Status: Currently Official on 13-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-937AA180-4142-4F82-BC93-A9EDA735FAFC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M3762_01_01
DOI Ref: enc0g

Ferric Ammonium Citrate for Oral Solution

» Ferric Ammonium Citrate for Oral Solution contains Ferric Ammonium Citrate and an effervescent mixture of a suitable organic acid and an alkali metal bicarbonate. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of Fe. It may contain one or more suitable flavors, colors, or stabilizing agents.

Packaging and storage—Preserve in tight, light-resistant containers, and store in a cool place.

Identification—A 6-g portion dissolves in 600 mL of water with effervescence. The collected gas meets the requirements of the test for *Bicarbonate* ⟨191⟩, and the resulting solution meets the requirements of the tests for *Iron* ⟨191⟩ and for *Citrate* ⟨191⟩.

Uniformity of dosage units ⟨905⟩—

FOR POWDER PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩—

FOR POWDER PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

Assay—Transfer about 6 g of Ferric Ammonium Citrate for Oral Solution, accurately weighed, to a 250-mL conical flask, and dissolve in 100 mL of water. Allow the gas to escape, add 5 mL of hydrochloric acid and 4 g of potassium iodide, insert the stopper, and allow to stand protected from light for 15 minutes. Add 25 mL of water, and titrate the liberated iodine with 0.1 N sodium thiosulfate VS, using starch TS as the indicator. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N sodium thiosulfate is equivalent to 5.585 mg of Fe.

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

Topic/Question	Contact	Expert Committee
FERRIC AMMONIUM CITRATE FOR ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 29(6)

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