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Flucytosine Capsules

DEFINITION

Flucytosine Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of flucytosine (C₄H₄FN₃O).

IDENTIFICATION

Change to read:

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

Wavelength range: 260–350 nm

Diluent: 0.1 N [hydrochloric acid](#)

Standard solution: 8 µg/mL of [USP Flucytosine RS](#) in *Diluent*

Sample stock solution: Nominally 1 mg/mL of flucytosine in *Diluent* prepared as follows. Remove the contents of Capsules (NLT 20) as completely as possible, and weigh. Transfer a portion of the powder, nominally equivalent to 250 mg of flucytosine, to a 250-mL volumetric flask. Add 50 mL of *Diluent*, shake by mechanical means for 30 min and dilute with *Diluent* to volume. Pass the solution through a suitable membrane filter of 0.45-µm pore size.

Sample solution: Nominally 8 µg/mL of flucytosine in *Diluent* from *Sample stock solution*

Blank: *Diluent*

Acceptance criteria: Meet the requirements ▲ (USP 1-May-2022)

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: Nominally 0.05 mg/mL of flucytosine in *Diluent* prepared as follows. Remove the contents of Capsules (NLT 10) as completely as possible, and weigh. Transfer a portion of the powder, nominally equivalent to 10 mg of flucytosine, to a 200-mL volumetric flask. Add 100 mL of *Diluent* and shake for 30 min. Dilute with *Diluent* to volume and mix. Pass a portion of the solution under test through a suitable filter.

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 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of flucytosine ($C_4H_4FN_3O$) in the portion of Capsules 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 = nominal concentration of flucytosine in the *Sample solution* (mg/mL)▲ (USP 1-May-2022)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**• [DISSOLUTION \(711\)](#)**Medium:** Water; 900 mL**Apparatus 2:** 75 rpm**Time:** 60 min

▲▲ (USP 1-May-2022)

Standard solution: [USP Flucytosine RS](#) in *Medium***Sample solution:** Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.▲ **Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 276 nm**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of flucytosine ($C_4H_4FN_3O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of [USP Flucytosine RS](#) in the *Standard solution* (mg/mL) D = dilution factor of the *Sample solution* V = volume of *Medium*, 900 mL L = label claim (mg/Capsule)▲ (USP 1-May-2022)**Tolerances:** NLT 80% (Q) of the labeled amount of flucytosine ($C_4H_4FN_3O$) is dissolved.• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements**Add the following:**▲ **IMPURITIES**• **ORGANIC IMPURITIES**