
USP monograph for zinc sulfate oral solution

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Zinc Sulfate Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labelled amount of zinc sulfate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$). It may contain one or more suitable flavours and sweeteners.

Packaging and storage: Preserve in well-closed containers protected from light, and store in a cool, dry place.

Labelling: Label the Oral Solution in terms of zinc sulfate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$) and in terms of elemental zinc.

Identification: The Oral Solution responds to the tests for *Zinc* and for *Sulfate*.

pH: Between 2.5 and 4.5.

Specific gravity: Between 1.18 and 1.24.

Residual solvents: Meets the requirements.

Assay: Transfer an accurately measured volume of Oral Solution, equivalent to about 99 mg of $\text{ZnSO}_4 \cdot \text{H}_2\text{O}$ to a 250-mL flask. Add 50 mL of water and 10 mL of ammonia–ammonium chloride buffer TS and 0.3 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a green endpoint. Each mL of 0.05 M edetate disodium is equivalent to 8.973 mg of zinc sulfate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$).