

USP monograph for zinc sulfate tablets

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Zinc Sulfate Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labelled amount of $ZnSO_4 \cdot H_2O$. It may contain one or more suitable flavours and sweeteners.

Packaging and storage: Preserve in well-closed containers, and store at controlled room temperature.

Labelling: Label the Tablets in terms of zinc sulfate ($ZnSO_4 \cdot H_2O$) and in terms of elemental zinc.

Identification:

- Test solution* — Dissolve a portion of powdered Tablets in water to obtain a solution containing about 0.05g of zinc sulfate per mL.
- Glycerine Solution* — a mixture of glycerine and water (85:15).
- Sodium Sulfide Solution* — Dissolve 12 g of sodium sulfide with heating in 45 mL of a mixture of water and glycerine solution (10:29), allow to cool, and dilute to 100 mL with the same mixture of solvents. The solution should be colourless.
- Hydrochloric Acid Solution* — Transfer 20g of hydrochloric acid to a 100-mL volumetric flask and dilute to volume with water and mix.
- Barium Chloride Solution* — Transfer 61 g of barium chloride to a 1000-mL volumetric flask, dissolve in water, and dilute to volume with the same solvent and mix.
- Sodium Hydroxide Solution* — Transfer 42 g of sodium hydroxide to a 100-mL volumetric flask, and dilute to volume with water and mix.
- Ammonium Chloride Solution* — Transfer 107 g of ammonium chloride to a 1000-mL volumetric flask, and dilute to volume with water and mix.

A: To 5 mL of the *Test solution* add 1 mL of *Hydrochloric Acid Solution* and 1 mL of *Barium Chloride Solution*. A white precipitate is formed.

B: To 5 mL of the *Test solution* add 0.2 mL of *Sodium Hydroxide Solution*. A white precipitate is formed. Add an additional 2 mL of *Sodium Hydroxide Solution*, and the precipitate dissolves. Add 10 mL of *Ammonium Chloride Solution* and the solution remains clear. Add 0.1 mL of *Sodium Sulfide Solution* and a white precipitate is formed.

Disintegration: 60 seconds.

Uniformity of dosage units: Meet the requirements.

Residual solvents: Meet the requirements.

Assay: Weigh and finely powder not fewer than 20 tablets. Transfer an accurately weighed portion of the powder, equivalent to about 90 mg of zinc, to a 200-mL volumetric flask. Dissolve in 15 mL of dilute acetic acid, and sonicate for 15 minutes. Dilute with water to volume, and mix. Add 50 mg of xylenol orange triturate to the solution, and mix. Neutralize the solution with about 2 g of methenamine until the solution is a violet-pink colour. Titrate with 0.1 M edetate disodium VS until the solution is yellow. Each mL of 0.1 M edetate disodium VS is equivalent to 17.946 mg of $\text{ZnSO}_4 \cdot \text{H}_2\text{O}$.