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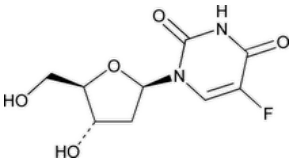
Floxuridine



$C_9H_{11}FN_2O_5$ 246.19

Uridine, 2'-deoxy-5-fluoro-;

2'-Deoxy-5-fluorouridine CAS RN®: 50-91-9; UNII: 039LU44I5M.

DEFINITION

Floxuridine contains NLT 98.5% and NMT 101.0% of floxuridine ($C_9H_{11}FN_2O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020)

Change to read:

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020)

Analytical wavelength: 268 nm

Sample solution: 20 µg/mL

Medium: 0.1 N potassium hydroxide

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

• **C.**

Sample solution: 20 mg/mL of Floxuridine in water

Analysis: Add a few drops of bromine TS to 10 mL of the *Sample solution*.

Acceptance criteria: The bromine color is discharged.

ASSAY

• **Procedure**

Sample: 800 mg of Floxuridine

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N tetrabutylammonium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 80 mL of dimethylformamide, and titrate with *Titrant*, determining the endpoint using a calomel–glass electrode system. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N tetrabutylammonium hydroxide is equivalent to 24.62 mg of floxuridine ($C_9H_{11}FN_2O_5$).

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Limit of Fluoride Ions**

Use plasticware throughout this test.

Buffer: Dissolve 110 g of sodium chloride and 1 g of sodium citrate in 700 mL of water in a 2000-mL volumetric flask. Cautiously add 150 g of sodium hydroxide, and dissolve with shaking. Cool to room temperature, and while stirring, cautiously add 450 mL of glacial acetic acid to the cooled solution. Cool, add 600 mL of isopropyl alcohol, and dilute with water to volume. The pH of the *Buffer* is 5.0–5.5.

Standard stock solution: Transfer 221 mg of sodium fluoride, previously dried at 150° for 4 h, to a 100-mL volumetric flask, add 20 mL of water, and mix to dissolve. Add 1.0 mL of sodium hydroxide solution (1 in 2500), dilute with water to volume, and mix. Each mL of the *Standard stock solution* contains 1 mg of fluoride ions. Store in a tightly closed, plastic container.

Standard solutions: 1, 3, 5, and 10 µg/mL of fluoride ion; from *Standard stock solution* in *Buffer*

Sample solution: 10 mg/mL of Floxuridine in *Buffer*

Analysis: Concomitantly measure the potential (see *Titrimetry ⟨541⟩*), in mV, of the *Standard solutions* and the *Sample solution*, with a pH meter capable of a minimum reproducibility of ±0.2 mV, equipped with a glass-sleeved calomel–fluoride specific-ion electrode system. When taking measurements, immerse the electrodes in the solution, which has been transferred to a 150-mL beaker containing a polytef-coated stirring bar. Allow to stir on a magnetic stirrer having an insulated top until equilibrium is attained (1–2 min), and record the potential. Rinse and dry the electrodes between measurements, taking care to avoid damaging the crystal of the specific-ion electrode. Plot the logarithm of the fluoride-ion concentrations, in µg/mL, of the *Standard solutions* versus potential, in mV. From the measured potential of the *Sample solution* and the standard curve, determine the concentration, in µg/mL, of fluoride ions in the *Sample solution*.

Acceptance criteria: NMT 0.05%

SPECIFIC TESTS

- **Melting Range or Temperature, *Class I*⟨741⟩:** 145°–153°, but the range between the beginning and end of melting does not exceed 2°.
- **Optical Rotation, *Specific Rotation*⟨781S⟩**

  Sample solution: 10 mg/mL of Floxuridine in water.

  Acceptance criteria: +36° to +39°
- **Loss on Drying ⟨731⟩**

  Analysis: Dry under vacuum over silica gel at 60° for 4 h.

  Acceptance criteria: NMT 0.2%
- **Pyrogen:** Where the label states that Floxuridine is sterile, it meets the requirements of *Pyrogen Test ⟨151⟩*, the test dose being 0.50 mL/kg of a solution prepared by diluting Floxuridine with Sodium Chloride Injection to a concentration of 100 mg/mL.
- **Other Requirements:** Where the label states that Floxuridine is sterile, it meets the requirements in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*. Where the label states that Floxuridine must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for the *Pyrogen* test.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.
- **Labeling:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected for further processing during the preparation of injectable dosage forms.
- **USP Reference Standards ⟨11⟩**

  USP Floxuridine RS

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

Topic/Question	Contact	Expert Committee
FLOXURIDINE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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