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## Fluorouracil Topical Solution

### DEFINITION

Fluorouracil Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of fluorouracil ( $C_4H_3FN_2O_2$ ).

### IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

### ASSAY

#### PROCEDURE

**Buffer:** 6.8 g/L of monobasic potassium phosphate in water. Adjust with 5 M potassium hydroxide to a pH of  $5.7 \pm 0.1$ .

**Mobile phase:** Acetonitrile and *Buffer* (5:95)

**Standard solution:** 10 µg/mL of [USP Fluorouracil RS](#) in water

**Sample stock solution:** Nominally equivalent to 0.1 mg/mL of fluorouracil prepared as follows. Transfer a portion of Topical Solution, nominally equivalent to 10 mg of fluorouracil, into a 100-mL volumetric flask. Add 20 mL of methanol, and mix on a vortex mixer to dissolve. Dilute with water to volume.

**Sample solution:** 10 µg/mL of fluorouracil in water, from *Sample stock solution*. Mix, and filter.

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm or diode array. [NOTE—Use the diode array detector to perform *Identification test B*.]

**Column:** 4.6-mm × 25-cm; 5-µm packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

#### System suitability

**Sample:** *Standard solution*

#### Suitability requirements

**Relative standard deviation:** NMT 0.73%, *Standard solution*

**Tailing factor:** NMT 1.5, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluorouracil ( $C_4H_3FN_2O_2$ ) in the portion of Topical Solution 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 Fluorouracil RS](#) in the *Standard solution* (µg/mL)

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

**Acceptance criteria:** 90.0%–110.0%

### SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(61\)](#), and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.
- **USP REFERENCE STANDARDS** (11).  
[USP Fluorouracil RS](#)

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

Topic/Question	Contact	Expert Committee
FLUOROURACIL TOPICAL SOLUTION	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

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