Alginic acid (Acidum alginicum)

Chemical name. Alginic acid; CAS Reg. No. 9005-32-7.

Description. A white to yellowish white, fibrous powder; almost odourless.

Solubility. Slightly soluble in water; practically insoluble in most organic solvents; dissolves in solutions of alkali hydroxides.

Category. Tablet binder and disintegrant; viscosity-increasing agent; release-rate modifier.

Storage. Alginic acid should be kept in a well-closed container.

Additional information. Alginic acid has an equivalent mass of about 240. Attention should be paid to the microbiological quality since Alginic acid is of natural origin.

Requirements

Definition. Alginic acid is a polyuronic acid composed of D-mannuronic and L-guluronic acids and is obtained chiefly from algae belonging to the Phaeophyceae, mainly species of *Laminaria*.

Identity tests

A. Dissolve 30 mg in 5 mL of sodium hydroxide (0.1 mol/l) VS and add 1 mL of calcium chloride (55 g/l) TS; a voluminous, gelatinous precipitate is produced.

B. Dissolve 30 mg in 5 mL of sodium hydroxide (0.1 mol/l) VS and add 1 mL of sulfuric acid (~570 g/l) TS; a heavy, gelatinous precipitate is formed.

C. To 5 mg in a test-tube add 5 mL of water and 1 mL of a freshly prepared solution of naphthalene-1,3-diol R containing 1 g in 100 mL of ethanol (~750 g/l) TS. Heat the mixture to boiling, boil gently for 3 minutes, and cool to about 15 °C. Transfer the contents of the test-tube to a 30-mL separator with the aid of 5 mL of water and extract with 15 mL of diisopropyl ether R. For the blank repeat the procedure without the Alginic acid being examined. The red-violet colour produced in the extract is not darker than that obtained in the blank.

Heavy metals. For the preparation of the test solution ignite carefully in a crucible 1.0 g with 2 mL of nitric acid (~1000 g/l) TS and 5 drops of sulfuric acid (~1760 g/l) TS until white vapours evolve, then ignite completely. Cool, add 2 mL of hydrochloric acid (~420 g/l) TS, and evaporate slowly on a water-bath until dry. To the residue add 1 drop of hydrochloric acid (~420 g/l) TS and 10 mL of water, then add sufficient ammonia (~260 g/l) TS to render the solution slightly alkaline, adjust the pH to 3-4 with acetic acid (~60 g/l) TS, and dilute to 40 mL with water. Determine the heavy metals content as described under 2.2.3 Limit test for heavy metals, Method A; not more than 40 µg/g.

Ash. Carry out the procedure as described under 4.1 Determination of ash and acid-insoluble ash; not more than 40 mg/g.

Loss on drying. Dry to constant mass at 105 °C; it loses not more than 0.18 g/g.

pH value. Disperse 3 g in 100 mL of water, pH 1.5-3.5.

Acid value. Suspend about 1 g, accurately weighed, in a mixture of 50 mL of water and 30 mL of calcium acetate (0.25 mol/l) VS. Shake thoroughly, allow to stand for 1 hour, and titrate with sodium hydroxide (0.1 mol/l) VS, using phenolphthalein/ethanol TS as indicator. Repeat the procedure without the Alginic acid being examined and make any necessary corrections. Proceed with the calculation as given in 4.6 Determination of acid value, using the number of mL of sodium hydroxide (0.1 mol/l) VS required as *a* and with reference to the dried substance; not less than 230.