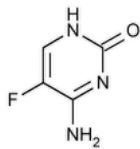


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2022
Document Type: USP Monographs
DocId: GUID-80257960-5270-4CB4-8A8A-48716A0B1B7C_5_en-US
DOI: https://doi.org/10.31003/USPNF_M33280_05_01
DOI Ref: qsv2v

© 2025 USPC
Do not distribute

Flucytosine



C₄H₄FN₃O 129.09

Cytosine, 5-fluoro-;

5-Fluorocytosine CAS RN®: 2022-85-7; UNII: D83282DT06.

Change to read:

DEFINITION

Flucytosine contains ▲NLT 98.0% and NMT 102.0%▲ (USP 1-May-2022) of flucytosine (C₄H₄FN₃O), calculated on the dried basis.

IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy](#):** 197U

Analytical wavelength: 285 nm

Medium: Dilute [hydrochloric acid](#) in [water](#) (1 in 100).

Sample solution: 8 µg/mL of flucytosine in *Medium*

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by NMT 2.0%.

Change to read:

- **B. ▲**The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2022)

ASSAY

Change to read:

• **PROCEDURE**

▲**Buffer:** 13.6 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.0.

Solution A: *Buffer* and [methanol](#) (98:2)

Solution B: *Buffer* and [methanol](#) (85:15)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
10	0	100
35	0	100
35.1	100	0
45	100	0

Diluent: Dissolve 13.6 g of [monobasic potassium phosphate](#) in 980 mL of [water](#). Add 20 mL of [methanol](#) and mix.

Standard solution: 0.05 mg/mL of [USP Flucytosine RS](#) in *Diluent*

Sample solution: 0.05 mg/mL of Flucytosine in *Diluent*

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 284 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)**Flow rate:** 1.1 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of flucytosine (C₄H₄FN₃O) in the portion of Flucytosine taken:

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

 r_U = peak response of flucytosine from the *Sample solution* r_S = peak response of flucytosine from the *Standard solution* C_S = concentration of [USP Flucytosine RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Flucytosine in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis ▲ (USP 1-May-2022)**OTHER COMPONENTS****Delete the following:**

▲ • FLUOROURACIL

Diluent: [Glacial acetic acid](#) and [water](#) (4:1)**Standard solution:** 0.025 mg/mL solution of [USP Fluorouracil RS](#) in *Diluent***Sample solution:** 25 mg/mL flucytosine in *Diluent***Application volume:** 20 μL**Chromatographic system**(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)**Mode:** TLC**Adsorbent:** 0.5-mm layer of chromatographic silica gel mixture**Developing solvent system:** [Chloroform](#) and [glacial acetic acid](#) (13:7)**Analysis****Samples:** *Standard solution* and *Sample solution*

Locate the spots on the plate by observing under short-wavelength UV radiation.

Acceptance criteria: Any spot from the *Sample solution* is not greater in size and intensity than the spot at the respective R_f produced by the*Standard solution*, corresponding to NMT 0.1% of fluorouracil. ▲ (USP 1-May-2022)**IMPURITIES****Add the following:**

▲ • ORGANIC IMPURITIES

Buffer, Solution A, Solution B, Mobile phase, and Diluent: Prepare as directed in the Assay.**Sensitivity solution:** 0.1 μg/mL of [USP Flucytosine RS](#) in *Diluent***Standard solution:** 0.00030 mg/mL of [USP Fluorouracil RS](#), 0.00045 mg/mL of [USP Fluorouracil Related Compound F RS](#), and 0.00015 mg/mL of [USP Flucytosine RS](#) in *Diluent***Sample solution:** 0.3 mg/mL of Flucytosine in *Diluent***Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 260 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)**Flow rate:** 1.1 mL/min**Injection volume:** 20 μL**System suitability**