

Zinc Sulfate Tablets

Zinc Sulfate Tablets, USP 29 page 2293. It is proposed to replace the Dissolution test with a Disintegration test because of the performance characteristics of this product. In addition, the tests for Identification have been revised to describe the preparation of several solutions used in the procedures. It is also proposed to implement these revisions via an immediate Fourth Interim Revision Announcement, with an official date of August 1, 2006. Immediate revisions to this monograph are necessary to support the efforts by the United Nations International Children's Emergency Fund (UNICEF), the United States Agency for International Development (USAID), and the World Health Organization (WHO). Although the product is not approved by the FDA, USP is giving this monograph special consideration to support efforts by the aforementioned organizations to ensure the availability of quality public standards for the product marketed outside the United States.

» Zinc Sulfate Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $\text{ZnSO}_4 \cdot \text{H}_2\text{O}$. It may contain one or more suitable flavors and sweeteners.

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

Labeling—Label the Tablets in terms of zinc sulfate ($\text{ZnSO}_4 \cdot \text{H}_2\text{O}$) 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. .4(USP30)

Glycerin Solution—a mixture of glycerin and water (85:15).

Sodium Sulfide Solution—Dissolve 12g of sodium sulfide with heating in 45 ml of a mixture of water and glycerin solution (10:29), allow to cool and dilute to 100 ml with the same mixture of solvents. The solution should be colorless.

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 61g 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 42g of sodium hydroxide to a 100-mL volumetric flask, and dilute to volume with water and mix.

Ammonium Chloride Solution—Transfer 107g of ammonium chloride to a 1000-mL volumetric flask, and dilute to volume with water and mix. .4(USP30)

A: To 5mL of the *Test solution* add 1ml of *Hydrochloric Acid Solution* and 1ml of *Barium Chloride Solution*. A white precipitate is formed. .4(USP30)

B: To 5mL 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. .4(USP30)

Disintegration <701>— 60 seconds. .4(USP30)

Uniformity of dosage units <905>: meet the requirements.

Residual solvents <467>: meet the requirements.

(Official January 1, 2007)

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 tritrate to the solution, and mix. Neutralize the solution with about 2 g of methenamine until the solution is a violet-pink color. 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 $\text{ZnSO}_4 \cdot \text{H}_2\text{O}$. ~USP29