

Klucel® hydroxypropylcellulose (HPC) provides premier performance as a tablet binder. Klucel exhibits a unique combination of thermoplasticity with organic solvent or aqueous solubility, allowing tough tablet preparation using many different formulation techniques.

Unmatched tablet hardness and friability are found with low viscosity grades of Klucel, at typical use levels of 2 to 8%, in a wide variety of processing options—

- **Wet Granulation (high or low shear or fluid bed):**

Grades EF and LF with regular particle size are often used in granulating solutions. Alternately, grade EXF or EXAF, with fine particle size, can be added dry to other ingredients, followed by granulation with water or solvent.

- **Direct Compression or Dry Granulation (roller compaction or slugging):**

Grade EXF or EXAF with fine particle size are most recommended.

Beyond unmatched tablet hardness and friability, benefits of tableting with Klucel include:

- Lower compression and ejection forces; and
- Reduction or elimination of tablet capping.

Thermoplastic Properties

The benefits of Klucel as a tough tablet binder are well known. In pure tablet compacts, the high energy absorption and ductility of Klucel is shown in Figure 1 versus other binders and fillers. (References A and B.)

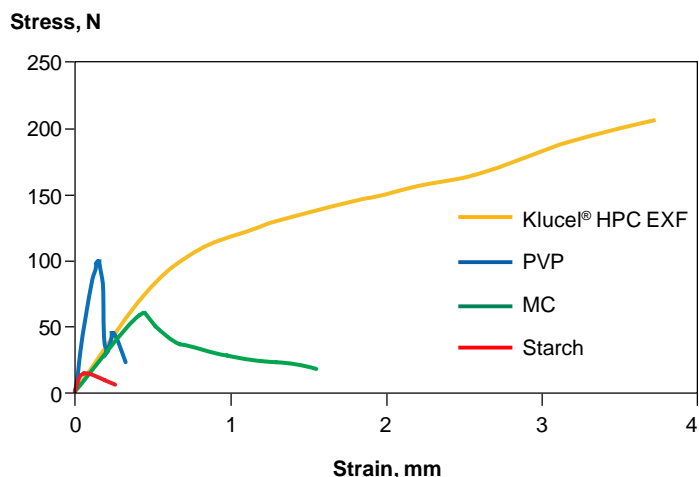


Figure 1: Pure Compacts Under Compression

High Tablet Hardness and Low Friability

The thermoplasticity of Klucel allows production of tough tablets. Figures 2 through 5 demonstrate the binder performance of Klucel in comparison studies utilizing low shear and fluid bed granulation of tablets formulated with 83.3% poorly-compressible acetaminophen. These high dose studies show Klucel can be used at lower use levels to yield superior tablets, compared to tablets with higher binders levels of HPMC, MC, PVP and pre-gelatinized starch. High-dose acetaminophen formulations using lower levels of these poorer binders were simply poor, due to capping. Aqualon has found similar comparative results with other drug compounds. (References C, D, E, and F)

Crushing Force, N

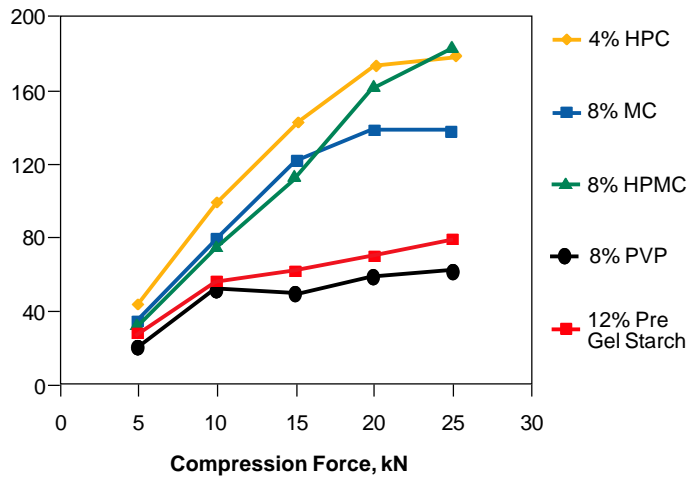


Figure 2: Low Shear Wet Granulation Tablets

Friability, %

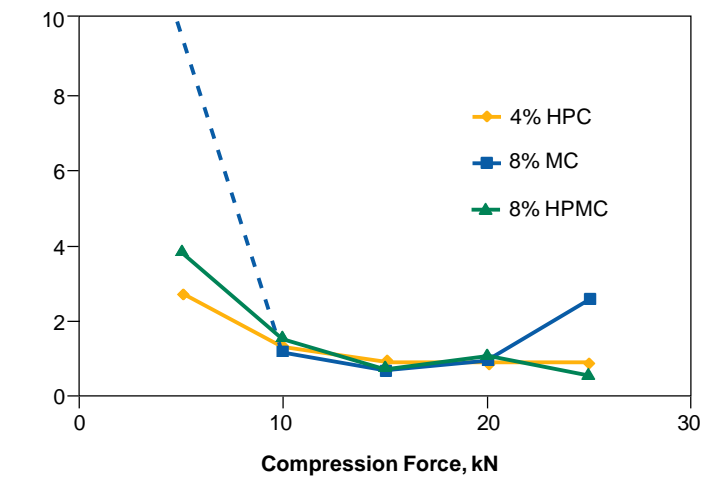


Figure 3: Low Shear Wet Granulation Tablets

80% Dissolution Time, min

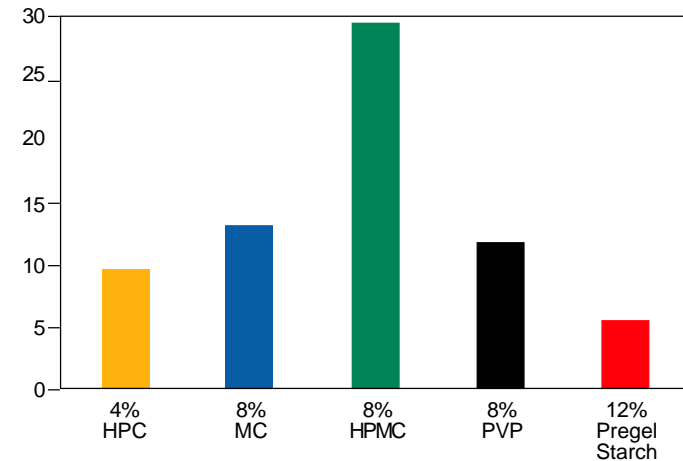


Figure 4: Low Shear Wet Granulation Tablets

Crushing Force, N

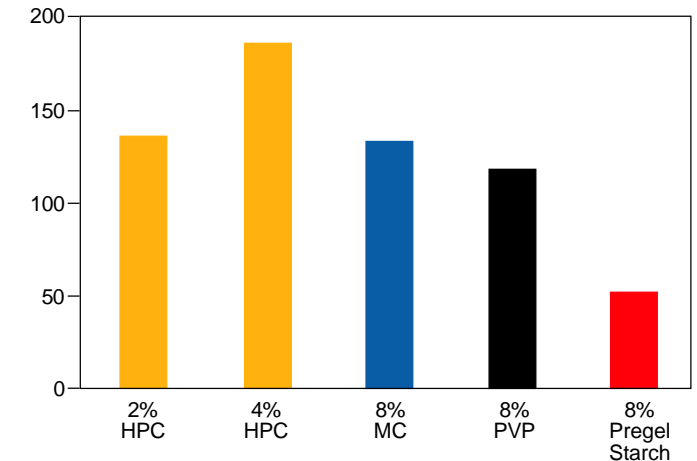


Figure 5: Fluid Bed Granulation Tablets

Lower Compression and Ejection Forces

Figure 6 demonstrates the lower ejection forces for HPC relative to PVP, measured at the tablet press. (Reference B.)

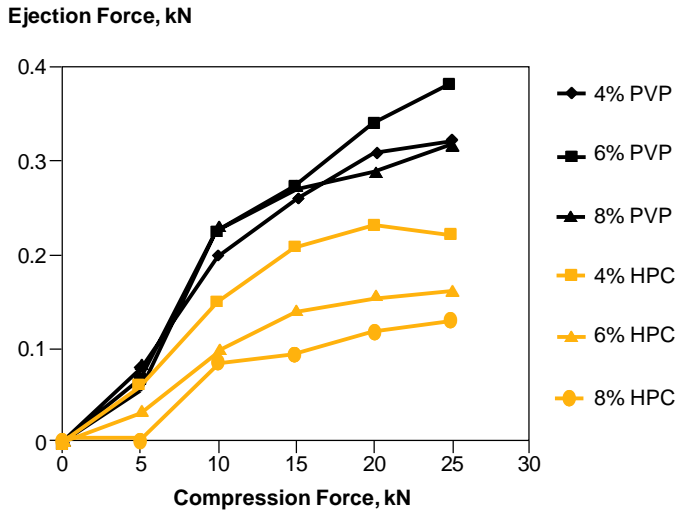


Figure 6: Fluid Bed Granulation Tablets

Selected references on tablet binding are available from this website by selecting on the direct link below or choosing the Literature link shown on the left or by contacting your regional Aqualon sales representative or office.

- Effects of Binder Toughness and Flowability on Pharmaceutical Tablet Performance* (Aqualon Pharmaceutical Technology Report PTR-15)
- Correlating the Ejection Force of Tablets with the Toughness of Binders in the Solid Dosage Forms* (Aqualon Pharmaceutical Technology Report PTR-9)
- Evaluation of Low-Viscosity Polymers in a Model High-Dose, Acetaminophen Formulation* (Aqualon Pharmaceutical Technology Report PTR-11)
- Effect of Klucel® EF and EXF Hydroxypropylcellulose as Granulating Agents in Low-Dose Hydrochlorothiazide Tablet Formulation* (Aqualon Technical Information Bulletin VC-572A)
- Validation of Tablet Dissolution Method by High Performance Liquid Chromatography* (Aqualon Pharmaceutical Technology Report PTR-6)
- An Evaluation of Fluidized Bed Granulation Methods for Preparing Tablets of a High-Dose, Poorly-Compactible Drug* (Aqualon Pharmaceutical Technology Report PTR-10)
- Lot-to-Lot Uniformity of Klucel® EXF Hydroxypropylcellulose as a Granulating Agent* (Aqualon Technical Information Bulletin VC-588A)
- Assessment of Low-Viscosity Polymers as Direct Compression Binders in a Model System* (Aqualon Pharmaceutical Technology Report PTR-5)
- G.W. Skinner et al, *Drug Dev Ind Pharm* 1999 Oct; 25(10):1121-8; *The evaluation of fine-particle hydroxypropylcellulose as a roller compaction binder in pharmaceutical applications*

The products and related information provided by Hercules are for **manufacturing purposes only**. Hercules makes no express, implied, or other representation, warranty, or guarantee concerning (i) the handling, use, or application of such products, whether alone, in combination with other products, or otherwise, (ii) the completeness, definitiveness, or adequacy of such information for users' or other purposes, (iii) the quality of such products, except that such products are of Hercules' standard quality. Users are advised to make their own tests to determine the safety and suitability of each such product or product combination for their own purposes. Read and understand the Material Safety Data Sheet (MSDS) before using this product. Hercules Incorporated does not recommend any use of its products that would violate any patent or other rights.



Hercules Incorporated
Aqualon Division
1313 North Market Street
Wilmington, DE 19894-0001
(800) 345-0447
www.aqualon.com