

TECHNICAL DATA SHEET

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2440120, 2440121 Klucel® Pharm, Hydropropylcellulose

Klucel® hydropropylcellulose (HPC) is a non ionic water-soluble cellulose ether with a versatile combination of properties. It combines organic solvent solubility, thermo plasticity, and surface activity with the thickening and stabilizing properties of other water-soluble cellulose polymers.

Properties and Uses

Klucel® HPC is soluble in many polar organic solvents and in water below 38 °C, but is insoluble in water above 45 °C. The polymer is available in a wide range of viscosity types, providing a large range of solution properties in both water and ethanol. It is thermoplastic and can be extruded. In films and coatings, Klucel® HPC is heat-sealable, and it is extremely flexible without plasticizers. The product is highly surface active, with low surface and interfacial tensions of solutions, and has a wide range of compatibility with synthetic and natural colloids.

Pharmaceutical Uses

The versatility of Klucel® HPC is apparent in a wide variety of pharmaceutical applications. Typically, low molecular weight grades provide unmatched, efficient tablet binding and adhesive and elastic tablet coating. The breadth of viscosity grades can also be used for modified release, especially in matrix tablets.

Typen

Klucel® Pharm HPC answers the need for a universally accepted single product that provide formulation and manufacturing site flexibility while reducing raw material inventory.

Typical Properties of Klucel® Pharm

Description:	off-white, flavorless powder
Particle size: Regular Grind	
- Through U.S. 30 mesh (0,59 mm)	85 %, min. ^{a)}
- Through U.S. 20 mesh (0,84 mm)	99 %, min.
Residues on ignition (as Na ₂ SO ₄)	0,2 %, max.
Loss on drying	5,0 %, max.
Substitution in moles	2,0 - 4,1
Bulk density: Softening temperature:	0,5 g/ml
Bake-out temperature in N ₂ or O ₂ :	100 - 150 °C
Heavy metals	450 - 500 °C
Lead	20 ppm
Organic volatile impurities / residual solvents	10 ppm
	Gemäß den USP/NF-Forderungen

^{a)} 80% min for Klucel® H-Types

Solutions in Water

Viscosity:	see table
pH:	5.0 - 7.5
Surface tension, 0.1 % conc.:	43.6 dynes/cm
Interfacial tension, 0.1 % Klucel®	
HPC in water vs. refined mineral oil:	12.5 dynes/cm
Specific gravity, 2 % solution at 30 °	1.010
C: Refractive index, 2 % solution:	1.337

Table 1: Viscosity* Specification of Klucel® Pharm HPC-Types, mPa.s (cps)

Pharm Types	Concentration in Water by weight			
	1	2	5	10
HF	1500 - 3000 %	---	---	---
MF	---	4000 - 6500 %	---	---
GF	---	150 - 400 %	---	---
EF	---	---	---	300 - 600 %

Pharm Typen	Concentration in Ethanol by weight			
	1	2	5	10
HF	1000 - 4000 %	---	---	---
MF	---	3000 - 6500 %	---	---
GF	---	75 - 400 %	---	---
EF	---	---	---	150 - 700 %

* Viscosities determined at 25 °C, using a Brookfield LVF viscosimeter with spindle and speed combinations depending on viscosity level. Ranges shown are not necessarily current specifications.

Regulatory Status

Klucel® Pharm HPC can be used in drug products as an excipient. Klucel Pharm HPC is available in grades that meet the requirements of the *National Formulary* (NF), the *European Pharmacopoeia* (EP), the *Japanese Pharmacopoeia* (JP) and/or the *Japanese Pharmacopoeia for Excipients* (JPE).

CAS No. 9004-64-2**CAS Name: Cellulose, 2-Hydroxypropyl ether**