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Flucytosine Compounded Oral Suspension

DEFINITION

Flucytosine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of flucytosine ($C_4H_4FN_3O$).

Prepare Flucytosine Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Flucytosine	1 g
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Empty the contents of the required number of capsules into a suitable mortar, or add *Flucytosine* powder to the mortar. Add 10 mL of *Vehicle*, and mix to a uniform paste. Add *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 1 g of ammonium acetate and 1 mL of diisopropylamine in 1 L of water. Adjust with glacial acetic acid to a pH of 7.5.

Mobile phase: Methanol and *Solution A* (50:50). Filter, and degas.

Standard solution: 50 µg/mL of USP Flucytosine RS in *Mobile phase*

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at −70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix on a vortex mixer for 30 s. Pipet 0.5 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 200-mm; 5-µm packing L3

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for flucytosine is about 3 min.]

Suitability requirements

Relative standard deviation: NMT 1.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flucytosine ($C_4H_4FN_3O$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Flucytosine RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of flucytosine in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored in a refrigerator

• **Labeling:** Label it to state that it is to be well shaken, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Flucytosine RS

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

Topic/Question	Contact	Expert Committee
FLUCYTOSINE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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