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Stavudine for Oral Solution

DEFINITION

Stavudine for Oral Solution, when reconstituted as directed in the labeling, yields a 1 mg/mL solution that contains NLT 90.0% and NMT 110.0% of the labeled amount of stavudine ($C_{10}H_{12}N_2O_4$). It may contain suitable flavors, preservatives, sweeteners, and stabilizers.

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-Aug-2019) The retention time of the major 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 major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

ASSAY

Change to read:

• **Procedure**

[Note—All testing solutions must be prepared immediately before use and remain refrigerated until use.]

Buffer: 1.93 mg/mL of ammonium acetate in water

Solution A: Methanol and *Buffer* (6:94)

Solution B: Methanol and *Buffer* (1:1)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
12	100	0
12.1	0	100
17	0	100
17.1	100	0
35	100	0

System suitability solution: 2.5 µg/mL each of ▲USP Zidovudine Related Compound C RS▲ (USP 1-Aug-2019) and ▲USP Zidovudine Related Compound D RS▲ (USP 1-Aug-2019) in water

Standard solution: 0.1 mg/mL of USP Stavudine RS in water

Sample solution: Nominally 0.1 mg/mL of stavudine in water, prepared as follows. Constitute Stavudine for Oral Solution as directed in the labeling. Dilute an accurately measured volume of Stavudine for Oral Solution quantitatively, and stepwise if necessary, with water.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 268 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Aug-2019)

Columns

Guard: 4-mm × 20-mm; ▲5-µm▲ (USP 1-Aug-2019) packing L1

Analytical: 4.6-mm × 3.3-cm; ▲3-µm▲ (USP 1-Aug-2019) packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 8.4 between ▲zidovudine related compound C▲ (USP 1-Aug-2019) and ▲zidovudine related compound D,▲ (USP 1-Aug-2019) *System suitability solution*

▲▲ (USP 1-Aug-2019)

Tailing factor: NMT 2 for the stavudine peak, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of stavudine ($C_{10}H_{12}N_2O_4$) in each milliliter of Stavudine for Oral Solution taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Stavudine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

[Note—All testing solutions must be prepared immediately prior to use and remain refrigerated until use.]

▲**Buffer,**▲ (USP 1-Aug-2019) **Solution A, Solution B,** ▲**Mobile phase,**▲ (USP 1-Aug-2019) **System suitability solution, Standard solution, Sample solution, Chromatographic system,** and ▲**System suitability:**▲ (USP 1-Aug-2019) Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Stavudine for Oral Solution taken:

$$\text{Result} = (r_U/r_T) \times 1/F \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses including that of the main stavudine peak from the *Sample solution*

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Zidovudine related compound C[a]▲ (USP 1-Aug-2019)	0.24	0.69	1.0
Any other individual impurity	—	1.0	0.2
Total impurities	—	—	1.5

[a] 5-Methylpyrimidine-2,4-(1*H*,3*H*)-dione.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample: Constitute as directed in the labeling.

Acceptance criteria: 5–7

• **Water Determination** ⟨921⟩, *Method I*: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tightly closed containers, protected from excessive moisture. Store at controlled room temperature. After constitution, store the Stavudine for Oral Solution in tightly closed containers under refrigeration. Discard unused portion after 30 days.

• **Labeling:** The label contains directions for constitution of the powder and states the equivalent amount of stavudine ($C_{10}H_{12}N_2O_4$) in a given volume of the Stavudine for Oral Solution obtained after constitution.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Stavudine RS

▲USP Zidovudine Related Compound C RS

Thymine;
5-Methylpyrimidine-2,4(1*H*,3*H*)-dione.
$C_5H_6N_2O_2$ 126.11

USP Zidovudine Related Compound D RS

Thymidine;
[1-(2-Deoxy-β-D-ribofuranosyl)]thymine.
$C_{10}H_{14}N_2O_5$ 242.23▲ (USP 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
STAVUDINE FOR ORAL 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

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