Calcium sulfate (Calcii sulfas)

$CaSO_4,2H_2O$

Relative molecular mass. 172.2

Chemical name. Calcium sulfate (1:1) dihydrate; CAS Reg. No. 10101-41-4.

Description. A white to almost white, fine powder; odourless or almost odourless.

Solubility. Slightly soluble in water; more soluble in dilute mineral acids; practically insoluble in most organic solvents.

Category. Tablet and capsule diluent.

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

Requirements

Calcium sulfate contains not less than **98.0%** and not more than the equivalent of **101.0%** of $CaSO_4$, calculated with reference to the dried substance.

Identity tests

Dissolve 1 g in 20 mL of a solution prepared by mixing equal volumes of water and hydrochloric acid (~420 g/l) TS. Heat to boiling for 2 minutes, cool, and filter if necessary. Use this solution for the following tests:

A. The solution yields the reactions described under 2.1 General identification tests as characteristic of calcium.

B. The solution yields the reactions described under 2.1 General identification tests as characteristic of sulfates.

Heavy metals. To 1.0 g add 10 mL of water and 20 mL of hydrochloric acid (~70 g/l) TS, heat to boiling until dissolved, cool, and adjust the pH as described under 2.2.3 Limit test for heavy metals, Procedure 1; determine the heavy metals content according to Method A; not more than 20 µg/g.

Clarity of solution. Dissolve 1 g in a mixture of 45 mL of water and 5 mL of hydrochloric acid (~420 g/l) TS, heating to 50 °C for 5 minutes; the solution is clear.

Loss on drying. Dry to constant mass at a temperature not lower than 250 °C; it loses not less than 190 mg/g and not more than 230 mg/g.

pH value. Slurry 20 g with 80 mL of carbon-dioxide-free water R, allow to settle, and filter, 6.0-7.6.

Assay. To about 0.3 g, accurately weighed, add a mixture of 100 mL of water and 6 mL of hydrochloric acid (~70 g/l) TS, heat to boiling until dissolved, and allow to cool. 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 6.807 mg of $CaSO_4$.