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Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-BA20F4D5-E572-4093-9119-20BA8F69CADE_2_en-US
DOI: https://doi.org/10.31003/USPNF_M89514_02_01
DOI Ref: 0xrm6

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Zidovudine Capsules

DEFINITION

Zidovudine Capsules contain 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: 15 µg/mL prepared as follows. Mix Capsule contents, equivalent to 300 mg of zidovudine, with 50 mL of *Solution A* in a 200-mL volumetric flask. Sonicate for 5 min, and dilute with methanol to volume. Allow insoluble solids to settle, and dilute the supernatant 100-fold with *Solution A*.

Acceptance criteria: Meet 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)

Diluent: Methanol and water (75:25)

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, dilute with methanol to volume.

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 10 mL of *Standard stock solution* and 1.0 mL of *Zidovudine related compound C standard stock solution* to a 100-mL volumetric flask, add 25 mL of water, and dilute with methanol to volume.

Sample stock solution: Nominally 1 mg/mL of zidovudine in *Diluent* prepared as follows. Weigh the contents of Capsules (NLT 20), mix, and transfer a portion of the powder, equivalent to 100 mg of zidovudine, to a 100-mL volumetric flask. Dissolve in *Diluent*, sonicate for 20 min, and dilute with *Diluent* to volume. Allow the solids to settle, and use the supernatant layer to prepare the *Sample solution*.

Sample solution: Nominally 0.1 mg/mL of zidovudine from a suitable volume of supernatant of *Sample stock solution* in *Diluent*. Filter, discarding the first 4 mL of the filtrate.

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 the zidovudine and zidovudine related compound C peaks

Tailing factor: NMT 2.0 for the zidovudine peak

Relative standard deviation: NMT 2.0% for the zidovudine peak

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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 Capsules 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 USP Zidovudine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

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

Standard solution: Prepare a solution having a known concentration of USP Zidovudine RS in *Medium*.

Sample solution: A filtered portion of the solution under test, suitably diluted with *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of zidovudine ($C_{10}H_{13}N_5O_4$) dissolved by using the procedure set forth in the *Assay*, making any necessary modifications.

Tolerances: NLT 75% (*Q*) of the labeled amount of zidovudine ($C_{10}H_{13}N_5O_4$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, Zidovudine related compound C standard stock solution, Standard stock solution, Standard solution, Sample stock 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 zidovudine related compound C in the portion of Capsules 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 3.0%

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.

$C_5H_6N_2O_2$ 126.12

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

Topic/Question	Contact	Expert Committee
ZIDOVUDINE CAPSULES	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. PF 34(3)

Current DocID: GUID-BA20F4D5-E572-4093-9119-20BA8F69CADE_2_en-US

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