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Ferrous Sulfate Prolonged-release Tablets

General Notices

Ferrous Sulphate Prolonged-release Tablets

Prolonged-release Ferrous Sulfate Tablets

Ferrous Sulfate Prolonged-release Tablets from different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable unless otherwise justified and authorised.

Action and use

Treatment of iron-deficiency anaemia.

DEFINITION

Ferrous Sulfate Prolonged-release Tablets contain Dried Ferrous Sulfate. They are formulated so that the medicament is released over a period of several hours. They are coated.

PRODUCTION

A suitable dissolution test is carried out to demonstrate the appropriate release of ferrous sulfate. The dissolution profile should reflect the *in vivo* performance which in turn is compatible with the dosage schedule recommended by the manufacturer.

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

Content of ferrous iron, Fe(II)

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The powdered tablets yield reaction A characteristic of *iron salts*, Appendix VI.
B. Extract a quantity of the powdered tablets containing 0.15 g of Dried Ferrous Sulfate with 10 mL of *2M hydrochloric acid* and filter. The filtrate yields reaction A characteristic of *sulfates*, Appendix VI.

ASSAY

Weigh and powder 20 tablets. Dissolve a quantity of the powder containing 0.5 g of Dried Ferrous Sulfate as completely as possible in a mixture of 30 mL of *water* and 20 mL of 1M *sulfuric acid* and titrate 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 active ingredient is stated both as the amount of dried ferrous sulfate and in terms of the equivalent amount of ferrous iron.