

Printed on: Tue Jul 28 2026, 15:16:37 pm

Printed by: Ita Aryani

Status: Currently Official on 28-Jul-2026

Official Date: Official as of 01-Nov-2022

Document Type: USP Monographs

DOI: https://doi.org/10.31003/USPNF_M34250_02_01Printed from: https://online.uspnf.com/uspnf/document/1_GUID-BC7ABEB0-D154-4EEE-8C5A-0D7F78E32298_2_en-US

© 2026 USPC

Do not distribute

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)

Loading Auxiliary Information...

Chromatographic Database Information: [Chromatographic Database](#)

DOI: https://doi.org/10.31003/USPNF_M34250_02_01