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Floxuridine for Injection

DEFINITION

Floxuridine for Injection is lyophilized Floxuridine suitable for intra-arterial infusion. It contains NLT 90.0% and NMT 110.0% of the labeled amount of floxuridine ($C_9H_{11}FN_2O_5$).

IDENTIFICATION

Change to read:

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

Sample: Use the *Sample solution* prepared for the *Assay*.

Acceptance criteria: Meets the requirements

• **B.**

Sample solution: Nominally 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**

Diluent: Potassium hydroxide solution (1 in 180)

Standard solution: 20 µg/mL of USP Floxuridine RS in *Diluent*

Sample stock solution: Nominally 0.4 mg/mL of Floxuridine for Injection in *Diluent*

Sample solution: 20 µg/mL from the *Sample stock solution* in *Diluent*

Blank: *Diluent*

Instrumental conditions

Mode: UV

Analytical wavelength: 268 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of floxuridine ($C_9H_{11}FN_2O_5$) in the portion of Floxuridine for Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Floxuridine RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: 1 in 50

Acceptance criteria: 4.0–5.5

• **Constituted Solution:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*

• **Pyrogen:** Meets the requirements of *Pyrogen Test ⟨151⟩*, the test dose being 0.50 mL/kg of a solution prepared by diluting Floxuridine for Injection with Sodium Chloride Injection to a concentration of 100 mg/mL

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*, and protect from light. Store containers of constituted Floxuridine for Injection under refrigeration for NMT 2 weeks.

• **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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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