Hydroxypropylcellulose (Hydroxypropylcellulosum)

Chemical name. Cellulose 2-hydroxypropyl ether; CAS Reg. No. 9004-64-2.

Description. A white or yellowish white powder; odourless.

Solubility. Soluble in cold water, ethanol (~750 g/l) TS, methanol R, and propylene glycol R giving colloidal solutions; practically insoluble in hot water.

Category. Film-coating agent; tablet binder; granulating agent; viscosity-increasing agent; suspending agent.

Storage. Hydroxypropylcellulose should be kept in a well-closed container.

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

Additional information. Hydroxypropylcellulose is hygroscopic after drying.

Requirements

Definition. Hydroxypropylcellulose is a cellulose having some of the hydroxyl groups in the form of 2-hydroxypropyl ether.

Identity tests

A. While stirring, add 1 g of dried Hydroxypropylcellulose 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. While stirring, heat 10 mL on a water-bath (keep the remaining solution for test B and for "pH value"); above 40 °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 onto 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, add carefully 0.6 mL of triketohydrindene/sodium metabisulfite TS, mix well, and allow to stand at 25 °C; a pink colour is immediately produced, which changes 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 5.0 mg/g.

Loss on drying. Dry to constant mass at 105 °C; it loses not more than 70 mg/g.

pH value. pH of the solution prepared for identity test A, 5.0-8.5.