Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2017
Document Type: USP Monographs
DocId: GUID-21E7662B-C998-4FCD-95FF-1BC02FAE9FDB_1_en-US
DOI: https://doi.org/10.31003/USPNF_M10959_01_01
DOI Ref: ay64x

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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(5)

Current DocID: GUID-21E7662B-C998-4FCD-95FF-1BC02FAE9FDB_1_en-US

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