



**World Health  
Organization**

**PAEDIATRIC ZINC SULFATE ORAL SOLUTION**  
**Revised draft proposal for *The International Pharmacopoeia***  
**( September 2007)**

***DRAFT FOR DISCUSSION***

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**SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/07.195**

***International Pharmacopoeia monograph on Paediatric Zinc Sulfate Oral Solution***

	<b>Date</b>
Preparation of first draft by laboratory	January-February 2007
First draft mailed out for comments	end March 2007
Comments reviewed in Consultation on Specifications for Medicines and Quality Control Laboratory Issues	27-29 June 2007
Contact with laboratory concerning specific issues to be resolved	August 2007
Second draft prepared	September 2007
Presentation to WHO Expert Committee on Specifications for Pharmaceutical Preparations for possible adoption	15-19 October 2007

[*Note from the Secretariat:* Preparation of the zinc monographs was initiated because zinc supplementation is included in the revised the WHO/UNICEF recommendations for the management of diarrhoea as an adjunct to oral rehydration therapy.]

## PAEDIATRIC ZINC SULFATE ORAL SOLUTION

### Revised draft proposal for *The International Pharmacopoeia* (September 2007)

*[Note from the Secretariat:* The term "paediatric" has been included in the title of this monograph since this oral solution is included in the 15<sup>th</sup> WHO Model list of essential medicines ( March 2007) under "medicines for diarrhoea in children" (section 17.5.2).]

**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 indicate the quantity in terms of the equivalent amount of elemental zinc.

**Additional information.** Strength in the current WHO Model list of essential medicines: 10 mg of zinc (as zinc sulfate monohydrate or zinc sulfate heptahydrate) per 5 ml. Additional strength available: 20 mg of zinc (as zinc sulfate monohydrate or zinc sulfate heptahydrate) per 5 ml.

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

### 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. Five 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. Each ml of disodium edetate (0.05 mol/l) VS is equivalent to 3.27 mg of zinc.

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