

## Methylcellulose (Methylcellulosum)

**Chemical name.** Cellulose methyl ether; CAS Reg. No. 9004-67-5.

**Description.** A white, yellowish white, or greyish white powder or loose, cotton-like, fibrous material; odourless.

**Solubility.** Practically insoluble in hot water, ethanol (~750 g/l) TS, ether R, and acetone R; soluble in glacial acetic acid R and in a mixture of equal volumes of ethanol (~750 g/l) TS and chloroform R.

**Category.** Coating agent; viscosity-increasing agent; tablet binder.

**Storage.** Methylcellulose should be kept in a well-closed container.

**Labelling.** The designation on the container of Methylcellulose should state its viscosity.

**Additional information.** Methylcellulose is hygroscopic after drying. In cold water it swells and produces a clear to opalescent, viscous, colloidal suspension which is neutral to litmus R.

### Requirements

**Definition.** Methylcellulose is a methyl ether of cellulose.

Methylcellulose contains not less than **26.0%** and not more than the equivalent of **32.0%** of methoxy ( $\text{-OCH}_3$ ) groups.

### Identity tests

A. While stirring, add 1 g of dried Methylcellulose to 50 mL of carbon-dioxide-free water R heated to 90 °C. Allow to cool, dilute to 100 mL with the same solvent, and stir until completely dissolved. Heat 10 mL in a water-bath while stirring (keep the remaining solution for test B); above 50 °C a cloudy solution or a flocculent precipitate is formed, and on cooling the solution becomes clear.

B. Place 1 mL of the above solution on a glass plate and allow to evaporate; a thin film is formed.

C. Dissolve without heating 0.2 g in 15 mL of sulfuric acid (~1125 g/l) TS. Pour the solution with stirring into 100 mL of ice-water, and dilute to 250 mL with ice-water. While cooling in ice-water, mix thoroughly in a test-tube 1 mL of the prepared solution with 8 mL of sulfuric acid (~1760 g/l) TS, added drop by drop. Heat in a water-bath for exactly 3 minutes and immediately cool in ice-water. While cold, carefully add 0.6 mL of triketohydrindene/sodium metabisulfite TS and mix well. Allow to stand at 25 °C; a pink colour is immediately produced, which does not change to violet within 100 minutes.

**Heavy metals.** Use 1.0 g for the preparation of the test solution as described under [2.2.3 Limit test for heavy metals](#), Procedure 3; determine the heavy metals content according to Method A; not more than 20 µg/g.

**Sulfated ash.** Not more than 10 mg/g.

**Loss on drying.** Dry to constant mass at 105 °C; it loses not more than 100 mg/g.

**Assay.** Carry out the assay as described under [2.9 Determination of methoxyl](#), using about 0.05 g, previously dried and accurately weighed.

Each mL of sodium thiosulfate (0.1 mol/l) VS is equivalent to 0.5172 mg of ( $\text{-OCH}_3$ ).