

Carmellose sodium (Carmellosum natricum)

Chemical name. Cellulose carboxymethyl ether, sodium salt; CAS Reg. No. 9004-32-4.

Other name. Carboxymethylcellulose sodium.

Description. A white to faintly yellowish powder or granules; odourless.

Solubility. Easily dispersed in water giving a colloidal solution; practically insoluble in acetone R, ethanol (~750 g/l) TS, ether R, and toluene R.

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

Storage. Carmellose sodium should be kept in a tightly closed container.

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

Additional information. Carmellose sodium is hygroscopic after drying. This substance is not necessarily suitable for the manufacture of parenteral preparations.

Requirements

Definition. Carmellose sodium is the sodium salt of a partially substituted polycarboxymethyl ether of cellulose.

Carmellose sodium contains not less than **6.5%** and not more than the equivalent of **10.8%** of Na, calculated with reference to the dried substance.

Identity tests

A. Sprinkle 1.0 g of powdered Carmellose sodium onto 90 mL of carbon-dioxide-free water R at 40-50 °C, stir vigorously until a colloidal solution is produced, cool, and dilute to 100 mL with carbon-dioxide-free water R. Transfer 0.5 mL to a test-tube (keep the remaining solution for "Chlorides", "Clarity and colour of solution", and "pH value"), add 1 mL of water and 5 drops of 1-naphthol TS1, mix, and carefully introduce down the side of the tube 2 mL of sulfuric acid (~1760 g/l) TS to form a lower layer; a red-violet colour develops at the interface.

B. To the sulfated ash, add 1 mL of hydrochloric acid (~420 g/l) TS, evaporate to dryness on a water-bath, and dissolve the residue in 20 mL of water. Use 5 mL, keeping the remaining solution for "Heavy metals"; it yields reaction B described under [2.1 General identification tests](#) as characteristic of sodium.

Heavy metals. Use 12 mL of the solution remaining from identity test B and determine the heavy metals content as described under [2.2.3 Limit test for heavy metals](#), Method A; not more than 40 µg/g.

Chlorides. Use 10 mL of the solution prepared for identity test A and proceed as described under [2.2.1 Limit test for chlorides](#); the chloride content is not more than 2.5 mg/g.

Clarity and colour of solution. The solution prepared in identity test A is not more opalescent than opalescence standard TS3 and not more intensely coloured than standard colour solution Yw2 when compared as described under [1.11.1 Colour of liquids](#).

Sulfated ash. Use 1.0 g and a mixture of equal volumes of sulfuric acid (~1760 g/l) TS and water. Calculate the result with reference to the dried substance; 0.200 g/g - 0.333 g/g corresponding to a content of Na equivalent to 6.5-10.8%. (Keep the residue for identity test B.)

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

pH value. pH of the solution prepared for identity test A, 6.0-8.5.