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Calcium Copperedetate Injection

General Notices

Action and use

Used in the treatment of copper deficiency.

DEFINITION

Calcium Copperedetate Injection is a sterile suspension of Calcium Copperedetate, with suitable stabilising and dispersing agents, in an oil-in-water emulsion.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of copper, Cu

92.0 to 108.0% of the stated amount.

CHARACTERISTICS

Macroscopical A blue, opaque, viscous suspension.

Microscopical When diluted with *glycerol* and examined microscopically, cubic crystals 10 to 30 µm in diameter are visible, but large plate-like crystals are absent.

IDENTIFICATION

Ignite 1 g and dissolve the residue by warming in 10 mL of a mixture of equal volumes of *hydrochloric acid* and *water*; filter if necessary. The solution complies with the following tests.

A. Neutralise 2 mL of the solution with 5M *ammonia*, and add 1 mL of 6M *acetic acid* and 2 mL of *potassium iodide solution*. A white precipitate is produced and iodine is liberated, colouring the supernatant liquid brown.
B. To 5 mL of the solution add 25 mL of a 10% v/v solution of *mercaptoacetic acid* and filter. Make the filtrate alkaline with 5M *ammonia* and add 5 mL of a 2.5% w/v solution of *ammonium oxalate*. A white precipitate is produced which is soluble in *hydrochloric acid* but only sparingly soluble in 6M *acetic acid*.

ASSAY

Evaporate a quantity containing the equivalent of 0.13 g of copper to dryness, ignite at 600° to 700°, cool and heat the residue with 5 mL of a mixture of equal volumes of *hydrochloric acid* and *water* on a water bath for 15 minutes. Add 5 mL of *water*, filter and wash the residue with about 20 mL of *water*. Combine the filtrate and the washings, add 10 mL of *bromine water*, boil to remove the bromine, cool and add *dilute sodium carbonate solution* until a faint permanent precipitate is produced. Add 3 g of *potassium iodide* and 5 mL of 6M *acetic acid* and titrate the liberated iodine with 0.1M *sodium thiosulfate VS*, using *starch mucilage* as indicator, until only a faint blue colour remains; add 2 g of *potassium thiocyanate* and continue the titration until the blue colour disappears. Each mL of 0.1M *sodium thiosulfate VS* is equivalent to 6.354 mg of Cu.

LABELLING

The strength is stated as the equivalent amount of copper in a suitable dose-volume.