

Hydroxyethylmethyl Cellulose

1 Nonproprietary Names

BP: Hydroxyethylmethylcellulose
PhEur: Methylhydroxyethylcellulosum

2 Synonyms

Cellulose, 2-hydroxyethyl methyl ester; *Culminal MHEC*; HEMC; hydroxyethyl methylcellulose; hmetellose; MHEC; methylhydroxyethylcellulose; *Tylopur MH*; *Tylopur MHB*; *Tylose MB*; *Tylose MH*; *Tylose MHB*.

3 Chemical Name and CAS Registry Number

Hydroxyethylmethylcellulose [9032-42-2]

4 Empirical Formula Molecular Weight

The PhEur 2002 describes hydroxyethylmethyl cellulose as a partly *O*-methylated and *O*-(2-hydroxyethylated) cellulose. Various different grades are available, which are distinguished by appending a number indicative of the apparent viscosity in millipascal seconds (mPa s) of a 2% w/v solution measured at 20°C.

5 Structural Formula

See Section 4.

6 Functional Category

Coating agent; suspending agent; tablet binder; thickening agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Hydroxyethylmethyl cellulose is used as an excipient in a wide range of pharmaceutical products, including oral tablets and suspensions and topical gel preparations.⁽¹⁾ It has similar properties to methylcellulose, but the hydroxyethyl groups make it more readily soluble in water and solutions are more tolerant of salts and have a higher coagulation temperature.

8 Description

A white, yellowish-white or greyish-white powder or granules, hygroscopic after drying.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for hydroxyethylmethyl cellulose.

Test	PhEur 2002
Identification	+
Appearance of solution	+
pH	5.5–8.0
Apparent viscosity	+
Chlorides	≤ 0.5%
Heavy metals	≤ 20 ppm
Loss on drying	≤ 10.0%
Sulfated ash	≤ 1.0%

10 Typical Properties

Acidity/alkalinity: pH = 5.5–8.0 (2% w/v aqueous solution)

Moisture content: ≤ 10%

Solubility: hydroxyethylmethyl cellulose is practically insoluble in hot water (above 60°C), acetone, ethanol, ether, and toluene. It dissolves in cold water to form a colloidal solution.

Viscosity (dynamic): 22–30 mPa s (22–30 cP) for a 2% w/v aqueous solution at 20°C.

11 Stability and Storage Conditions

Hydroxyethylmethyl cellulose is hygroscopic and should therefore be stored under dry conditions away from heat.

12 Incompatibilities

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13 Method of Manufacture

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14 Safety

Hydroxyethylmethyl cellulose is used as an excipient in various oral and topical pharmaceutical preparations and is generally regarded as an essentially nontoxic and nonirritant material.

See Hypromellose for further information.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of the material handled. Eye protection and gloves are recommended.

16 Regulatory Status

GRAS listed. Included in nonparenteral medicines licensed in Europe (oral suspensions, tablets, and topical preparations).

17 Related Substances

Ethylcellulose; hydroxyethyl cellulose; hypromellose; methylcellulose.

18 Comments

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19 Specific References

- 1 Bogdanova S. Model suspensions of indomethacin 'solvent deposited' on cellulose polymers. *Pharmazie* 2000; 55(11): 829–832.

20 General References

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21 Authors

SC Owen, PJ Sheskey.

22 Date of Revision

4 July 2002.