

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 manufacturers 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.

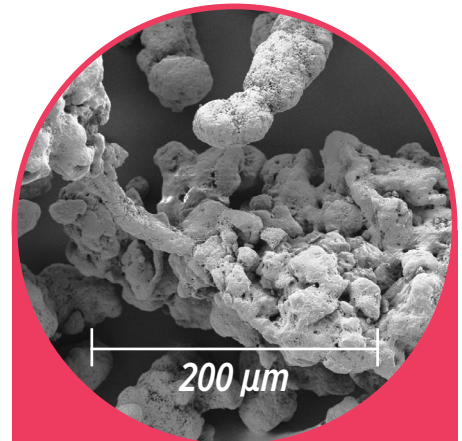
Now MEGGLE is proud to introduce its first lactose-free excipient: **Reta M[®]**. It's comprising 50% Mannitol and 50% hypromellose (K4M) and easily enables sustained drug formulation through direct compression.

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



Reta M[®]

lactose-free

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.

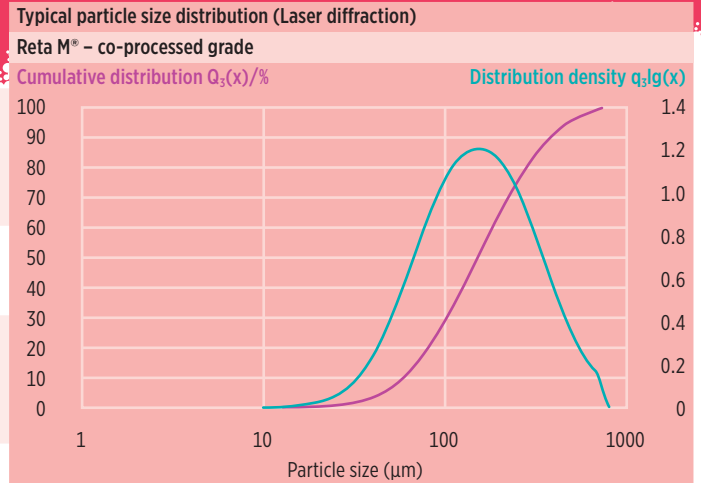
Sustained release

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.

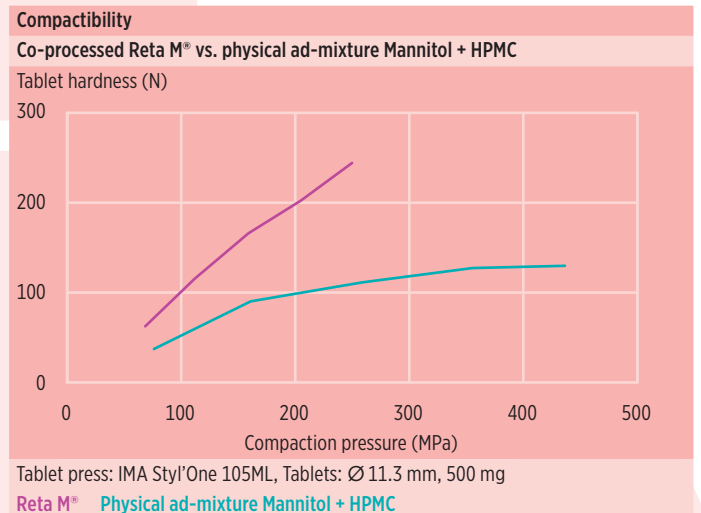
Packaging, storage, shelf-life

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

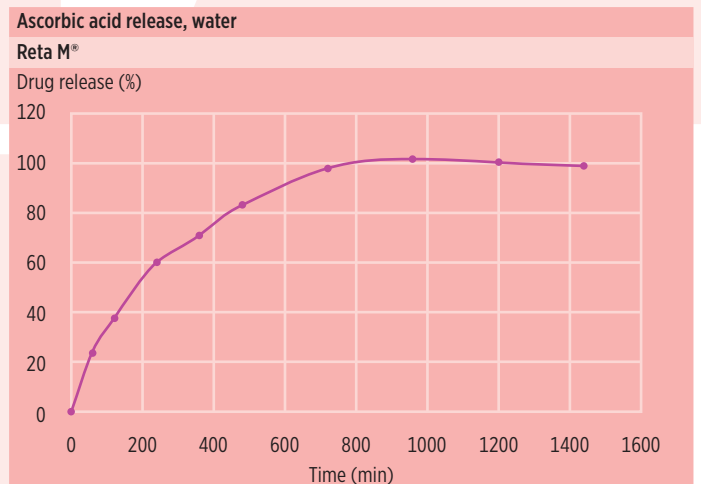
**MEGGLE's first lactose-free product Reta M[®]:
Co-processed excipient enabling sustained release
formulation through direct compression.**



Typical cumulative 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)