
Specifications of zinc products for use in the management of diarrhoea

1. Dosage

- Each individual dose of zinc should contain 10 mg or 20 mg of elemental zinc.
- For oral solutions, the concentration of elemental zinc should be either 10 mg/5 mL or 20 mg/5 mL.
- For tablets, each tablet should contain either 10 mg or 20 mg of elemental zinc. Tablets containing 20 mg of elemental zinc should be scored.

2. Type of zinc salt

The zinc salt used to prepare oral solutions or tablets for use in the management of diarrhoea should be soluble in water. Therefore, only the following zinc salts should be used:

- Zinc sulfate
- Zinc acetate
- Zinc gluconate.

3. Type of tablets

As the zinc tablets will be used in infants and young children, it is essential that the tablets be dispersible. This means that the tablets should completely disaggregate in less than 60 seconds in 5 mL of tap water or breast milk.

4. Taste-masking

Zinc salts have a bad metallic taste that led to the use of zinc as a vomiting agent until the beginning of the twentieth century. To get infants and young children to take zinc tablets or zinc oral solution repeatedly every day for 10–14 days, it is essential that this metallic taste be totally masked.

5. Packaging

Tablets and oral solutions should be packaged to provide a full treatment of 10–14 daily doses of zinc (i.e., for oral solutions containing 20 mg/5 mL, bottles should contain 50–75 mL of oral solution; for tablets, a blister should contain 10–14 tablets).

6. Shelf life

The zinc product should have a shelf life of at least two years.