Edition: BP 2025 (Ph. Eur. 11.6 update)

Ferrous Sulfate Heptahydrate

General Notices

Ferrous Sulphate Heptahydrate

(Ph. Eur. monograph 0083)

$FeSO_4,7H_2O$ 278.0 *7782-63-0*

Action and use

Treatment of iron-deficiency anaemia.

Preparation

Paediatric Ferrous Sulfate Oral Solution

Ph Eur

DEFINITION

Content

98.0 per cent to 105.0 per cent.

CHARACTERS

Appearance

Light green, crystalline powder or bluish-green crystals, efflorescent in air.

Solubility

Freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 per cent).

Ferrous sulfate heptahydrate is oxidised in moist air, becoming brown.

IDENTIFICATION

A. It gives the reactions of sulfates (*2.3.1*).
B. It gives reaction (a) of iron (*2.3.1*).
C. It complies with the limits of the assay.

TESTS

Solution S

Dissolve 4.0 g in a 5 per cent *V/V* solution of *lead-free nitric acid R* and dilute to 100.0 mL with the same solution.

pH (*2.2.3*)

3.0 to 4.0.

Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 20 mL with the same solvent.

Chlorides (*2.4.4*)

Maximum 200 ppm.

Dilute 5 mL of solution S to 10 mL with *water R* and add 5 mL of *dilute nitric acid R*. Prepare the standard with a mixture of 2 mL of *water R*, 5 mL of *dilute nitric acid R* and 8 mL of *chloride standard solution (5 ppm Cl) R*. Use 0.15 mL of *silver nitrate solution R2* in this test.

Elemental impurities

Any method that fulfils the requirements of general chapter *2.4.20*. *Determination of elemental impurities* may be used.

Element	Maximum content (ppm)
Chromium	50
Cobalt	25
Copper	50
Nickel	50

Ferric ions

Maximum 0.3 per cent.

In a ground-glass-stoppered flask, dissolve 5.00 g in a mixture of 10 mL of *hydrochloric acid R* and 100 mL of *carbon dioxide-free water R*. Add 3 g of *potassium iodide R*, close the flask and allow to stand in the dark for 5 min. Titrate the liberated iodine with *0.1 M sodium thiosulfate*, using 0.5 mL of *starch solution R*, added towards the end of the titration, as indicator. Carry out a blank test in the same conditions. Not more than 2.7 mL of *0.1 M sodium thiosulfate* is used, taking into account the blank titration.

Manganese

Maximum 0.1 per cent.

Atomic absorption spectrometry (*2.2.23, Method II*).

Test solution Dilute 1.0 mL of solution S to 20.0 mL with a 5 per cent *V/V* solution of *lead-free nitric acid R*.

Reference solutions Prepare the reference solutions using *manganese standard solution (1000 ppm Mn) R*, diluting with a 5 per cent *V/V* solution of *lead-free nitric acid R*.

Source Manganese hollow-cathode lamp using a transmission band preferably of 1 nm.

Wavelength 279.5 nm.

Atomisation device Air-acetylene flame.

Zinc

Maximum 50 ppm.

Atomic absorption spectrometry (*2.2.23, Method II*).

Test solution Solution S.

Reference solutions Prepare the reference solutions using *zinc standard solution (100 ppm Zn) R*, diluting with a 5 per cent *V/V* solution of *lead-free nitric acid R*.

Source Zinc hollow-cathode lamp using a transmission band preferably of 1 nm.

Wavelength 213.9 nm.

Atomisation device Air-acetylene flame.

ASSAY

Dissolve 2.5 g of *sodium hydrogen carbonate R* in a mixture of 150 mL of *water R* and 10 mL of *sulfuric acid R*. When the effervescence ceases add to the solution 0.500 g of the substance to be examined and dissolve with gentle swirling. Add 0.1 mL of *ferroin R* and titrate with *0.1 M ammonium and cerium nitrate* until the red colour disappears.

1 mL of *0.1 M ammonium and cerium nitrate* is equivalent to 27.80 mg of $FeSO_4,7H_2O$.

STORAGE

In an airtight container.

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