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Ferrous Sulfate Tablets

DEFINITION

Ferrous Sulfate Tablets contain NLT 95.0% and NMT 110.0% of the labeled amount of ferrous sulfate heptahydrate ($FeSO_4 \cdot 7H_2O$). [NOTE—An equivalent amount of Dried Ferrous Sulfate may be used in place of $FeSO_4 \cdot 7H_2O$ in preparing Ferrous Sulfate Tablets.]

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL,** *Iron, Ferrous Salts* ⟨191⟩ and *Sulfate* ⟨191⟩

Sample solution: Equivalent to 10 mg/mL of ferrous sulfate heptahydrate from powdered Tablets in water acidified with hydrochloric acid

Acceptance criteria: Meets the requirements

ASSAY

• **PROCEDURE**

Sample: Equivalent to 500 mg of ferrous sulfate heptahydrate from finely powdered Tablets (NLT 20)

Blank: Proceed as in the *Analysis* without the *Sample*.

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N ceric sulfate VS

Indicator: Orthophenanthroline TS

Endpoint detection: Visual

Analysis: In a beaker, dissolve the *Sample* in a mixture of 20 mL of 2 N sulfuric acid and 80 mL of freshly boiled and cooled water. Filter the solution rapidly as soon as all soluble ingredients in the Tablets are dissolved, and wash the container and the filter with small portions of a mixture of 20 mL of 2 N sulfuric acid and 80 mL of freshly boiled and cooled water.

Add orthophenanthroline TS, and immediately titrate the filtrate in the suction flask with *Titrant* until the color changes. Perform a blank determination.

Calculate the percentage of the labeled amount of ferrous sulfate heptahydrate ($FeSO_4 \cdot 7H_2O$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 278.0 mg/mEq

W = nominal weight of ferrous sulfate heptahydrate in the *Sample* taken (mg)

Acceptance criteria: 95.0%–110.0%

PERFORMANCE TESTS

• **DISSOLUTION** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: Solution having a known concentration of iron in the *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 248.3 nm

Lamp: Iron hollow-cathode

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the concentration of iron (Fe) in the *Sample solution* in comparison with a *Standard solution*.

Calculate the percentage of the labeled amount of ferrous sulfate heptahydrate ($FeSO_4 \cdot 7H_2O$) dissolved:

$$\text{Result} = (M_r/A_r) \times (C \times D \times V/L) \times 100$$

M_r = molecular weight of ferrous sulfate heptahydrate, 278.02

A_r = atomic weight of iron, 55.85

C = measured concentration of iron in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of ferrous sulfate heptahydrate ($FeSO_4 \cdot 7H_2O$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label the Tablets in terms of ferrous sulfate heptahydrate ($FeSO_4 \cdot 7H_2O$) and in terms of elemental iron.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
FERROUS SULFATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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