Hypromellose (Hypromellosum)

Chemical name. Cellulose 2-hydroxypropyl methyl ether; CAS Reg. No. 9004-65-3.

Other name. Hydroxypropylmethylcellulose.

Description. A white or creamy white, fibrous or granular powder; odourless or almost odourless.

Solubility. Soluble in cold water, forming a clear or viscous, colloidal solution; practically insoluble in ethanol (~750 g/l) TS and ether R; soluble in mixtures of methanol R and dichloromethane R.

Category. Suspending agent; tablet binder; viscosity-increasing agent.

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

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

Requirements

Definition. Hypromellose is a propylene glycol ether of methylcellulose.

Identity tests

A. Disperse 1 g of Hypromellose in 100 mL of water, allow the beaker to stand until the dispersion becomes transparent and mucilaginous (about 5 hours), swirl the beaker, and stir until completely dissolved. To two 10-mL aliquots (keep the remaining solution for test B and for "pH value") add an equal volume of either sodium hydroxide (1 mol/l) VS or hydrochloric acid (1 mol/l) VS; both mixtures remain unchanged.

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

C. Add 1 g of powdered Hypromellose to 100 mL of boiling water and stir the mixture; a slurry is formed, but the powdered material does not dissolve. Cool the slurry to 20 °C and stir; the resulting liquid is a clear or opalescent, mucilaginous colloidal mixture.

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, adding 1 mL of hydroxylamine hydrochloride (200 g/l) TS to the solution of the residue; determine the heavy metals content according to Method A; not more than 10 µg/g.

Sulfated ash. Not more than 15 mg/g.

Loss on drying. Dry at 105 °C for 2 hours; it loses not more than 50 mg/g.

pH value. pH of the solution prepared for identity test A, 5.0-8.0.