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

Ferrous Fumarate Tablets

General Notices

Action and use

Treatment of iron-deficiency anaemia.

DEFINITION

Ferrous Fumarate Tablets contain Ferrous Fumarate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of ferrous iron, Fe(II)

90.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Heat 1 g of the powdered tablets with 25 mL of a mixture of equal volumes of *hydrochloric acid* and *water* on a water bath for 15 minutes, cool and filter. Retain the residue for test B. The filtrate yields reaction A characteristic of *iron salts*, Appendix VI.
B. Wash the residue reserved in Test A with a mixture of 1 volume of *2M hydrochloric acid* and 9 volumes of *water* and dry at 105°. Suspend 0.1 g of the residue in 2 mL of *dilute sodium carbonate solution* and add *dilute potassium permanganate solution* drop wise. The permanganate is decolourised and a brownish solution is produced.
C. Mix a quantity of the powdered tablets containing 0.5 g of Ferrous Fumarate with 1 g of *resorcinol*. To 0.5 g of the mixture in a crucible add 0.15 mL of *sulfuric acid* and heat gently; a deep red, semi-solid mass is produced. Add the mass to a large volume of *water*; an orange–yellow solution is produced which exhibits no fluorescence.

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 75 revolutions per minute.
(b) Use 900 mL of 0.1M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

After 45 minutes withdraw a sample of 100 mL of the medium and filter. Titrate the filtrate with 0.01M *ammonium cerium(IV) sulfate VS* using *ferroin solution* as indicator.

DETERMINATION OF CONTENT

Calculate the total content of Fe(II) in the medium taking each mL of 0.01M *ammonium cerium(IV) sulfate VS* to be equivalent to 0.5585 mg of Fe(II).

Ferric iron

In a flask with a ground-glass stopper dissolve a quantity of the powder prepared for the Assay containing 1.5 g of Ferrous Fumarate in a mixture of 10 mL of *hydrochloric acid* and 100 mL of *water* by heating rapidly to boiling. Boil for 15 seconds. Cool rapidly, add 3 g of *potassium iodide*, stopper the flask and allow to stand protected from light for 15 minutes. Add 2 mL of *starch solution* as indicator. Titrate the liberated iodine with 0.1M *sodium thiosulfate VS*. Carry out a blank test. The difference between the volumes used in the two titrations corresponds to the amount of iodine liberated by ferric ion. The difference between the titrations is not more than 13.4 mL (5%).

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.3 g of Ferrous Fumarate in 7.5 mL of 1M *sulfuric acid* with gentle heating. Cool, add 25 mL of *water* and titrate immediately with 0.1M *ammonium cerium(IV) sulfate VS* using *ferroin solution* as indicator. Each mL of 0.1M *ammonium cerium(IV) sulfate VS* is equivalent to 5.585 mg of Fe(II).

LABELLING

The quantity of the active ingredient is stated both as the amount of ferrous fumarate and in terms of the equivalent amount of ferrous iron.