

BeneceTM 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.

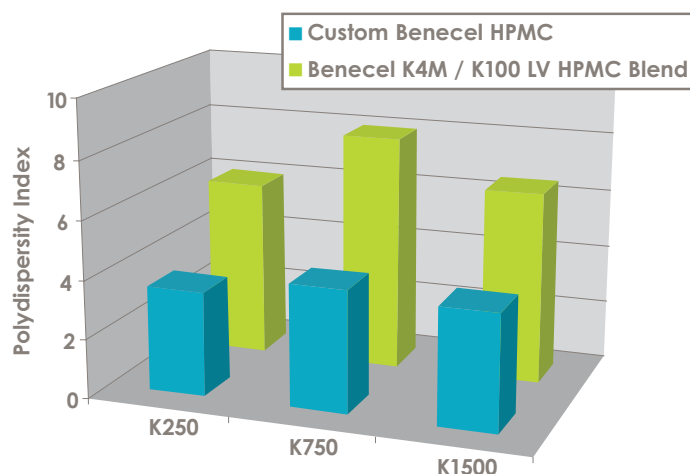
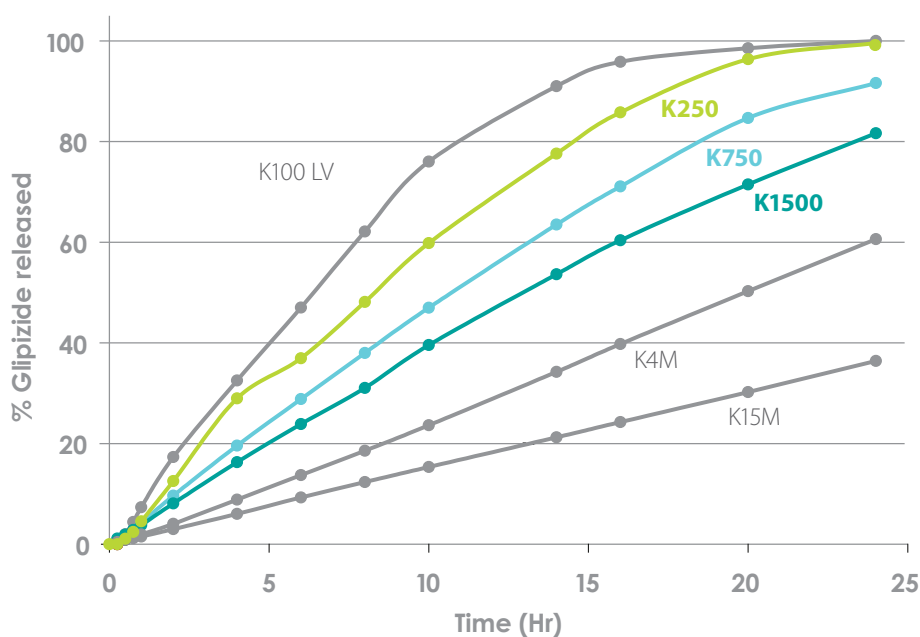




Figure 2. Release profiles for highly soluble glipizide using various grades of hypromellose. Benecel K250 PH PRM HPMC, Benecel K750 PH PRM HPMC and Benecel K1500 PH PRM HPMC fill the gap that would otherwise require a blend of commercially available grades.



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.

North America — Wilmington, DE USA
Tel: +1 877 546 2782

Europe — Switzerland
Tel: +41 52 560 55 00

India — Maharashtra
Tel: +91 22 61489696

Asia Pacific — Singapore
Tel: +65 6775 5366

Middle East, Africa — Dubai, U.A.E.
Tel: +971 4 3818515

Latin America — Mexico
Tel: +52 55 52 76 6121

ashland.com/contact

® Registered trademark, Ashland or its subsidiaries, registered in various countries

™ Trademark, Ashland or its subsidiaries, registered in various countries

© 2017, Ashland / PC-10643.8

The information contained in this brochure and the various products described are intended for use only by persons having technical skill and at their own discretion and risk after they have performed necessary technical investigations, tests and evaluations of the products and their uses. Certain end uses of these products may be regulated pursuant to rules or regulations governing medical devices, drug uses, or pesticidal or antimicrobial uses. It is the end user's responsibility to determine the applicability of such regulations to its products.

All statements, information, and data presented herein are believed to be accurate and reliable, but are not to be taken as a guarantee of fitness for a particular purpose, or representation, express or implied, for which seller assumes legal responsibility. No freedom to use any patent owned by Ashland, its subsidiaries, or its suppliers is to be inferred.

