

## Folic Acid Tablets

Folic Acid Tablets contain not less than 90.0 percent and not more than 115.0 percent of the labeled amount of folic acid ( $C_{19}H_{19}N_7O_6$ ).

**Packaging and storage**— Preserve in well-closed containers.

**Identification**— Digest a quantity of powdered Tablets, equivalent to about 100 mg of folic acid, with 100 mL of sodium hydroxide solution (1 in 250), and filter. Proceed as directed in the Identification test under [Folic Acid Injection](#), beginning with “Adjust with hydrochloric acid to a pH of 3.0.”

[Dissolution](#) [711](#) —

Medium: water; 500 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

**Procedure**— Determine the amount of  $C_{19}H_{19}N_7O_6$  dissolved, employing the procedure set forth in the Assay, making any necessary modifications.

Tolerances— Not less than 75% (Q) of the labeled amount of  $C_{19}H_{19}N_7O_6$  is dissolved in 45 minutes.

[Uniformity of dosage units](#) [905](#) : meet the requirements.

**Assay**—

Mobile phase— Transfer 35.1 g of sodium perchlorate and 1.40 g of monobasic potassium phosphate, accurately weighed, to a 1-L volumetric flask, add 7.0 mL of 1 N potassium hydroxide and 40 mL of methanol, dilute with water to volume, and mix. Adjust with 1 N potassium hydroxide or phosphoric acid to a pH of 7.2. Make adjustments if necessary

**System suitability solution**— Prepare a solution containing about 0.2 mg per mL each of [USP Folic Acid RS](#) and [USP Folic Acid Related Compound A RS](#) in an aqueous solvent containing 2 mL of ammonium hydroxide and 1 g of sodium perchlorate per 100 mL. Before use, pass through a filter having a 1- $\mu$ m or finer porosity.

**Standard preparation**— Accurately weigh about 30 mg of [USP Folic Acid RS](#), corrected for water content, and dissolve in an aqueous solvent containing 2 mL of ammonium hydroxide and 1

g of sodium perchlorate per 100 mL. Using the same solvent, adjust the volume quantitatively to obtain a solution having a known concentration of about 0.20 mg per mL.

Assay preparation— Weigh and finely powder not fewer than 20 Tablets. Transfer a portion of the powder, accurately weighed and equivalent to about 10 mg of folic acid, to a 50-mL volumetric flask with the aid of an aqueous solvent containing 2 mL of ammonium hydroxide and 1 g of sodium perchlorate per 100 mL. Shake gently until the folic acid has dissolved, dilute with the same solvent to volume, mix, and pass through a dry filter, discarding the first portion of the filtrate.

Chromatographic system— The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute.

Chromatograph the System suitability solution and the Standard preparation, and record the peak responses as directed for Procedure: the resolution, R, between folic acid related compound A (calcium formyltetrahydrofolate) and folic acid is not less than 3.6; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 25 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of folic acid (C<sub>19</sub>H<sub>19</sub>N<sub>7</sub>O<sub>6</sub>) in the portion of Tablets taken by the formula:

$$(CV)(rU / rS)$$

in which C is the concentration, in mg per mL, of [USP Folic Acid RS](#) in the Standard preparation; V is the volume, in mL, of the Assay preparation; and rU and rS are the peak responses obtained from the Assay preparation and the Standard preparation, respectively.