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# Folic Acid Tablets

**DEFINITION**
Folic Acid Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of folic acid ($C_{19}H_{19}N_7O_6$).

**IDENTIFICATION**

• **A. Ultraviolet Absorption**

**Sample solution:** Digest the quantity of powdered Tablets, equivalent to 100 mg of folic acid, with 100 mL of 0.1 N sodium hydroxide, and filter. Adjust with hydrochloric acid to a pH of 3.0. Cool to 5°, 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 h. Dissolve the residue in 0.1 N sodium hydroxide to obtain a 10-µg/mL solution.

**Acceptance criteria:** The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Folic Acid RS, concomitantly measured. The absorbance ratio $A_{256}/A_{365}$ is 2.80–3.00.

***Change to read:***

**ASSAY**

• **Procedure**

**Mobile phase:** Transfer 35.1 g of sodium perchlorate and 1.40 g of monobasic potassium phosphate 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.

**Diluent:** Aqueous solution containing 2 mL of ammonium hydroxide and 1 g of sodium perchlorate per 100 mL

**System suitability solution:** 0.2 mg/mL each of USP Folic Acid RS and ▲USP Leucovorin Calcium RS▲ (IRA 1-Nov-2022) in *Diluent*

[Note—Before use, pass through a filter of 1-µm or finer pore size.]

**Standard solution:** 0.20 mg/mL of USP Folic Acid RS, corrected for water content in *Diluent*

**Sample solution:** Equivalent to 0.2 mg/mL of folic acid, from NLT 20 powdered Tablets in *Diluent*; shake gently to aid dissolution, and filter, discarding the first portion.

**Chromatographic system**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 25-cm; packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 25 µL

**System suitability**

**Samples:** *System suitability solution* and *Standard solution*

**Suitability requirements**

**Resolution:** NLT 3.6 between ▲leucovorin▲ (IRA 1-Nov-2022) and folic acid, *System suitability solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of folic acid ($C_{19}H_{19}N_7O_6$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$ = peak area of folic acid from the *Sample solution*

$r_S$ = peak area of folic acid from the *Standard solution*

$C_S$ = concentration of USP Folic Acid RS in the *Standard solution* (mg/mL)

$C_U$ = nominal concentration of folic acid in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–115.0%

**PERFORMANCE TESTS**

• **Dissolution** ⟨711⟩

**Medium:** Water; 500 mL, deaerated

**Apparatus 2:** 50 rpm

**Time:** 45 min

**Standard solution:** Solution having a known concentration of USP Folic Acid RS, corrected for water content, in *Medium*

**Sample solution:** Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Proceed as directed in the *Assay*, making any necessary modifications.

Calculate the percentage of the labeled amount of folic acid ($C_{19}H_{19}N_7O_6$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D \times V/L) \times 100$$

$r_U$ = peak area of folic acid from the *Sample solution*

$r_S$ = peak area of folic acid from the *Standard solution*

$C_S$ = concentration of USP Folic Acid RS in the *Standard solution* (mg/mL)

$D$ = dilution factor for the *Sample solution*

$V$ = volume of *Medium*, 500 mL

$L$ = label claim (mg/Tablet)

**Tolerances:** NLT 75% ($Q$) of the labeled amount of folic acid ($C_{19}H_{19}N_7O_6$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Preserve in well-closed containers.

***Change to read:***

• **USP Reference Standards** ⟨11⟩

USP Folic Acid RS

▲ USP Leucovorin Calcium RS▲ (IRA 1-Nov-2022)

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| FOLIC ACID TABLETS | Natalia Davydova<br>Scientific Liaison | NBDS2020 Non-botanical Dietary Supplements |

**Chromatographic Database Information:** Chromatographic Database

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