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Zidovudine Injection

DEFINITION

Zidovudine Injection is a sterile solution of Zidovudine in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of zidovudine ($C_{10}H_{13}N_5O_4$).

IDENTIFICATION

Change to read:

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

Solution A: Methanol and water (75:25)

Sample solution: Nominally 15 µg/mL of zidovudine from Injection in *Solution A*

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

Mobile phase: Methanol and water (20:80)

Standard stock solution: 1.0 mg/mL of [USP Zidovudine RS](#) in methanol

Zidovudine related compound C standard stock solution: 0.2 mg/mL of [USP Zidovudine Related Compound C RS](#) in methanol prepared as follows. Transfer 20 mg of [USP Zidovudine Related Compound C RS](#) to a 100-mL volumetric flask, add 75 mL of methanol, sonicate for 15 min, and dilute with methanol to volume.

Standard solution: 0.1 mg/mL of [USP Zidovudine RS](#) and 4 µg/mL of [USP Zidovudine Related Compound C RS](#) prepared as follows. Transfer a suitable volume of *Standard stock solution* and *Zidovudine related compound C standard stock solution* to a suitable volumetric flask. Add 25% of the flask volume of water, and dilute with methanol to volume.

Sample solution: Nominally 0.1 mg/mL of zidovudine from Injection in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

Columns

Guard: Recommended dimensions are 3.2-mm × 1.5-cm; packing L1.

Analytical: 4.0-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for zidovudine related compound C and zidovudine are about 0.2 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5.0 between zidovudine and zidovudine related compound C

Tailing factor: NMT 1.5 for the zidovudine peak

Relative standard deviation: NMT 2.0% for the zidovudine peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of zidovudine ($C_{10}H_{13}N_5O_4$) in the portion of Injection taken:

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

r_U = peak response of zidovudine from the *Sample solution*

r_S = peak response of zidovudine from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **ORGANIC IMPURITIES**

Mobile phase, Standard stock solution, Zidovudine related compound C standard stock solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard solution: 0.1 mg/mL of [USP Zidovudine RS](#) and 2 µg/mL of [USP Zidovudine Related Compound C RS](#) prepared as follows. Transfer a suitable volume of *Standard stock solution* and *Zidovudine related compound C standard stock solution* to a suitable volumetric flask. Add 25% of the flask volume of water, and dilute with methanol to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of zidovudine related compound C in the portion of Injection taken:

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

r_U = peak response of zidovudine related compound C from the *Sample solution*

r_S = peak response of zidovudine related compound C from the *Standard solution*

C_S = concentration of [USP Zidovudine Related Compound C RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

- **STERILITY TESTS (71):** Meets the requirement when tested as directed in [Test for Sterility of the Product to Be Examined, Membrane Filtration](#)
- **pH (791)**

Sample solution: A mixture containing a volume of Injection equivalent to 150 mg of zidovudine and 5 mL of 0.12 M potassium chloride

Acceptance criteria: 3.5–7.0

- **BACTERIAL ENDOTOXINS TEST (85):** NMT 1.0 USP Endotoxin Unit/mg of zidovudine
- **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11).**

[USP Zidovudine RS](#)

[USP Zidovudine Related Compound C RS](#)

Thymine.



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

Topic/Question	Contact	Expert Committee
ZIDOVUDINE 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:

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