Kaolin (Kaolinum)

Chemical name. Kaolin; CAS Reg. No. 1332-58-7.

Other name. Bolus alba.

Description. A white or greyish white, unctuous powder, free from gritty particles; odour, clay-like.

Solubility. Practically insoluble in water and in organic solvents; insoluble in mineral acids and solutions of alkali hydroxides.

Category. Tablet and capsule diluent; suspending agent.

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

Labelling. The designation on the container of Kaolin should state whether it is intended for internal use.

Additional information. Attention should be paid to the microbiological quality, since Kaolin is of mineral origin.

Requirements

Definition. Kaolin is a purified, natural hydrated aluminium silicate, the composition of which is variable.

Identity tests

A. Boil 0.5 g with 1 g of sodium hydroxide R and 5 mL of water for 5 minutes. Dilute the mixture with sufficient water to produce 10 mL and filter. To 5 mL (keep the remaining filtrate for test B) add 0.5 g of ammonium chloride R, shake, and boil the solution; a white, gelatinous precipitate is produced.

B. To the filtrate from test A, add 1 mL of hydrochloric acid (~420 g/l) TS; an almost colourless, gelatinous precipitate is produced.

Acid-soluble substances. To 5 g add 7.5 mL of hydrochloric acid (~70 g/l) TS and 27.5 mL of water, and boil for 5 minutes. Filter, wash the residue with water, and dilute the combined filtrate and wash liquids with sufficient water to produce 50 mL. To 10 mL (keep the remaining solution for "Heavy metals") add 1.5 mL of sulfuric acid (~100 g/l) TS, evaporate to dryness on a water-bath, ignite, and weigh; the residue weighs not more than 10 mg (10 mg/g).

Heavy metals. To 5 mL of the solution prepared above add 5 mL of water, 10 mL of hydrochloric acid (~420 g/l) TS, and 25 mL of methylisobutylketone R. Shake for 2 minutes, allow to separate, and evaporate the aqueous layer to dryness on a water-bath. Dissolve the residue in 1 mL of acetic acid (~300 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 50 µg/g.

Iron. Triturate 2 g in a mortar with 10 mL of water and add 0.5 g of sodium salicylate R; not more than a slight red tint is produced.

Loss on ignition. Ignite to constant mass between 550 and 600 °C; it loses not more than 150 mg/g.

Acidity or alkalinity. To 1 g add 20 mL of carbon-dioxide-free water R, shake for 2 minutes, and filter. To 10 mL of the filtrate add 0.1 mL of phenolphthalein/ethanol TS; the solution remains colourless. Titrate with sodium hydroxide (0.01 mol/l) VS; not more than 0.25 mL is required to obtain a pink colour.

Swelling power. Triturate 2 g with 2 mL of water; the mixture does not flow.

Adsorption capacity. Transfer 1 g to a 25-mL glass stoppered tube, add 10 mL of a solution containing 0.37 g of methylthioninium chloride R in 100 mL of water, and shake vigorously for 2 minutes. Centrifuge and dilute 1 mL of the supernatant solution to 100 mL with water; the colour produced is not darker than that of a solution containing 3.0 mg of methylthioninium chloride R in 100 mL of water.

Additional requirement for Kaolin intended for internal use

Heavy metals. To 10 mL of the solution prepared under "Acid-soluble substances", add 10 mL of water, 20 mL of hydrochloric acid (~420 g/l) TS, and 25 mL of methylisobutylketone R. Shake for 2 minutes, allow to separate, and evaporate the aqueous layer to dryness on a water-bath. Dissolve the residue in 1 mL of acetic acid (~300 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 25 µg/g.