Hydroxypropyl Cellulose

1 Nonproprietary Names

BP: Hydroxypropylcellulose

JP: Hydroxypropylcellulose

PhEur: Hydroxypropylcellulose

USP–NF: Hydroxypropyl Cellulose

2 Synonyms

AeroWhip; cellulose, hydroxypropyl ether; *Coatcel*; E463; HPC; hydroxypropylcellulosum; hyprolose; *Klucel*; *Nisso HPC*; oxypropylated cellulose.

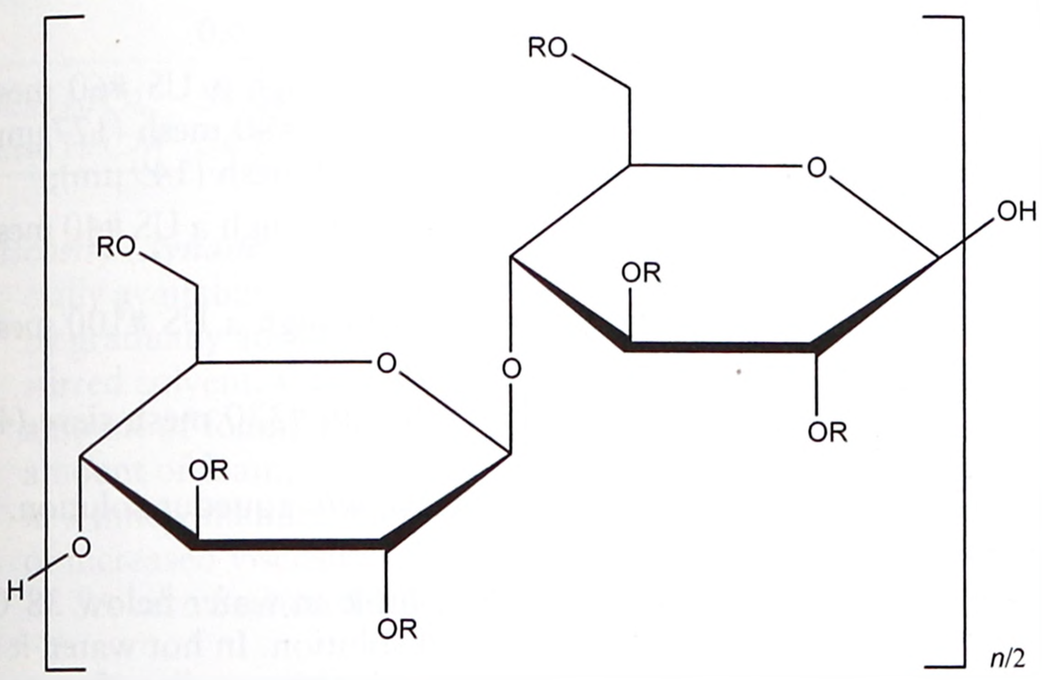
3 Chemical Name and CAS Registry Number

Cellulose, 2-hydroxypropyl ether [9004-64-2]

4 Empirical Formula and Molecular Weight

The PhEur 9.2 and USP 40–NF 35 S1 describe hydroxypropyl cellulose as a partially substituted poly(hydroxypropyl) ether of cellulose. It may contain not more than 0.6% of silica (SiO_2) or another suitable anticaking agent. Hydroxypropyl cellulose is commercially available in a number of different grades that have various solution viscosities and molecular weights; *see also* Section 10. Molecular weight is influenced by the degree of substitution. A molar substitution of 3 is achieved by complete substitution of the cellulose hydroxyl groups. The propylene oxide side chain contains a reactive hydroxyl group which may be subject to further substitution resulting in a higher degree of molar substitution.

5 Structural Formula



R is H or $[CH_2CH(CH_3)O]_mH$ where m is an integral number of hydroxypropyl units.

6 Functional Category

Coating agent; emulsifying agent; film-forming agent; modified-release agent; suspending agent; tablet and capsule binder; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Hydroxypropyl cellulose is widely used in oral and topical pharmaceutical formulations; *see* Table I.

In oral products, hydroxypropyl cellulose is primarily used in tableting as a binder,[1] film-coating,[2] and extended-release-matrix former.[3–5] Concentrations of hydroxypropyl cellulose of 2–6% w/w may be used as a binder in either wet-granulation or dry, direct-compression tableting processes.[6–10] Concentrations of 15–35% w/w of hydroxypropyl cellulose may be used to produce tablets with an extended drug release.[11] The release rate of a drug increases with decreasing viscosity of hydroxypropyl cellulose. Blends of hydroxypropyl cellulose and other cellulosic polymers have been used to improve wet granulation characteristics and tableting characteristics, as well as to achieve better control and manipulation of the rate of drug release.[12–15] As an alternative technology to wet granulation, dry granulation and direct compression of hydroxypropyl cellulose formulations have been reported to exhibit acceptable tableting and flow characteristics for application in extended-release matrix tablets.[16,17]

Solubility of hydroxypropyl cellulose in water as well as in polar organic solvents offers a wide choice in preparing solutions for casting films or for coating purposes. Typically, a 5% w/w solution of hydroxypropyl cellulose may be used to film-coat tablets. Aqueous solutions containing hydroxypropyl cellulose together with an amount of methyl cellulose or ethanolic solutions have been used.[18–22] Hydroxypropyl cellulose cast-films show excellent flexibility and heat sealability, lack tackiness, and provide barrier to oils and fats. It is not necessary to add plasticizers to cast films. In extruded films, plasticizers provide desirable die lubrication, and a reduction in melt viscosity. Plasticizer levels of 5% or less are recommended. Hydroxypropyl cellulose shows good compatibility with several plasticizers including propylene glycol, glycerine, triethylolpropane, and polyethylene glycols. Stearic acid or palmitic acids have also been used as plasticizers for hydroxypropyl cellulose especially in ethanolic solutions. Low-substituted hydroxypropyl cellulose is used as a tablet disintegrant; *see* Hydroxypropyl Cellulose, Low-substituted.

Hydroxypropyl cellulose is also used in microencapsulation processes[23] as a thickening agent. In topical formulations, hydroxypropyl cellulose is used in transdermal patches and also in ophthalmic preparations[24–27] to aid moisture retention, stabilize the tear film and lubricate the eye.[27] In addition, hydroxypropyl cellulose is used in capsule preparation by an injection molding process.[28,29]

Hydroxypropyl cellulose is also used in hot-melt extruded films for topical use. When it is produced with chlorpheniramine maleate, the matrix is stabilized, allowing film processing at lower temperatures.[30]

Mucoadhesive hydroxypropyl cellulose microspheres have been prepared for powder inhalation preparations.[31]

Table I: Typical uses of hydroxypropyl cellulose.

Use	Concentration (%)
Extended release-matrix former	15–35
Tablet binder	2–6
Tablet film coating	5

8 Description

Hydroxypropyl cellulose occurs as a white to off-white or slightly yellow-colored, odorless and tasteless powder.

9 Pharmacopeial Specifications

The pharmacopeial specifications for hydroxypropyl cellulose have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table II. *See also* Section 18.