

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-D90AC009-60BF-4B35-AF49-E7CDF3F36A25_3_en-US
DOI: https://doi.org/10.31003/USPNF_M33750_03_01
DOI Ref: k36yd

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Fluorouracil Cream

DEFINITION

Fluorouracil Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of fluorouracil ($C_4H_3FN_2O_2$). It may contain Sodium Hydroxide to adjust the pH.

IDENTIFICATION

Change to read:

- A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-May-2020)
Sample: Dry a portion of Cream nominally equivalent to 50 mg of fluorouracil at a pressure NMT 0.7 kPa. Mix with 100 mL of ether. Decant, wash the residue with 50 mL of ether, and allow to air dry.
Acceptance criteria: Meets the requirements
- B.** The retention time 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 ± 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 Cream, 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
Column: 4.6-mm × 25-cm; 5-µm packing L1
Flow rate: 1.0 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 Cream 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%

IMPURITIES

LIMIT OF UREA

Standard solution: 0.05 mg/mL of [USP Urea RS](#) in water

Sample solution: Nominally equivalent to 5 mg/mL of fluorouracil prepared as follows. Shake a portion of Cream containing 100 mg of fluorouracil with 10 mL of water for 5 min. Add 10 mL of alcohol, and mix. Pass through a glass-fiber filter, and use the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: Chromatographic silica gel

Application volume: 20 µL

Developing solvent system: Ethyl acetate, acetone, and water (70:40:10)

Reagent solution: Prepare a 10-mg/mL solution of *p*-dimethylaminobenzaldehyde in alcohol. Prepare a mixture of this solution and hydrochloric acid (10:1).

Analysis

Samples: *Standard solution* and *Sample solution*

Procedure: Develop with *Developing solvent system*, followed by air drying. Spray the plate at least twice with *Reagent solution*, and dry the plate in an oven at 100° until the maximum intensity of the spots is obtained. Examine the plate under daylight.

Acceptance criteria: NMT 1.0%; the spot of urea in the *Sample solution* is not more intense than the spot of urea from the *Standard solution*.

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

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](#)

[USP Urea RS](#)

Urea.

CH₄N₂O

60.06

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

Topic/Question	Contact	Expert Committee
FLUOROURACIL CREAM	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 39(3)

Current DocID: GUID-D90AC009-60BF-4B35-AF49-E7CDF3F36A25_3_en-US

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