

## Ferrous Ascorbate and Folic Acid Tablets

Ferrous Ascorbate and Folic Acid Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amounts of ferrous ascorbate,  $C_{12}H_{16}FeO_{12}$ , equivalent to elemental iron and not less than 90.0 per cent of folic acid,  $C_{19}H_{19}N_7O_6$ .

**Usual strength.** Ferrous ascorbate 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. Dissolve 100 mg of powdered tablets in 10 ml of *water*, add 1 ml of 0.05 M *sulphuric acid*, 1 ml of 2,6-dichlorophenolindophenol solution and 1 ml of dinitrophenylhydrazine solution. Mix the solutions and keep in boiling water-bath for 10 minutes. The solution gives orange-red colour.
- C. It gives reaction (A) of ferrous salts (2.3.1).

### Tests

**Uniformity of Content.** Determine by liquid chromatography (2.4.14).

*For Folic Acid -*

Determine by liquid chromatography (2.4.14) as described under Assay with the following modification.

*Test solution.* Disperse one tablet insolvent mixture 1 and dilute suitably to obtain a solution containing 0.0004 per cent w/v of folic acid in solvent mixture 2 and filter.

Inject the reference solution and the test solution.

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

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

### Assay.

*For Ferrous Iron-*

*Test solution.* Weigh and powder 20 tablets. Disperse a quantity of powder containing 75 mg of elemental iron in sufficient amount of *water*, add 8 ml of *acetic acid* and dilute to 250.0 ml with *water*. Dilute 10.0 ml the solution to 100.0 ml with *water*.

*Reference solution.* Dissolve 250 mg of *ferrous ammonium sulphate RS* in sufficient amount of *water*, add 8 ml of *acetic acid* and dilute to 100.0 ml with *water*. Dilute 10.0 ml of the solution to 100.0 ml with *water*.

Transfer 5.0 ml of the reference solution and the test solution separately into 100.0 ml volumetric flask, add 20 ml of *water* and 3.0 ml of 1,10-phenanthroline solution. Mix well and dilute to volume with *water*. Measure the absorbance after 1 hour at 515 nm (2.4.7). Calculate the content of ferrous iron.

*For Folic Acid -*

*Solvent mixture 1.* 80 volumes of 0.57 per cent w/v of *dipotassium hydrogen orthophosphate* and 13.5 volumes of *methanol*.

*Solvent mixture 2.* 90 volumes of a solution containing 1.075 per cent w/v of *sodium perchlorate monohydrate* and 0.075 per cent w/v of *dipotassium hydrogen orthophosphate* and 10 volumes of *methanol*.

*Test solution.* Weigh and powder 20 Tablets. Weigh a quantity of the powder containing 4 mg of folic acid, disperse in 180 ml of solvent mixture 1 with the aid of ultrasound and dilute to 250.0 ml with same solvent. Centrifuge the solution at 3000 RPM. Dilute 5.0 ml of the supernatant solution to 20.0 ml with the solvent mixture 2.

*Reference solution.* A 0.0175 per cent w/v solution of *folic acid RS* in solvent mixture 1. Dilute 5.0 ml of the solution to 50.0 ml with solvent mixture 1. Further dilute 5.0 ml of the solution to 20.0 ml with solvent mixture 2.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5  $\mu$ m), (Such as YMC triart)
- sampler temperature: 5 $^{\circ}$ ,
- mobile phase: a mixture of 93 volumes of a buffer solution prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water* and 7 volumes of *acetonitrile*, adjusted to pH 6.0 with 5N *sodium hydroxide*,

- flow rate: 1.5 ml per minute,
- spectrophotometer set at 283 nm,
- injection volume: 50 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and relative standard deviation for replicate injection is not more than 2.0 per cent.

Inject the reference solution and the test solution.

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

**Storage.** Store protected from moisture, at a temperature not exceeding 30°.

**Labelling.** The label states, the strength in terms of ferrous ascorbate equivalent to elemental iron and folic acid.

Draft for Comments