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Ferrous Sulfate Syrup

DEFINITION
Ferrous Sulfate Syrup contains, in each 100 mL, NLT 3.75 g and NMT 4.25 g of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$), equivalent to NLT 0.75 g and NMT 0.85 g of elemental iron.
Ferrous Sulfate Syrup is prepared as follows.

Ferrous Sulfate	40 g
Citric Acid, hydrous	2.1 g
Peppermint Spirit	2 mL
Sucrose	825 g
Purified Water, a sufficient quantity to make	1000 mL

Dissolve the *Ferrous Sulfate*, *Citric Acid*, *Peppermint Spirit*, and 200 g of *Sucrose* in 450 mL of *Purified Water*, and filter the solution until clear. Dissolve the remainder of the *Sucrose* in the clear filtrate, and add *Purified Water* to make 1000 mL. Mix, and filter if necessary, through a pledget of cotton.

IDENTIFICATION
• **A.** [IDENTIFICATION TESTS—GENERAL, Iron, Ferrous Salts<191>](#) and [Sulfate<191>](#).
Sample solution: Dilute 1 mL of Syrup with water to 100 mL.
Acceptance criteria: Meets the requirements

ASSAY
• **PROCEDURE**
Sample: 25 mL of Syrup
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 15 mL of 2 N sulfuric acid and 100 mL of water to the *Sample*, and shake well. Add 3 drops of orthophenanthroline TS, and titrate with *Titrant* until the color changes. Perform a blank determination.
Calculate the amount of ferrous sulfate heptahydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$) in g per each 100 mL of Syrup:

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

- 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, 0.278 g/mEq

W = volume of Ferrous Sulfate Syrup for the *Sample* taken (mL)

Acceptance criteria: 3.75–4.25 g in each 100 mL

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label the Syrup 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 SYRUP	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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