Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical profile of Folic acid & Ferrous ascorbate Tablets

Analytical Profile No.: FFT 074/075/ AP 022

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

1. Identification:

1.1. Folic acid

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference solution.

1.2 Ferrous Ascorbate

Dissolve a quantity of the powdered tablets containing 10 mg of Iron in 2 ml of water, add 1 ml of potassium ferricyanide solution; a blue precipitate is formed that does not dissolve on addition of 5 ml of dilute hydrochloric acid.

2. Uniformity of content (Folic acid)

2.1 Solvent mixture: 80 volumes of 0.57 % w/v solution of dipotassium hydrogen orthophosphate and 13.5 volumes of methanol.

2.2 Test Solution: Weigh individually 10 tablets. Transfer one tablet individually into ten 100 ml amber volumetric flask. Disperse the tablet with solvent mixture, add about 70 ml of solvent mixture, sonicate for about 15 minutes and make up the volume to 100 ml with solvent mixture. Centrifuge the resulting solution and dilute 2 ml of the solution to 20 ml with solvent mixture.

2.3 Reference Solution: Weigh accurately about 25 mg of folic acid RS and transfer into 100 ml amber volumetric flask. Dissolve with solvent mixture and make up the volume to 100 ml with solvent mixture. Dilute 5 ml of the resulting solution to 50 ml with solvent mixture. Again dilute 5 ml of the resulting solution to 100 ml with solvent mixture.

2.4 Chromatographic system

Column: Octyldecylsilane (C18), (250*4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 277 nm

Injection volume: 50 µl

Oven temperature: Ambient

Mobile Phase: A mixture of 135 volumes of methanol and 800 volumes of buffer and pH adjusted to 7.2 and adjust the volume to 1000 ml with HPLC grade water.

Buffer: Solution containing 0.938 % w/v of sodium perchlorate and 00075 % w/v of potassium dihydrogen orthophosphate.

2.5 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, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of folic acid.

3. Assay

3.1 Folic acid

Determine the assay of folic acid from the average of the uniformity of content of the 10 tablets.

3.2 Ferrous ascorbate equivalent to elemental iron

3.2.1 Test Solution: Weigh 20 tablets **i**ndividually and crush the tablet in the fine powder. Weigh powder eq. to 100 mg of elemental iron and transfer into 100 ml volumetric flask. Add about10 ml of dilute sulphuric acid and heat in water bath until dissolves. Cool and make up the volume to 100 ml with water. Filter the solution and dilute 2 ml of the resulting solution to 50 ml with water.

3.2.2 Reference Solution: Weigh accurately about 100 mg of ferrous ascorbate RS and transfer in 100 ml of volumetric flask. Dissolve in 10 ml of dilute sulphuric acid and heat in water bath until it dissolves. Cool and make up the volume to 100 ml with water. Dilute 5 ml of the filtrate to 50 ml with water.

3.2.3 Procedure: Pipette 5 ml of the test solution and reference solution, add 2 ml of 0.1 % w/v sodium acetate solution, 4 ml of 0.25 % w/v hydroquinone solution and add 4 ml of 0.25 % w/v of 1, 10 phenanthroline, allow to stand for 1 hour. Prepare blank in the similar manner except sample solution. Make up the volume to 50 ml with water. Measure the absorbance of the solution at 515 nm.

4. Other tests: As per pharmacopoeial requirements.