Microcrystalline cellulose (Cellulosum microcrystallinum)

Chemical name. Cellulose; CAS Reg. No. 9004-34-6.

Description. A white or almost white, fine crystalline or granular powder; odourless.

Solubility. Practically insoluble in water and most organic solvents; slightly soluble in dilute solutions of sodium hydroxide.

Category. Tablet and capsule diluent; suspending agent; disintegrant.

Storage. Microcrystalline cellulose should be kept in a well-closed container.

Additional information. Microcrystalline cellulose is usually defined by its particle size which ranges between 20 and 150 µm.

Requirements

Definition. Microcrystalline cellulose is partially depolymerized cellulose prepared from alpha cellulose.

Identity tests

A. Place 20 g on an air-jet sieve with a screen having a nominal aperture of 38 µm and shake for 5 minutes. If more than 1 g is retained on the screen, mix 30 g with 270 mL of water; otherwise, mix 45 g with 255 mL of water. Perform the mixing in a high-speed blender (18 000 rev/min) for 5 minutes. Transfer 100 mL of the mixture to a 100-mL graduated cylinder and allow to stand for 3 hours; a white, opaque, bubble-free dispersion is obtained without any supernatant liquid.

B. Dissolve 0.05 g in 10 mL of copper tetramine hydroxide TS; it dissolves completely without any residue. Add 5 mL of ethanol (~750 g/l) TS; a precipitate is produced.

Heavy metals. To 1.0 g add 4 mL of magnesium sulfate/sulfuric acid TS, mix, and heat cautiously to dryness on a water-bath. Progressively heat to ignition, not exceeding a temperature of 800 °C, and continue to heat until a white to greyish residue is obtained. Moisten the residue with 1 drop of hydrochloric acid (~250 g/l) TS and continue 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 10 µg/g.

Water-soluble substances. Shake 5 g with 80 mL of water for 10 minutes. Filter into a tared dish, evaporate to dryness on a water-bath, dry at 105 °C for 1 hour, and weigh; the residue weighs not more than 2.0 mg/g.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry for 5 hours at 105 °C; it loses not more than 60 mg/g.

pH value. Shake 2 g with 100 mL of carbon-dioxide-free water R for 5 minutes; pH of the supernatant liquid, 5.0-7.5.

Organic impurities. Place 10 mg on a watch-glass and add 0.05 mL of a freshly prepared solution of 0.1 g of phloroglucinol R in 5 mL of hydrochloric acid (~420 g/l) TS; no red colour appears.

Starch and dextrins. Shake 0.1 g with 5 mL of water and add 0.2 mL of iodine (0.05 mol/l) VS; no blue or red-brown colour develops.