Hypromellose

1 Nonproprietary Names

BP: Hypromellose
JP: Hypromellose
PhEur: Hypromellose
USP–NF: Hypromellose

2 Synonyms

Anycoat C; *Benecel hypromellose*; *BonuCel*; E464; *Headcel Cellulose*; HPMC; hydroxypropyl methylcellulose; 2-hydroxypropyl methyl ether cellulose; hypromellosum; *Mecellose*; *Methocel*; methylcellulose propylene glycol ether; methyl hydroxypropylcellulose; *Metolose*; MHPC; *Pharmacoat*; *Rutocel*; *Vivapharm HPMC*.

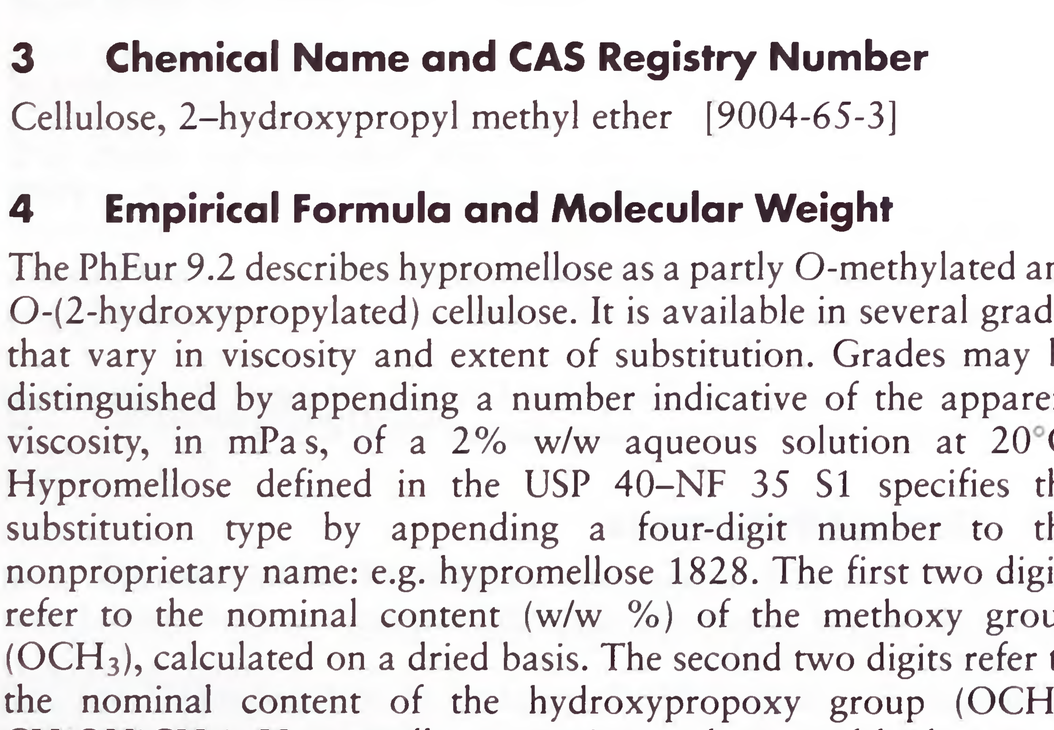
3 Chemical Name and CAS Registry Number

Cellulose, 2–hydroxypropyl methyl ether [9004-65-3]

4 Empirical Formula and Molecular Weight

The PhEur 9.2 describes hypromellose as a partly *O*-methylated and *O*-(2-hydroxypropylated) cellulose. It is available in several grades that vary in viscosity and extent of substitution. Grades may be distinguished by appending a number indicative of the apparent viscosity, in mPa s, of a 2% w/w aqueous solution at 20°C. Hypromellose defined in the USP 40–NF 35 S1 specifies the substitution type by appending a four-digit number to the nonproprietary name: e.g. hypromellose 1828. The first two digits refer to the nominal content (w/w %) of the methoxy group (OCH_3), calculated on a dried basis. The second two digits refer to the nominal content of the hydroxypropoxy group ($OCH_2CH(OH)CH_3$). Hypromellose contains methoxy and hydroxypropoxy contents conforming to the pharmacopeial limits for the various chemistries; *see* Section 9. Molecular weight ranges from approximately 10 000–1 500 000 Da.

5 Structural Formula



where R is H, CH_3, or $CH_2CH(OH)CH_3$

6 Functional Category

Capsule shell material; coating agent; dispersing agent; emulsifying agent; film-forming agent; modified-release agent; solubilizing agent; suspending agent; tablet and capsule binder; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Hypromellose is widely used in oral, ophthalmic, nasal, and topical formulations.

In oral products, hypromellose is primarily used as a tablet binder,[1] in film-coating,[2–7] and as a matrix for use in extended-release tablet formulations.[8–12] Concentrations between 2% and 5% w/w may be used as a binder in either wet- or dry-granulation processes. Hypromellose is also used in liquid oral dosage forms as a suspending and/or thickening agent at concentrations ranging from 0.25–5.0%.[13] Hypromellose 2910 and hypromellose 2208 (more commonly) are used to retard the release of drugs from monolithic matrices at levels of 10–80% w/w.

Depending upon the viscosity grade, concentrations ranging from 2% to 25% (w/w) are used for film-forming solutions to coat tablets. Lower-viscosity grades are used in aqueous film-coating solutions, while higher-viscosity grades are used with organic solvents.

Hypromellose is also used as a suspending and/or thickening agent in topical formulations. Compared with methylcellulose, hypromellose produces aqueous solutions of greater clarity and with fewer undissolved fibers present, so it is preferentially used in ophthalmic formulations. Hypromellose at concentrations between 0.45% and 1.0% (w/w) may be added as a thickening agent in eye drop and artificial tear formulations. It is also used commercially in liquid nasal formulations at a concentration of 0.1%.[13]

Hypromellose is used as an emulsifier, suspending agent, and stabilizer in topical gels and ointments. As a protective colloid, it can minimize or prevent coalescence or agglomeration of droplets or particles.

Hypromellose is used as film-forming agent in the manufacture of hard-shell capsules, as an adhesive in plastic bandages, and as a wetting agent for hard contact lenses. It is also commonly used in cosmetics and food products.

8 Description

Hypromellose is an odorless and tasteless, white or creamy-white fibrous or granular powder, hygroscopic when dry.

See also Section 10.

SEM 1: Excipient: *Methocel E5*; manufacturer: Dow Wolff Cellulosics; magnification: 200×; voltage: 3 kV.