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Ferric Sulfate

$\text{Fe}_2(\text{SO}_4)_3 \cdot x\text{H}_2\text{O}$ (anhydrous) 399.88

Ferric persulfate.

Ferric sesquisulfate.

Ferric tersulfate CAS RN®: 10028-22-5.

Hydrate CAS RN®: 142906-29-4.

» Ferric Sulfate is hydrated $\text{Fe}_2(\text{SO}_4)_3$. It contains not less than 73.0 percent and not more than 80.0 percent of $\text{Fe}_2(\text{SO}_4)_3$.

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

Labeling—Label it to indicate that it is intended for use in compounding topical and periodontal dosage forms only.

Identification—Dissolve 0.5 g in a mixture of 50 mL of water and 3 mL of hydrochloric acid: this solution meets the requirements for the *Ferric Salts* test under [Iron \(191\)](#).

Limit of insoluble matter—Transfer 10 g in a covered beaker, and dissolve in a mixture of 100 mL of water and 5 mL of sulfuric acid. Heat to boiling, and warm on a steam bath for 1 hour. Filter the hot solution through a tared sintered-glass crucible of fine porosity. Wash the beaker and the filter with hot water, dry the crucible at 105°, cool in a desiccator, and weigh: not more than 2 mg of insoluble matter is found (0.02%).

Limit of chloride—Dissolve 1 g by warming with a mixture of 10 mL of water and 1 mL of nitric acid, add 4 mL of additional nitric acid, and dilute with water to 50 mL. To 25 mL of this solution add 1 mL of phosphoric acid and 1 mL of silver nitrate TS. Any turbidity does not exceed that produced in a control containing 0.01 mg of chloride ion (Cl), 1 mL of nitric acid, 1 mL of phosphoric acid, and 1 mL of silver nitrate TS (0.002%).

Limit of ferrous iron—Dissolve 4 g by warming with 50 mL of dilute sulfuric acid (1 in 10), cool, and titrate with 0.1 N potassium permanganate: not more than 0.16 mL is required to produce a permanent pink color (0.02% as Fe^{++}).

Change to read:

Limit of copper and zinc—

[NOTE—If the reagents used in the tests for *Copper* and *Zinc* contain excessive amounts of copper and zinc, then they should first be purified by extracting with *Dithizone Extraction Solution* (see [▲Lead \(251\), Procedures, Procedure 1▲](#) (CN 1-Jun-2023)).]

Copper—Dissolve 1.2 g in 100 mL of water. To 10 mL of this test solution add 50 mL of a solution containing 5 g of ammonium tartrate and 5 mL of ammonium hydroxide. Add 10 mL of *Standard Dithizone Solution* (see [▲Lead \(251\), Procedures, Procedure 1▲](#) (CN 1-Jun-2023)), shake for 2 minutes, draw off the dithizone layer, and compare the pink color with that in a control containing 6 µg of copper ion (Cu) and treated exactly as the 10-mL portion of test solution. If the color in the test solution is less than that in the control, then less than 0.005% of Cu and of Zn is found and the test for *Zinc* is not necessary. If the color in the test solution is more than that in the control, add 15 mL of dilute hydrochloric acid (1 in 250), and shake for 2 minutes. Draw off the dithizone solution, and shake with a second 15 mL of dilute hydrochloric acid (1 in 250) for 2 minutes. [NOTE—Draw off the dithizone, combine the two acid extracts, and reserve for the test for *Zinc*.] Any pink color in the dithizone solution is not darker than that in the control solution treated exactly as the test solution (0.005%).

Zinc—To the combined acid extracts saved from the test for *Copper*, add sufficient 0.5 M sodium acetate to bring the pH to between 5.0 and 5.5, and then add 1 mL of 0.1 N sodium thiosulfate. Add 10 mL of *Standard Dithizone Solution* (see [▲Lead \(251\), Procedures, Procedure 1▲](#) (CN 1-Jun-2023)), shake for 2 minutes, and allow the layers to separate. Draw off the dithizone layer, and discard the water layer. Any pink color in the dithizone layer is not greater than that in a control prepared by adding 0.006 mg of zinc ion (Zn) to the combined acid extracts from the control used in the test for *Copper* (0.005%).

Limit of nitrate—Dissolve 10 g in 100 mL of dilute sulfuric acid (1 in 100), heat to boiling, and pour, slowly, into a mixture of 140 mL of water and 50 mL of ammonium hydroxide. Pass through a folded filter while still hot, wash the filter with hot water until the volume of filtrate is 300 mL, mix, and cool. To 15 mL of the diluted filtrate add 1 mL of sodium chloride solution (1 in 200), 0.10 mL of indigo carmine TS, and 15 mL of sulfuric acid. The blue color is not completely discharged at the end of 5 minutes (0.01%).

Substances not precipitated by ammonia—Evaporate to dryness 30 mL of the diluted filtrate obtained in the test for *Limit of nitrate*, and ignite gently: the weight of residue does not exceed 1 mg (0.1%).

Assay—Transfer about 700 mg of Ferric Sulfate, accurately weighed, to a glass-stoppered conical flask. Add a mixture of 50 mL of water and 3 mL of hydrochloric acid, and swirl to dissolve. Add 3 g of potassium iodide, insert the stopper into the flask, and allow to stand in the dark for 30 minutes. Then add 100 mL of water, and titrate the liberated iodine with 0.1 N sodium thiosulfate VS, adding starch TS as the endpoint is approached. Each mL of 0.1 N sodium thiosulfate is equivalent to 19.994 mg of ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$].

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
FERRIC SULFATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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