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Idoxuridine Ophthalmic Solution

DEFINITION

Idoxuridine Ophthalmic Solution is a sterile, aqueous solution of Idoxuridine. It contains NLT 0.09% and NMT 0.11% of idoxuridine ($C_9H_{11}IN_2O_5$).

It may contain suitable buffers, stabilizers, and antimicrobial agents.

IDENTIFICATION

• **A.**

Standard solution and **Sample solution:** Use as directed in the *Assay*.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*.

ASSAY

• **Procedure**

Chromatographic column: Mix 4 g of chromatographic siliceous earth with 4 mL of 0.1 N hydrochloric acid in a glass mortar until the mixture is fluffy. Transfer to a 19- × 250-mm chromatographic tube (see *Chromatography* ⟨621⟩) that contains a pledget of glass wool and is fitted with a stopcock at the bottom. Tamp gently to compress to a uniform mass.

Eluting solvent: Butyl alcohol and chloroform (1:5)

Standard stock solution: 0.5 mg/mL of USP Idoxuridine RS in methanol

Standard solution: Dilute 5.0 mL of *Standard stock solution* with *Eluting solvent* to 100.0 mL.

Sample solution: Nominally 25 µg/mL of idoxuridine in eluant obtained from the *Chromatographic column*. Mix an equivalent to 5 mg of idoxuridine from Ophthalmic Solution with 3 g of chromatographic siliceous earth in a glass mortar until the mixture is fluffy.

Instrumental conditions

Mode: UV

Analytical wavelengths: 320 and 283 nm

Cell: 1 cm

Blank: *Eluting solvent*

Analysis

Samples: *Standard solution* and *Sample solution*

Transfer the *Sample solution* to the prepared *Chromatographic column*. Transfer 2 g of chromatographic siliceous earth and 2 mL of 0.1 N hydrochloric acid to the glass mortar, and mix until fluffy. Use this material to rinse the mortar and pick up any remaining Ophthalmic Solution. Transfer half of this mixture to the tube, and tamp gently until the column appears uniform. Transfer the remaining portion to the *Chromatographic column*, and tamp as before. Wipe the walls of the mortar with a small pledget of glass wool, and insert the pledget in the top of the column. Elute with 200 mL of *Eluting solvent* at a flow rate of approximately 1 mL/min, discarding the first 20 mL of the eluate. Collect the remainder of the eluate in a 200-mL volumetric flask, and dilute with *Eluting solvent* to volume. Determine the absorbances of this solution and the *Standard solution*.

Calculate the percentage of idoxuridine ($C_9H_{11}IN_2O_5$) in the portion of Ophthalmic Solution taken:

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

A_U = difference in the absorbances of the *Sample solution* at the wavelengths indicated by ($A_{283} - A_{320}$)

A_S = difference in the absorbances of the *Standard solution* at the wavelengths indicated by ($A_{283} - A_{320}$)

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

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

Acceptance criteria: 0.09%–0.11%

SPECIFIC TESTS

• **Sterility Tests** ⟨71⟩**:** Meets the requirements

• **pH** ⟨791⟩**:** 4.5–7.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers in a cold place.
- **USP Reference Standards** ⟨11⟩
  USP Idoxuridine RS

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

Topic/Question	Contact	Expert Committee
IDOXURIDINE OPHTHALMIC SOLUTION	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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