGGLE's Reta M®



Comparison of compactibility – Reta M® against its physical ad-mixture, made up of 50 % Mannitol and HPMC alike.



Fixed dose combination tablet 22 × 10 mm oblong. Vitamine C (300 mg), Zinc gluconate (105 mg – 15 mg Zinc), Histidine (100 mg), Reta M® (485 mg), Magnesium stearate (10 mg), Aerosil (5 mg)

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