



ZINCI SULFAS ZINC SULFATE

Zinc sulfate monohydrate
Zinc sulfate heptahydrate

Final text for addition to *The International Pharmacopoeia*

This monograph was adopted at the Forty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2007 for addition to the 4th edition of The International Pharmacopoeia.

ZnSO₄·H₂O (monohydrate); ZnSO₄·7H₂O (heptahydrate)

Relative molecular mass. 179.5 (monohydrate); 287.5 (heptahydrate).

Chemical name. Zinc sulfate monohydrate; CAS Reg. No. 7446-19-7 (monohydrate). Zinc sulfate heptahydrate; CAS Reg. No. 7446-20-0 (heptahydrate).

Description. A white or almost white, crystalline powder, or colourless, transparent crystals.

Solubility. Very soluble in water, practically insoluble in ethanol (~750 g/l) TS.

Category. Adjunct to oral rehydration salts in(prevention and) treatment of dehydration due to diarrhoea; astringent.

Storage. Zinc sulfate should be kept in a well-closed, non-metallic container.

Labelling. The designation on the container should state whether the substance is in the monohydrate or heptahydrate form and, where appropriate, that it is suitable for use in the manufacture of parenteral dosage forms.

Requirements

Definition. Zinc sulfate monohydrate contains not less than 99.0% and not more than 101.0% of ZnSO₄·H₂O. Zinc sulfate heptahydrate contains not less than 99.0% and not more than 104.0% of ZnSO₄·7H₂O.

Identity tests

- A. Dissolve 0.25 g in 5 ml of water R and add 0.2 ml of sodium hydroxide (400 g/l) TS. A white precipitate is formed. Add a further 2 ml of sodium hydroxide (400 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 flocculent white precipitate is formed.
- B. A 50 mg/ml solution yields the reactions described under 2.1 General identification tests as characteristic of sulfates.
- C. The test substance complies with the limits of the assay.

pH value. (1.13) pH of a 50 mg/ml solution in carbon-dioxide-free water R, 4.4-5.6.

Clarity and colour of solution. If intended for use in the manufacture of parenteral preparations, a 50 mg/ml solution in carbon-dioxide-free water R is clear and colourless.

Chlorides. Use 0.83 g in 20 ml for the preparation of the test solution as described under 2.2.1 Limit test for chlorides; not more than 300 µg/g.

Iron. Use 0.40 g for the preparation of the test solution as described under 2.2.4 Limit test for iron; not more than 100 µg/g.

Lead. Dissolve 0.25 g (or an amount of the substance equivalent to 0.25 g of ZnSO₄) in 5 ml of water R and transfer to a suitable colour comparison tube (tube A). Add 10 ml of potassium cyanide solution (100 g/l) TS, mix and allow the mixture to become clear. In a second matched tube (tube B), to 5 ml of water R add 0.5 ml of dilute lead PbTS and 10 ml of potassium cyanide solution (100 g/l) TS. Add 0.1 ml of sodium sulphide (100 g/l) TS to each tube, mix and allow to stand for 5 minutes. Compare the solutions as described under 1.11 Colour of liquids; the colour of the solution in tube A is not more intense than the solution in tube B (20µg/g).

Assay

For the monohydrate Dissolve about 80 mg, accurately weighed, in 5 ml of acetic acid (~120 g/l) TS and proceed with the titration as described under 2.5 Complexometric titrations for zinc*. Each ml of disodium edetate (0.05 mol/l) VS is equivalent to 8.975 mg of ZnSO₄·H₂O.

For the heptahydrate Dissolve about 0.13 g, accurately weighed, in 5 ml of acetic acid (~120 g/l) TS and proceed with the titration as described under 2.5 Complexometric titrations for zinc*. Each ml of disodium edetate (0.05 mol/l) VS is equivalent to 14.38 mg of ZnSO₄·7H₂O.

[*Note from the Secretariat: The general method text will be amended with respect to the description of the end-point after addition of methenamine. For "and sufficient methenamine R (about 5 g) to turn the solution red" read: "and sufficient methenamine R (about 5 g) to turn the solution pink-violet".]

New reagent

Sodium sulfide (100 g/l) TS Dissolve 1 g of sodium sulfide R in sufficient water R to produce 10 ml. Note: this solution must be freshly prepared.