# Ferrous Fumarate and Folic Acid Tablets

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

**Please send any comments you may have on this draft document to arnd-ipc@gov.in , with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**

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# Ferrous Fumarate and Folic Acid Tablets

Ferrous Fumarate and Folic Acid Tablets contain not less than 90.0 per cent and not more than 105.0 per cent of the stated amount of ferrous fumarate, $C_4H_2FeO_4$, equivalent to elemental iron and not less than 90.0 per cent and not more than 115.0 per cent of folic acid, $C_{19}H_{19}N_7O_6$.

**Usual strength**. Ferrous fumarate, 152 mg (equivalent to 50 mg of elemental iron) and 1.5 mg folic acid.

## Identification

A. In the Assay of folic acid, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

B. Heat a quantity of the powdered tablets containing 0.77 g of Ferrous Fumarate with 25 ml of a mixture of equal volumes of *hydrochloric acid* and *water* on a water bath for 15 minutes, cool and filter. Reserve the precipitate for test C; the filtrate gives reaction (A) of ferrous salts (2.3.1).

C. Wash the precipitate reserved in test B with a mixture of 1 volume of *2 M hydrochloric acid* and 9 volumes of *water* and dry at 105°. Suspend 0.1 g of the residue in 2 ml of *sodium carbonate solution* and add *potassium permanganate solution* dropwise; the permanganate is decolourised and a brownish solution is obtained.

## Tests

**Dissolution** (2.5.2).

Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*.
Speed and time. 75 rpm and 60 minutes.

Withdraw a suitable volume of the medium and filter.

*For folic acid —*

Determine by liquid chromatography (2.4.14).

*Test solution*. Use the filtrate, dilute, if necessary, with the dissolution medium, to obtain a solution having a known concentration similar to the expected concentration of the reference solution.

*Reference solution*. Dissolve 10 mg of *folic acid IPRS* in 75 ml of *methanol* with the aid of ultrasound for 15 minutes, add 125 ml of the dissolution medium, further sonicate for 15 minutes and dilute to 250.0 ml with the dissolution medium. Dilute 1.0 ml of the solution to 100.0 ml with the dissolution medium.

Chromatographic system

– a stainless steel column 15 cm × 4.6 mm, packed with base-deactivated octadecylsilane bonded to porous silica (5 µm) (such as Zorbax SB-C18),

– column temperature: 30°,

– mobile phase: A. a mixture of 900 volumes of *water*, 100 volumes of *methanol* and 1 volume of *formic acid*,

B. a mixture of 900 volumes of *methanol*, 100 volumes of *water* and 1 volume of *formic acid*,

– a gradient programme using the conditions given below,

– flow rate: 0.7 ml per minute,

– spectrophotometer set at 235 nm,

– injection volume: 300 µl.

| Time (in min.) | Mobile phase A (per cent v/v) | Mobile Phase B (per cent v/v) |
|---|---|---|
| 0 | 100 | 0 |
| 4 | 100 | 0 |
| 9.5 | 10 | 90 |
| 9.6 | 100 | 0 |
| 20 | 100 | 0 |

Inject the reference solution and the test solution.

Calculate the content of $C_{19}H_{19}N_7O_6$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{19}H_{19}N_7O_6$.

*For ferrous fumarate —*

Withdraw a suitable volume of the medium and filter.

Titrate 100 ml of the filtrate with *0.01 M ceric ammonium sulphate* using *ferroin solution* as indicator.

1 ml of *0.01 M ceric ammonium sulphate* is equivalent to 0.001699 g of $C_4H_2FeO_4$.

Q. Not less than 75 per cent of the stated amount of $C_4H_2FeO_4$.

**Ferric ion**. Not more than 5.0 per cent, determined by the following method. Dissolve 1.5 g of powdered tablets in a mixture of 100 ml of *water* and 10 ml of *hydrochloric acid* by heating rapidly to the boiling point. Boil for 15 seconds, cool rapidly, add 3 g of *potassium iodide*, stopper the flask, allow to stand in the dark for 15 minutes and titrate the liberated iodine with *0.1 M sodium thiosulphate* using *starch mucilage* as indicator. Carry out a blank titration. The difference between the titrations is not more than 13.4 ml.

**Uniformity of dosage units** (2.5.4). Complies with the test stated under Uniformity of dosage units.

**Other tests**. Comply with the tests stated under Tablets.

**Assay**.

*For ferrous fumarate —*

Weigh and powder 20 tablets. Disperse a quantity of the powder containing 0.3 g of Ferrous Fumarate in 7.5 ml of *1 M sulphuric acid* with gentle heating. Cool, add 25 ml of *water* and immediately titrate with *0.1 M ceric ammonium sulphate* using *ferroin solution* as indicator.

1 ml of *0.1 M ceric ammonium sulphate* is equivalent to 0.01699 g of $C_4H_2FeO_4$.

*For folic acid —*

Determine by liquid chromatography (2.4.14).

*Solvent mixture*. 800 volumes of a 0.57 per cent w/v solution of *dipotassium hydrogen orthophosphate* and 135 volumes of *methanol*.

*Test solution*. Weigh and powder 20 tablets. Disperse a quantity of the powdered tablets containing 7.5 mg of Folic Acid in the solvent mixture, with the aid of ultrasound for 10 minutes, shake for a further 15 minutes and dilute to 100.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture, filter.

*Reference solution*. A 0.00075 per cent w/v solution of *folic acid IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Spherisorb ODS 1),
- mobile phase: a mixture of 135 volumes of *methanol*, 800 volumes of a buffer solution containing 0.938 per cent w/v of *sodium perchlorate* and 0.075 per cent w/v of *potassium dihydrogen orthophosphate*, adjusted to pH 7.2 with *0.1 M potassium hydroxide* and dilute to 1000 volumes with *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 277 nm,
- injection volume: 20 µl.

Inject the reference solution and the test solution.

Calculate the content of $C_{19}H_{19}N_7O_6$ in the tablets.

**Storage**. Store protected from light and at a temperature not exceeding 30°.

**Labelling**. The label states the quantity of the active ingredient both as the amount of ferrous fumarate and in terms of the equivalent amount of ferrous iron.