

Klucel™ hydroxypropylcellulose

Hydrophilic Matrix Systems

The Premier Polymer for Superior Products

Klucel hydroxypropylcellulose (HPC) has a long history of safe and effective use in pharmaceutical applications, including hydrophilic matrix tablets.

Features and Benefits

- Multiple molecular weight grades enable a wide range of drug release profiles
- Fine particle size provides rapid gel layer formation
- Non-reactive nature and high purity ensure compatibility with active ingredients and other excipients
- Unique polymer structure allows for multiple processing options: wet granulation, direct compression, roller compaction, and hot melt extrusion.
- Extensive history and safety testing allow for high use levels -up to 25 mg/kg body weight/day

Table 1: Fine Particle Pharmaceutical Grades of Klucel HPC

Grade	Weight Average Molecular Weight, kDa
EXF	80
LXF	95
JXF	140
GXF	370
MXF	850
HXF	1,150

Mechanism

When used in matrix tablets, fine particle size of grades (designated by "X") of Klucel HPC rapidly form a gel layer upon contact with water. The gel layer retards release of the active ingredient, either by diffusion or erosion. Klucel HPC levels of at least 20% ensure robust, reproducible performance.

For poorly soluble drugs, where erosion is the preferred release mechanism, low molecular weight grades of Klucel HPC are

Figure 1: Swelling and Erosion with Klucel HPC

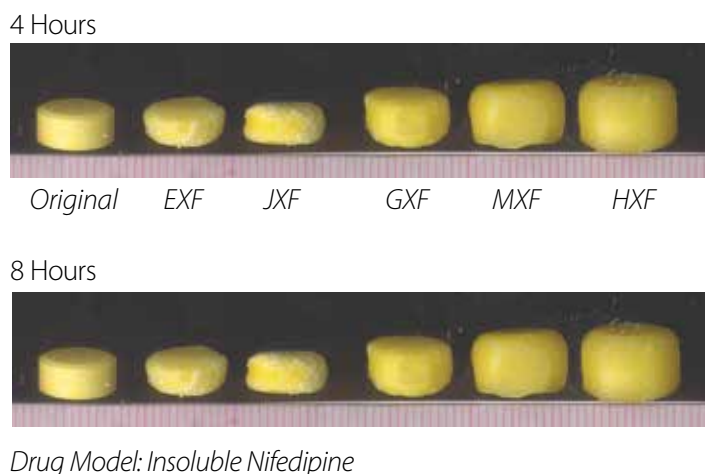
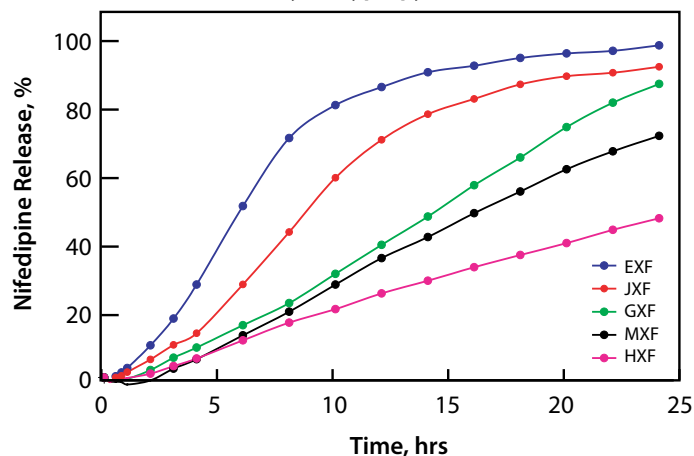


Figure 2: Control Over Release by Varying the Grade of Klucel Hydroxypropylcellulose



recommended. Higher molecular weight grades provide diffusion controlled release for highly soluble drugs. Klucel HPC grades for hydrophilic matrix systems are found in Table 1.

The effect of molecular weight on the release of insoluble nifedipine is depicted in Figure 2. Figure 1 illustrates the erosion in tablets prepared with low molecular weight Klucel HPC, and the swelling produced with higher molecular weight grades.

Global Headquarters

Ashland Inc.
50 East RiverCenter Blvd.
P.O. Box 391
Covington, KY 41012-0391 U.S.A.
Tel: +1 859 815 3333

Ashland Specialty Ingredients
8145 Blazer Drive
Wilmington, DE 19808 U.S.A.
Tel: +1 877 546 2782

Regional Centers

Europe — Switzerland
Tel: +41 52 560 55 00
Fax: +41 52 560 55 99

India — Maharashtra
Tel: +91 22 61489696
Fax: +91 22 61712514

Asia Pacific — Singapore
Tel.: +65 6775 5366
Fax: +65 6776 9690

Latin America — Mexico
Tel.: +5255 5211 0111
Fax: +5255 5212 0883

pharmaceutical@ashland.com

ashland.com/pharmaklucel

* Registered trademark, Ashland or its subsidiaries, registered in various countries
™ Trademark, Ashland or its subsidiaries, registered in various countries
© 2011, 2013, Ashland
PC-10691.1

All statements, information and data presented herein are believed to be accurate and reliable, but are not to be taken as a guarantee, an express warranty, or an implied warranty of merchantability or fitness for a particular purpose, or representation, express or implied, for which Ashland Inc. and its subsidiaries assume legal responsibility.

Please contact your Ashland Specialty Ingredients sales representative to learn more about Ashland's pharmaceutical and nutraceutical products.

Compendial Compliance

Klucel HPC meets the monograph requirements of the European Pharmacopoeia (EP), the National Formulary (NF), and the Japanese Pharmacopoeia (JP).