

# Benece<sup>TM</sup> hypromellose

## custom grades

### Custom excipients for robust and predictable controlled release matrix tablets

Hypromellose (HPMC) is the most widely used polymer in hydrophilic matrix systems and has found wide-spread use in controlled-release dosage forms. Molecular weight (MW) plays a key role in dictating drug release, so formulators choose specific MW grades based on drug solubility and desired release profile.

There are a limited number of commercially available grades due to historical convention and the scale of commercial production. As a result, formulators often need to blend two or more grades to achieve a target release profile, which can be problematic.

First, determining the blend ratio is a lengthy, trial-and-error process. Second, predicting release profiles from viscosities is not straightforward, because the higher MW component often dominates the release. Third, using two or more grades in production contributes to batch-to-batch variability. A wider MW distribution or larger polydispersity index of a blend vs single component system (Figure 1) causes the release profile to be less consistent. Dissolution variability in blends is exacerbated by variations in gastrointestinal tract hydrodynamic conditions and fluid compositional factors, such as fat or bile salt content and ionic strength. Minimizing variability is of increasing importance driven by the Quality by Design (QbD) initiative.

To remedy these blending problems, Ashland has launched three intermediate-MW HPMC grades for controlled-release matrix tablets (Figure 2) - Benece K250 PH PRM HPMC, Benece K750 PH PRM HPMC and Benece K1500 PH PRM HPMC. The intermediate-MW grades of Benece HPMC provide reliability of results and eliminate the batch-to-batch variability that often results when two or more grades of HPMC are blended to provide a particular release profile. In addition, custom grades of Benece HPMC are

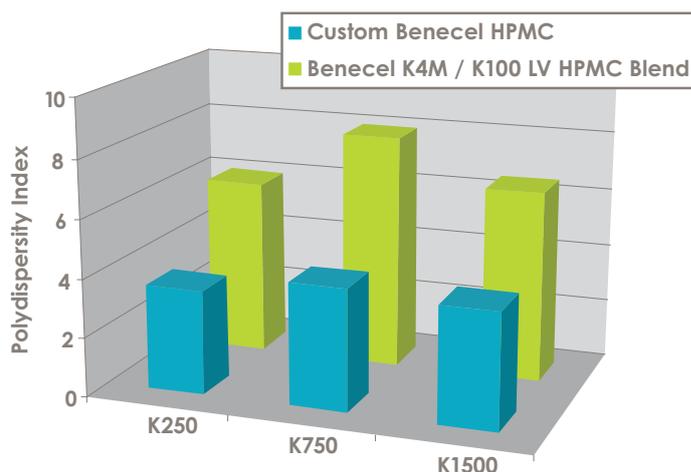
optimized for hydrophilic matrix tablets with fine, narrow particle size distributions.

Other MW grades can be commercialized depending on market requirements. Please contact your Ashland sales representative for more information.

### Features and Benefits

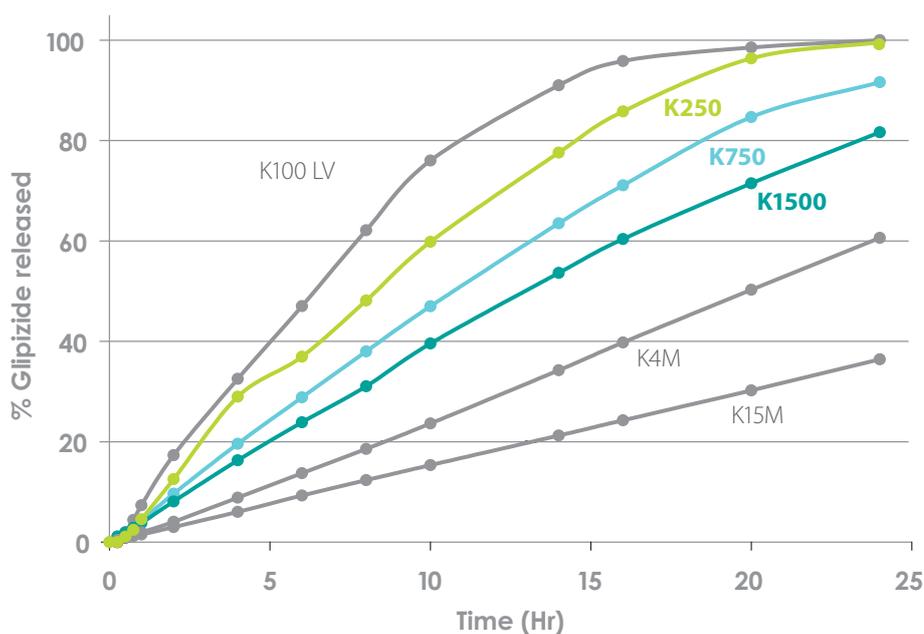
- Increase predictability and reproducibility of drug release profiles
- Decrease research and development time needed to optimize blend ratio
- Decrease manufacturing time – no need to blend and manage multiple raw materials
- Opportunity to develop custom excipients

**Figure 1. Comparison of polydispersity index (PDI) of Benece K250 PH PRM HPMC, Benece K750 PH PRM HPMC and Benece K1500 PH PRM HPMC.**





**Figure 2. Release profiles for highly soluble glipizide using various grades of hypromellose. Benecel K250 PH PRM HPMC, Benecel K750 PH PRM HPMC and Benecel K1500 PH PRM HPMC fill the gap that would otherwise require a blend of commercially available grades.**



## Always solving

We at Ashland are passionate, tenacious, solvers who thrive on developing practical, innovative, and elegant solutions to complex problems in drug delivery, always pushing the boundaries of what's possible, and advancing the competitiveness of our customers in the pharmaceutical industry.

Our people bring exceptional product knowledge, technical support and industry insights to help our customers amplify the efficacy, refine the usability, add to the allure, ensure the integrity, and improve the profitability of their pharmaceutical products and applications.

Contact us and let our team of experts help you solve your next drug delivery challenge with Benecel™ Hypromellose custom grades.

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