

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