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Ferrous Sulfate Oral Solution

DEFINITION

Ferrous Sulfate Oral Solution contains NLT 94.0% and NMT 106.0% of the labeled amount of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$).

IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL, Iron, Ferrous Salts\(191\)](#) and [Sulfate\(191\)](#): Meets the requirements

ASSAY

• PROCEDURE

Sample: A volume of Oral Solution equivalent to 625 mg of $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ accurately measured

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: Add 25 mL of 2 N sulfuric acid and 75 mL of freshly boiled and cooled water to the *Sample*, and shake well. Then add orthophenanthroline TS, and immediately titrate with *Titrant* until the color changes. Perform a blank determination.

Calculate the percentage of the labeled amount of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$) 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 amount of ferrous sulfate heptahydrate in the *Sample* taken (mg)

Acceptance criteria: 94.0%–106.0% of the labeled amount of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$)

SPECIFIC TESTS

- [pH\(791\)](#): 1.4–5.3

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** Label the Oral Solution in terms of the content of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$) and in terms of the content of elemental iron.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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