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Folic Acid Injection

» Folic Acid Injection is a sterile solution of Folic Acid in Water for Injection prepared with the aid of Sodium Hydroxide or Sodium Carbonate. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of folic acid (C₁₉H₁₉N₇O₆).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

Change to read:

USP REFERENCE STANDARDS (11).—

[USP Folic Acid RS](#)

▲ ▲ (ERR 1-Aug-2018)

Identification—To a volume of the Injection equivalent to about 100 mg of folic acid add water to make about 25 mL. Adjust with hydrochloric acid to a pH of 3.0, cool to 5°, then filter, and wash the precipitate of folic acid with cold water until the last washing shows an absence of chloride. Then wash with acetone, and dry at 80° for 1 hour: the UV absorption spectrum of a 1 in 100,000 solution of the folic acid so obtained in sodium hydroxide solution (1 in 250) exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Folic Acid RS](#), concomitantly measured. The ratio A_{256}/A_{365} is between 2.80 and 3.00.

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 357.1 USP Endotoxin Units per mg of folic acid.

pH (791): between 8.0 and 11.0.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Mobile phase, System suitability solution, Standard preparation, and Chromatographic system—Proceed as directed in the [Assay](#) under [Folic Acid Tablets](#).

Assay preparation—Dilute an accurately measured volume of Injection, quantitatively and stepwise, with an aqueous solvent containing 2 mL of ammonium hydroxide and 1 g of sodium perchlorate per 100 mL, to obtain a solution having a concentration close to that of the *Standard preparation* and between 0.20 and 0.80 mg per mL.

Procedure—Proceed as directed in the Assay under [Folic Acid Tablets](#), and calculate the quantity, in mg, of folic acid (C₁₉H₁₉N₇O₆) in each mL of the Injection.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
FOLIC ACID INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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