

Folic Acid Compounded Oral Solution

DEFINITION
Folic Acid Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of folic acid ($C_{19}H_{19}N_7O_6$).
Prepare Folic Acid Compounded Oral Solution, 1 mg/mL, as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Folic Acid	100 mg
Sodium Bicarbonate	1000 mg
Glycerin	35 mL
Purified Water, a sufficient quantity to make	100 mL

Dissolve the Sodium Bicarbonate in 60 mL of Purified Water followed by the Folic Acid. Add the Glycerin to the mixture. Mix well. Add sufficient Purified Water to bring to final volume.

ASSAY
• **PROCEDURE**
Solution A: 50 mM monobasic potassium phosphate adjusted with phosphoric acid to a pH of 2.5
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Methanol (%)
0.0	95	5
2.0	95	5
10.0	90	10
25.0	85	15
26.0	65	35
26.1	95	5
36.0	95	5

Diluent: 0.01 N sodium hydroxide
Standard solution: 0.2 mg/mL of [USP Folic Acid RS](#) in Diluent
Sample solution: Transfer 1.0 mL of Oral Solution to a 5-mL volumetric flask and add Diluent to volume.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 280 nm
Column: 4.6-mm × 10-cm; 2.6-μm packing L1
Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for folic acid is about 21.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Solution taken:

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

r_U = peak response of folic acid from the *Sample solution*

r_S = peak response 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%–110.0%

SPECIFIC TESTS

- **pH** (791): 7.8–8.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant plastic containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature.
- **LABELING:** Label it to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS** (11).
[USP Folic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
FOLIC ACID COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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