

Gelatin (Gelatina)

Chemical name. Gelatin; CAS Reg. No. 9000-70-8.

Description. Faintly yellow to amber-coloured sheets, flakes, granules, or powder; practically odourless; in solution it has a slight, characteristic, bouillon-like odour.

Solubility. Practically insoluble in most organic solvents. In cold water it swells and softens, absorbing 5-10 times its own mass of water. After swelling, soluble in hot water, in acetic acid (~300 g/l) TS, and in a hot mixture of glycerol R and water.

Category. Encapsulating agent; tablet binder; coating agent; suspending agent; viscosity-increasing agent.

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

Additional information. These specifications do not necessarily apply to gelatin for parenteral use or other particular application. Attention should be paid to the microbiological quality since gelatin is of natural origin.

The type of gelatin may be distinguished by the following test:

Dissolve 1 g in 100 mL of hot water. Place aliquots of 5 mL into six separate test-tubes and add 5 mL of a buffer to each tube, using buffers of pH 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0 (citrate buffer, pH 4.0, TS, phosphate buffer, pH 4.0, TS, or phthalate buffer, pH 4.0, TS; acetate buffer, pH 5.0, TS; phosphate/citrate buffer, pH 6.0, TS or acetate buffer, pH 6.0, TS; phosphate buffer, pH 7.0, TS; phosphate buffer, pH 8.0, TS or buffer borate, pH 8.0, TS; buffer borate, pH 9.0, TS). Cool the test-tubes and allow them to stand at 4 °C for 24 hours; the type of gelatin is recognized by the resulting opalescence - a maximum opalescence appearing at pH 5.0 indicates gelatin type B, while a maximum opalescence between pH 7.0 and pH 9.0 indicates gelatin type A.

Requirements

Definition. Gelatin is a purified protein obtained either by the partial acid hydrolysis (type A) or by the partial alkali hydrolysis (type B) of animal collagen. It can exist as a mixture of both types.

Identity tests

A. Dissolve 1 g in carbon-dioxide-free water R, heat to about 55 °C, and dilute to 100 mL with the same solvent. Keep the solution at this temperature throughout the following test (retain the solution for test C): to 2 mL add 0.05 mL of copper(II) sulfate (160 g/l) TS, mix, and add 0.5 mL of sodium hydroxide (~80 g/l) TS; a violet colour is produced.

B. Transfer 0.5 g to a test-tube, add 10 mL of water, and allow to stand for 10 minutes. Heat at 60 °C for 15 minutes and keep the tube in a vertical position at 0 °C for 6 hours. Invert the tube; the content does not immediately flow out.

C. Acidify 2 mL of the solution prepared for test A and add 0.5 mL of potassium dichromate (100 g/l) TS; a yellow precipitate is formed.

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 10 µg/g.

Arsenic. Use a solution of 1.0 g in a mixture of 2.5 mL of sulfuric acid (~1760 g/l) TS, 2.5 mL of nitric acid (~1000 g/l) TS, and a slight excess of bromine TS1, allow to stand for 30 minutes, and boil under a reflux condenser for 1 hour. Proceed with the test as described under [2.2.5 Limit test for arsenic](#); the arsenic content is not more than 1 µg/g.

Odour and water-insoluble substances. Dissolve 1 g in 40 mL of hot water; no disagreeable odour is perceptible. Observe the solution through a layer of 2 cm; only a slight opalescence appears.

Sulfated ash. Use 2.0 g; not more than 30 mg/g.

Loss on drying. Weigh 10 g and dry to constant mass at 105 °C; it loses not more than 150 mg/g.

Sulfur dioxide. Dissolve 20 g in 150 mL of hot water using a round-bottom flask with a long neck. Add 5 mL of phosphoric acid (~1440 g/l) TS and 1 g of sodium hydrogen carbonate R, and without delay connect the flask to a condenser. (*Note.* Excessive foaming can be reduced by adding a few drops of an antifoaming agent.) Distil 50 mL, allowing the distillate to be collected under a 50 mL surface of iodine (0.05 mol/l) VS. Acidify the distillate with a few drops of hydrochloric acid (~70 g/l) TS, add 2 mL of barium chloride (50 g/l) TS, and heat on a water-bath until the liquid is nearly colourless. If any, filter the precipitated barium sulfate, wash, ignite, and weigh. Repeat the procedure without the Gelatin being examined and make any necessary corrections. The content of barium sulfate is not more than 109.3 mg, which corresponds to not more than 1.5 mg/g of sulfur dioxide.