



World Health
Organization

ZINCI SULFATIS COMPRESSI PAEDIATRICI PAEDIATRIC ZINC SULFATE TABLETS

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.

[Note from the Secretariat: The term "paediatric" has been included in the title of this monograph since these tablets are included in the 15th WHO Model list of essential medicines (EML) (March 2007) under "medicines for diarrhoea in children" (section 17.5.2) and in the same section of the 1st WHO Model list of essential medicines for children (October 2007).]

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 indicate the quantity 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: 10 mg of elemental zinc (as zinc sulfate monohydrate). Additional strength available: 20 mg of elemental zinc (as zinc sulfate monohydrate).

[Note from the Secretariat. This additional strength is given since, although not in the EMLs, it is included in the WHO/UNICEF Guidelines on Production of Zinc tablets and Zinc Oral Solution.]

Requirements

Comply with the monograph for "Tablets".

Definition. Paediatric zinc sulfate tablets contain Zinc Sulfate as the 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. For solution (A) 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. Five 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.

*[*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".]
