

**Paediatric zinc sulfate oral solution (Zinci sulfatis liquidum peroralum paediatricum)**

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

**Storage.** Paediatric zinc sulfate oral solution should be kept in a well-closed container.

**Labelling.** The designation of the container of Paediatric zinc sulfate oral solution should state that the active ingredient is in the monohydrate form or the heptahydrate form and the quantity should be indicated in terms of the equivalent amount of elemental zinc.

**Additional information.** Available strengths: 10 mg or 20 mg of zinc per 5 mL.

**Requirements**

Complies with the monograph for [Liquid Preparations for Oral Use](#).

**Definition.** Paediatric zinc sulfate oral solution is a solution of Zinc sulfate as the monohydrate or heptahydrate in a suitable flavoured vehicle. It contains not less than 90.0% and not more than 110.0% of the amount of zinc stated on the label.

**Manufacture.** The formulation of the oral solution and the manufacturing process are designed and controlled so as to ensure that the metallic taste of the zinc salt is adequately masked.

**Identity tests**

A. To 5 mL 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. 5 mL yields reaction A described under [2.1 General identification tests](#) as characteristic of sulfates.

**pH value (1.13).** pH of the oral solution: 2.5–4.5.

**Relative density (1.3).** Relative density of the oral solution: 1.18–1.24.

**Assay**

To a quantity of the oral solution equivalent to about 10 mg of zinc, accurately measured, add 50 mL of water R and 5 mL of ammonia buffer TS and titrate with disodium edetate (0.01 mol/l) VS, using about 50 mg of Mordant Black 11 indicator mixture R as indicator, until the solution turns from violet to blue. Each mL of disodium edetate (0.01 mol/l) VS is equivalent to 0.6539 mg of zinc.