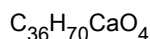


Calcium stearate (Calcii stearas)

Chemical name. Calcium stearate; calcium octadecanoate; CAS Reg. No. 1592-23-0.

Description. A white to yellowish white, fine, bulky powder; odour, slight, characteristic.

Solubility. Practically insoluble in water, ethanol (~750 g/l) TS, acetone R, and ether R.

Category. Tablet and capsule lubricant.

Storage. Calcium stearate should be kept in a well-closed container.

Additional information. The degree of lubrication depends on the particular form and size of the material.

Requirements

Definition. Calcium stearate consists of calcium salts mainly of stearic acid and palmitic acid in variable proportions.

Calcium stearate contains not less than **9.0%** and not more than the equivalent of **10.5%** of CaO, calculated with reference to the dried substance.

Identity tests

A. Heat 1 g with a mixture of 25 mL of water and 5 mL of hydrochloric acid (~420 g/l) TS; fatty acids are liberated and float as an oil on the surface of the liquid. The aqueous layer yields the reactions described under [2.1 General identification tests](#) as characteristic of calcium.

B. Mix 25 g with 200 mL of hot water, add 60 mL of sulfuric acid (~100 g/l) TS, and heat the mixture until the separated fatty acids layer is clear. Wash it with boiling water until free from sulfates, transfer it to a beaker, and warm on a water-bath until the water separates and the fatty acids are clear. Allow to cool, pour off the water layer, melt the fatty acids, and filter into a dry beaker. Dry at 105 °C for 20 minutes; congealing temperature, not lower than 54 °C.

Loss on drying. Heat at 105 °C for 2 hours and weigh; repeat the heating using 2-hour increments until a constant mass is obtained; not more than 40 mg/g.

Assay. To about 1.2 g, accurately weighed, add 50 mL of hydrochloric acid (0.1 mol/l) V, and heat to boiling for 10 minutes or until the separated fatty acids layer is clear, adding water if necessary to maintain the original volume. Cool, filter, and wash the filter and the flask thoroughly with water until the washing is free from acid when tested with litmus paper R. Neutralize the filtrate with sodium hydroxide (1 mol/l) VS against litmus paper R and proceed with the titration as described under [2.5 Complexometric titrations](#) for calcium.

Each mL of disodium edetate (0.05 mol/l) VS is equivalent to 2.804 mg of CaO.