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Ferrous Fumarate Tablets

DEFINITION

Ferrous Fumarate Tablets contain NLT 95.0% and NMT 110.0% of the labeled amount of ferrous fumarate ($C_4H_2FeO_4$).

IDENTIFICATION

• **A. Identification Tests—General ⟨191⟩, *Iron***

Sample solution: To a portion of powdered Tablets, equivalent to 1 g of ferrous fumarate, add 25 mL of dilute hydrochloric acid (1 in 2), mix, and add 25 mL of water. Boil the solution for a few min, cool, and filter.

Acceptance criteria: The filtrate meets the requirements.

ASSAY

• **Procedure**

Sample: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 500 mg of ferrous fumarate

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

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Indirect titration

Titrant: 0.1 N sodium thiosulfate VS

Indicator: Starch TS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 250-mL beaker. Add 25 mL of water, 25 mL of nitric acid, and 7.5 mL of perchloric acid. Cover with a ribbed watch glass, and heat to the production of strong fumes. Cool, rinse the watch glass and the sides of the beaker with water, and evaporate in a hood to near-dryness. Wash down the watch glass and the sides of the beaker with 2 mL of hydrochloric acid and then with a small volume of water. Warm slightly, if necessary, to dissolve the residue. Transfer to a glass-stoppered, 250-mL conical flask. Repeat the washing with 2 mL of hydrochloric acid, and complete the transfer to the flask, using NMT 20–25 mL of water for the transfer. Add 4 g of potassium iodide to the flask, insert the stopper, and allow to stand in the dark for 5 min. Add 75 mL of water and titrate with *Titrant*, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination.

Calculate the percentage of the labeled amount of ferrous fumarate ($C_4H_2FeO_4$) in the portion of Tablets taken:

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

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

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

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

F = equivalency factor, 169.9 (mg/mEq)

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

Acceptance criteria: 95.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid in 0.5% sodium lauryl sulfate; 900 mL

Apparatus 2: 75 rpm

Time: 45 min

▲[Note—Dissolution acceptance criteria may be met by using either of the *Procedures* below.]

Procedure 1▲ (USP 1-Dec-2021)

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

Flame: Air–acetylene

Analysis

Samples: *Standard solution* and *Sample solution*

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

Calculate the percentage of the labeled amount of ferrous fumarate ($C_4H_2FeO_4$) dissolved:

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

M_r = molecular weight of ferrous fumarate, 169.9

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 = labeled amount of ferrous fumarate (mg/Tablet)

▲**Procedure 2**

Sample solution: Filtered portion of the solution under test, 100.0 mL

Blank: *Medium*, 100.0 mL

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.01 N ceric ammonium sulfate VS

Indicator: Ferroin TS

Endpoint detection: Visual

Analysis

Samples: *Sample solution* and *Blank*

Add 0.1 mL of *Indicator* to the *Sample solution*, and titrate with *Titrant*. Perform the same procedure for the *Blank*.

Calculate the percentage of the labeled amount of ferrous fumarate ($C_4H_2FeO_4$) dissolved:

$$\text{Result} = [(V_S - V_B) \times N_A \times F \times V_M/V_{SS}] \times 100/L$$

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

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

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

F = equivalency factor, 169.9 (mg/mEq)

V_M = volume of *Medium*, 900 (mL)

V_{SS} = volume of the *Sample solution*, 100.0 (mL)

L = labeled amount of ferrous fumarate (mg/Tablet)▲ (USP 1-Dec-2021)

Tolerances: NLT 75% (Q) of the labeled amount of ferrous fumarate 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 fumarate ($C_4H_2FeO_4$) and in terms of elemental iron.

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

Chromatographic Database Information: Chromatographic Database

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