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Zidovudine Oral Solution

DEFINITION

Zidovudine Oral Solution 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.▲** (USP 1-MAY-2022) The retention time of the zidovudine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲ **B.** The UV spectrum of the zidovudine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲
 (USP 1-May-2022)

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Methanol](#), [acetonitrile](#), [glacial acetic acid](#), and [0.040 M sodium acetate](#) (90:10:2:900)

Standard stock solution: 1 mg/mL of [USP Zidovudine RS](#) in *Mobile phase*

Zidovudine related compound C stock solution: 0.1 mg/mL of [USP Zidovudine Related Compound C RS](#) in *Mobile phase*. [NOTE—Sonicate for 10 min before making final volume.]

Standard solution: Transfer 10.0 mL of the *Standard stock solution* and 2.0 mL of *Zidovudine related compound C stock solution* to a 100-mL volumetric flask. Dilute with *Mobile phase* to volume.

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

Chromatographic system

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

Mode: LC

Detector: UV 240 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm. ▲ (USP 1-May-2022)

Column: 4.0-mm × 12.5-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 0.12 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between zidovudine and zidovudine related compound C

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Oral Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Change to read:

[NOTE—On the basis of ▲knowledge of the product,▲ (USP 1-May-2022) perform either *Organic Impurities, Procedure 1* or *Procedure 2*.]

• ORGANIC IMPURITIES, PROCEDURE 1

Mobile phase, Standard stock solution, Zidovudine related compound C solution, 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 zidovudine related compound C in the portion of Oral Solution taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response 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%

Change to read:

• ORGANIC IMPURITIES, PROCEDURE 2

Buffer: 5.44 mg/mL of [sodium acetate trihydrate](#) in water. Pass the solution through a suitable filter of 0.45-μm pore size.

Mobile phase: [Methanol](#), [acetonitrile](#), [glacial acetic acid](#), and *Buffer* (50:10:2:940)

Impurity stock solution: 0.625 mg/mL of [USP Zidovudine Related Compound C RS](#), 0.375 mg/mL of thymidine, 0.375 mg/mL of [USP Stavudine RS](#), and 0.25 mg/mL of [USP Zidovudine Related Compound B RS](#) dissolved initially with methanol at 25% of the final volume.

Dilute with *Mobile phase* to final volume. [NOTE—Sonicate with intermittent shaking to dissolve, if necessary, and cool to room temperature before diluting to final volume.]

Impurity solution: 0.05 mg/mL of [USP Zidovudine Related Compound C RS](#), 0.03 mg/mL of thymidine, 0.03 mg/mL of [USP Stavudine RS](#), and 0.02 mg/mL of [USP Zidovudine Related Compound B RS](#) in *Mobile phase* from the *Impurity stock solution*

System suitability solution: 1 mg/mL of [USP Zidovudine RS](#), 0.005 mg/mL of [USP Zidovudine Related Compound C RS](#), 0.003 mg/mL of thymidine, 0.003 mg/mL of [USP Stavudine RS](#), and 0.002 mg/mL of [USP Zidovudine Related Compound B RS](#) in *Mobile phase* from [USP Zidovudine RS](#) and the *Impurity solution*

Standard stock solution: 0.25 mg/mL of [USP Zidovudine RS](#) in *Mobile phase*. Sonicate to dissolve, if necessary.

Standard solution: 0.002 mg/mL of [USP Zidovudine RS](#) in *Mobile phase* from the *Standard stock solution*

Sample solution: Nominally 1 mg/mL of zidovudine in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 10-cm; 3-μm packing [L1](#)

Column temperature: 25°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.4 between zidovudine and zidovudine related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*



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