Calamine (Calaminum)

Chemical name. Calamine; CAS Reg. No. 8011-96-9.

Description. A fine, amorphous pink or reddish brown powder; odourless.

Solubility. Practically insoluble in water; soluble with effervescence in mineral acids.

Category. Antipruritic drug.

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

Additional information. Attention should be paid to the microbiological quality since Calamine is of natural origin.

Requirements

Definition. Calamine is zinc oxide with a small proportion of ferric oxide.

Calamine contains not less than **98.0%** and not more than the equivalent of **100.5%** of ZnO, calculated with reference to the ignited substance.

Identity tests

A. Shake 1 g with 10 mL of hydrochloric acid (~70 g/l) TS and filter. To 5 mL of the filtrate add 0.3 mL of sodium hydroxide (~80 g/l) TS; a white precipitate is formed. Add a further 2 mL of sodium hydroxide (~80 g/l) TS; the precipitate dissolves. Add 10 mL of ammonium chloride (100 g/l) TS; the solution remains clear. Add 0.1 mL of sodium sulfide TS; a white, flocculent precipitate is formed.

B. To 1 g add 10 mL of hydrochloric acid (~70 g/l) TS, heat to boiling, and filter. To the filtrate add a few drops of ammonium thiocyanate (75 g/l) TS; a reddish colour is produced.

Calcium or magnesium. Digest 1 g in 25 mL of hydrochloric acid (~70 g/l) TS for 30 minutes and filter. To the filtrate, add slowly ammonia (~100 g/l) TS until the precipitate first formed redissolves, then add an excess of 5 mL of ammonia (~100 g/l) TS. To 10 mL of this solution add 2 mL of ammonium oxalate (25 g/l) TS; not more than a slight turbidity is produced. To a further 10 mL portion add 2 mL of disodium hydrogen phosphate (100 g/l) TS; not more than a slight turbidity is produced.

Lead. Dissolve 2 g in a mixture of 20 mL of water and 5 mL of glacial acetic acid R, filter, and add 0.1 mL of potassium chromate (100 g/l) TS to the filtrate; the solution remains clear for 5 minutes.

Acid-insoluble substances. Dissolve 2.0 g in 50 mL of hydrochloric acid (~70 g/l) TS, and filter. Wash the residue with water and dry to constant mass at 105 °C; the residue weighs not more than 40 mg (2.0%).

Alkaline substances. Digest 1 g with 20 mL of water and warm on a water-bath for 15 minutes. Filter and add 2 drops of phenolphthalein/ethanol TS to the filtrate; if a red colour is produced, titrate with sulfuric acid (0.05 mol/l) VS; not more than 0.2 mL of acid is required to discharge the colour.

Ethanol-soluble dyes. Shake 1 g with 10 mL of ethanol (~710 g/l) TS and filter; the filtrate is colourless.

Water-soluble dyes. Shake 1 g with 10 mL of water and filter; the filtrate is colourless.

Loss on ignition. Weigh 2.0 g and ignite at 500 °C to constant mass; it loses not more than 20 mg/g.

Assay. Add to about 1.5 g, accurately weighed, 50 mL of sulfuric acid (0.5 mol/l) VS, heat gently until no further precipitation occurs, and filter. Wash the residue with hot water until the last washing is neutral to litmus paper R. Combine the wash liquid and the filtrate, add 2.5 g of ammonium chloride R, cool, and back-titrate with sodium hydroxide (1 mol/l) VS using methyl orange/ethanol TS as indicator.

Each mL of sulfuric acid (0.5 mol/l) VS is equivalent to 40.69 mg of ZnO.