DEPARTMENT OF DRUG ADMINISTRATION

National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

Ferrous ascorbate & Folic acid Capsules

Analytical Profile No.: FFC 076/077/AP 076

Ferrous ascorbate & Folic acid Capsules contains not less than 90.0% and not more than 110.0% of the stated amount of Ferrous ascorbate and not less than 90.0% of the stated amount of Folic acid.

1. Identification:

1.1 Iron

Weigh accurately a quantity of powder containing 100mg of elemental iron and transfer into 100ml volumetric flask, add 10ml distilled water, shake well and add 5ml of 1M sulfuric acid with shaking, make up to the mark with distilled water, stir about 5minutes in magnetic stirrer and filter, dilute 10ml to 100ml with distilled water. Pipette 10ml of this solution in 100ml volumetric flask, add 5ml of 20% citric acid, 5ml 10% thioglycolic acid and 5ml ammonia solution gives reddish brown color.

1.2 Folic acid

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Uniformity of content (Folic acid)

Determine by liquid chromatography, as described in the Assay, using the following test solution and reference solution.

2.1 Test solution: Shake 1 capsule with 5.0ml of 0.1M sodium hydroxide, add sufficient mobile phase to make volume up to 100ml, centrifuge and use the supernatant liquid.

2.2 Reference Solution: Add 100ml of 0.5M hydrochloric acid to 5.0ml of 0.002% w/v solution of folic acid WS in 0.1M sodium hydroxide and dilute to 10.0ml with mobile phase.

3. Assay

3.1Folic Acid

3.1.1 Test Solution: Weigh accurately a quantity of powder sample equivalent to 10mg of folic acid in 100ml volumetric flask and dissolve with 0.1M sodium hydroxide and make up the volume to the mark with same solvent. Centrifuge and dilute 5ml of this solution to 50ml with mobile phase.

3.1.2 Reference Solution: Dilute 5.0ml of a 0.02% w/v solution of folic acid WS in 0.1M sodium hydroxide to 100.0ml with mobile phase.

3.1.3 Chromatographic system

- **Column:** C18, 250mm x 4.6 mm, 5 µm
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 283 nm
- **Injection volume:** 20 µl
- **Detector:** UV
- **Mobile Phase:** a mixture of 93 volumes of 0.05M potassium dihydrogen phosphate and 7 volumes of acetonitrile adjusted to pH 6.0 with 5M sodium hydroxide

3.1.4 Procedure: Inject the reference solution five times and sample solutions. 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 the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak responses. Calculate the content of folic acid in the capsules.

3.2 Ferrous ascorbate equivalent to elemental iron

3.2.1 Test Solution: Weigh powder eq. to 200mg of ferrous ascorbate and transfer to 100ml volumetric flask, add 10ml distilled water, shake well and add 5ml of 1M sulfuric acid with shaking dilute up to the amrk with distilled water, stir about 5 minute in magnetic stirrer and filter. Dilute 10ml of this solution to 100ml with distilled

3.2.2 Reference Solution: Weigh accurately about a quantity 200mg of ferrous ascorbate WS and transfer to 100ml volumetric flask, add 10ml distilled water, shake well and add 5ml of 1M sulfuric acid with shaking dilute up to the mark with distilled water. Dilute 10ml to 100ml with distilled water.

3.2.3 Procedure: Pipette 10 ml of the test and reference solution to 100ml volumetric flask, add 5ml 20% citric acid, 5ml 10% thioglycolic acid and 5ml ammonia solution and dilute up to the mark with distilled water. Measure the absorbance of the solution at 540 nm by using distilled water as a blank. Calculate the content of Iron in the capsules by comparision.

4. Other tests: As per pharmacopoeial requirements.