Hypromellose Phthalate

1 Nonproprietary Names

BP: Hypromellose Phthalate

JP: Hypromellose Phthalate

PhEur: Hypromellose Phthalate

USP–NF: Hypromellose Phthalate

2 Synonyms

Cellulose phthalate hydroxypropyl methyl ether; *Deepcoat*; *HPMCP*; hydroxypropyl methylcellulose benzene-1,2-dicarboxylate; 2-hydroxypropyl methylcellulose phthalate; hypromellosi phthalas; *Mantrocel HP-55*; methylhydroxypropylcellulose phthalate.

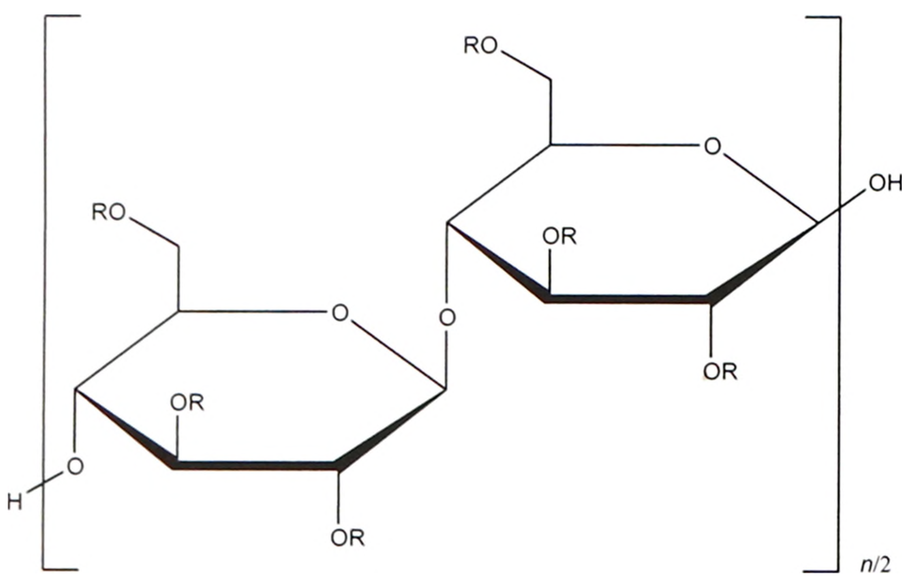
3 Chemical Name and CAS Registry Number

Cellulose, hydrogen 1,2-benzenedicarboxylate, 2-hydroxypropyl methyl ether [9050-31-1]

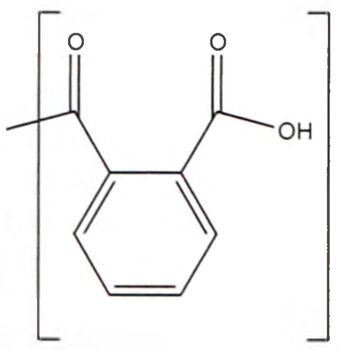
4 Empirical Formula and Molecular Weight

Hypromellose phthalate is a cellulose in which some of the hydroxyl groups are replaced with methyl ethers, 2-hydroxypropyl ethers, or phthalyl esters. Several different types of hypromellose phthalate are commercially available with molecular weights in the range 20 000–200 000. Typical average values are 80 000–130 000.[1]

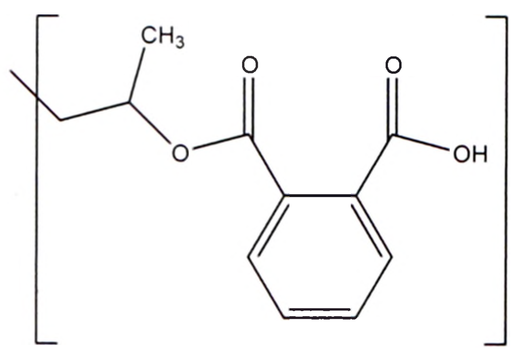
5 Structural Formula



R = H, CH_3, $CH_2CH(OH)CH_3$,



or



6 Functional Category

Coating agent.

7 Applications in Pharmaceutical Formulation or Technology

Hypromellose phthalate is widely used in oral pharmaceutical formulations as an enteric coating material for tablets or granules.[2–8] Hypromellose phthalate is insoluble in gastric fluid but will swell and dissolve rapidly in the upper intestine. Generally, concentrations of 5–10% of hypromellose phthalate are employed with the material being dissolved in either a dichloromethane-ethanol (50:50) or an ethanol-water (80:20) solvent mixture. Hypromellose phthalate can normally be applied to tablets and granules without the addition of a plasticizer or other film formers, using established coating techniques. However, the addition of a small amount of plasticizer or water can avoid film cracking problems; many commonly used plasticizers, such as diacetin, triacetin, diethyl and dibutyl phthalate, castor oil, acetyl monoglyceride, and polyethylene glycols, are compatible with hypromellose phthalate. Tablets coated with hypromellose phthalate disintegrate more rapidly than tablets coated with cellulose acetate phthalate.

Hypromellose phthalate can be applied to tablet surfaces using a dispersion of the micronized hypromellose phthalate powder in an aqueous dispersion of a suitable plasticizer such as triacetin, triethyl citrate, or diethyl tartrate together with a wetting agent.[9]

Hypromellose phthalate may be used alone or in combination with other soluble or insoluble binders in the preparation of granules with sustained drug-release properties; the release rate is pH-dependent. Since hypromellose phthalate is tasteless and insoluble in saliva, it can also be used as a coating to mask the unpleasant taste of some tablet formulations. Hypromellose phthalate has also been co-precipitated with a poorly soluble drug to improve dissolution characteristics.[10]

8 Description

Hypromellose phthalate occurs as white to slightly off-white, free-flowing flakes or as a granular powder. It is odorless or with a slightly acidic odor and has a barely detectable taste.

9 Pharmacopeial Specifications

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

See Table I. *See also* Section 18.

Table I: Pharmacopeial specifications for hypromellose phthalate.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	—	+	—
Water	≤5.0%	≤5.0%	≤5.0%
Viscosity (20°C)	+	+	+
Residue on ignition	≤0.2%	≤0.2%	≤0.2%
Chloride	≤0.07%	≤0.07%	≤0.07%
Heavy metals[a]	≤10 ppm	—	≤0.001%
Free phthalic acid	≤1.0%	≤1.0%	≤1.0%
Phthalyl content	+	21.0-35.0%	21.0–35.0%
Type 200731	27.0–35.0%	—	—
Type 220824	21.0–27.0%	—	—

(a) This test has not been fully harmonized at the time of publication.