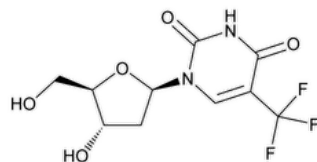


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Trifluridine



$C_{10}H_{11}F_3N_2O_5$ 296.20

Thymidine, α,α,α -trifluoro-

2'-Deoxy-5-(trifluoromethyl)uridine CAS RN®: 70-00-8; UNII: RMW9V5RW38.

DEFINITION

Trifluridine contains NLT 98.0% and NMT 102.0% of trifluridine ($C_{10}H_{11}F_3N_2O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Change to read:

- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 25 µg/mL in [0.1 N hydrochloric acid](#)

Acceptance criteria: Meets the requirements

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

ASSAY

Change to read:

• PROCEDURE

Mobile phase: 0.15% [sodium citrate](#) solution. Adjust with [1 N hydrochloric acid](#) to a pH of 6.8.

Standard stock solution: 1 mg/mL of [USP Trifluridine RS](#) and 0.01 mg/mL each of [USP Trifluridine Related Compound A RS](#) and [5-\(trifluoromethyl\)uracil](#) in [water](#). [NOTE—This stock preparation may be stored at 0°–5° for 3 months.]

Standard solution: 0.2 mg/mL of [USP Trifluridine RS](#) and 0.002 mg/mL each of [USP Trifluridine Related Compound A RS](#) and [5-\(trifluoromethyl\)uracil](#) in [water](#) from the *Standard stock solution*

Sample solution: 0.2 mg/mL of Trifluridine in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: ▲ 4.6-mm ▲ (USP 1-Dec-2019) × 25-cm; ▲ 10-µm ▲ (USP 1-Dec-2019) packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

▲ **Run time:** NLT 3.75 times the retention time of trifluridine ▲ (USP 1-Dec-2019)

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between [5-\(trifluoromethyl\)uracil](#) and trifluridine related compound A; NLT 4.0 between trifluridine related compound A and trifluridine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trifluridine ($C_{10}H_{11}F_3N_2O_5$) in the portion of Trifluridine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response ▲ of trifluridine ▲ (USP 1-Dec-2019) from the *Sample solution*

r_S = peak response ▲ of trifluridine ▲ (USP 1-Dec-2019) from the *Standard solution*

C_S = concentration of [USP Trifluridine RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Trifluridine in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Mobile phase, Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trifluridine related compound A and 5-(trifluoromethyl)uracil in the portion of Trifluridine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of trifluridine related compound A or 5-(trifluoromethyl)uracil from the *Sample solution*

r_S = peak response of trifluridine related compound A or 5-(trifluoromethyl)uracil from the *Standard solution*

C_S = concentration of [USP Trifluridine Related Compound A RS](#) ▲ or ▲ (USP 1-Dec-2019) 5-(trifluoromethyl)uracil in the *Standard solution* (mg/mL)

C_U = concentration of Trifluridine in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.0% of each related compound

SPECIFIC TESTS

• [OPTICAL ROTATION \(781S\)](#), [Procedures, Specific Rotation](#)

Sample solution: 30 mg/mL in water

Acceptance criteria: +47° to +51°

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Trifluridine RS](#)

[USP Trifluridine Related Compound A RS](#)

5-Carboxy-2'-deoxyuridine.

$C_{10}H_{12}N_2O_7$ 272.22

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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