

**Paediatric zinc sulfate tablets (Zinci sulfatis compressi paediatrici)**

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

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

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

**Additional information.** Strength in the current WHO Model list of essential medicines and in the WHO Model list of essential medicines for children: 20 mg of zinc. Additional strength available: 10 mg of zinc.

**Requirements**

Comply with the monograph for [Tablets](#).

**Definition.** Paediatric zinc sulfate tablets contain Zinc sulfate monohydrate in a suitable dispersible basis that may contain suitable flavouring agents. They contain 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 tablets 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**

Prepare a solution (A) as follows: shake a quantity of the powdered tablets containing the equivalent of 100 mg of zinc with 20 mL, filter and use the clear filtrate.

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

**Disintegration**

Comply with [5.3 Disintegration test for tablets and capsules](#) operating the apparatus for 60 seconds.

**Assay**

Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 30 mg of zinc, accurately weighed, add 5 mL of acetic acid (~120 g/l), sonicate for 15 minutes and add about 50 mL water R. 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 3.27 mg of zinc.