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Stavudine Capsules

DEFINITION

Stavudine Capsules contain NLT 90.0% and NMT 105.0% of the labeled amount of stavudine ($C_{10}H_{12}N_2O_4$).

IDENTIFICATION

Change to read:

- **A.** [▲]The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ^{▲2S}
 (USP41)
- **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

Change to read:

• PROCEDURE

All solutions containing stavudine must be prepared immediately before use and remain refrigerated until use.

Solution A: 0.77 g/L of [ammonium acetate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (5:95)

System suitability solution: 0.1 µg/mL each of [▲][USP Zidovudine Related Compound C RS](#) ^{▲2S} (USP41) and [▲][USP Zidovudine Related Compound D RS](#) ^{▲2S} (USP41) in [water](#)

Standard solution: 0.1 mg/mL of [USP Stavudine RS](#) in [water](#). Use sonication to dissolve before dilution.

Sample solution: Nominally 0.1 mg/mL of stavudine prepared as follows. Open NLT 3 Capsules, and dissolve the contents in [water](#). Dilute with water to obtain the final concentration.

Chromatographic system

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

Mode: LC

Detector: UV 268 nm. [▲]For *Identification A*, use a diode array detector in the range of 190–400 nm. ^{▲2S} (USP41)

Column: 4.6-mm × 3.3-cm; [▲]3-µm ^{▲2S} (USP41) packing [L1](#)

Flow rate: 0.7 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The retention time of the stavudine peak in the *Standard solution* is between 2.8 and 5.0 min.]

Suitability requirements

Resolution: NLT 2.0 between [▲]zidovudine related compound C ^{▲2S} (USP41) and [▲]zidovudine related compound D; zidovudine related compound C ^{▲2S} (USP41) is resolved from the void volume, *System suitability solution* ^{▲2S} (USP41)

Tailing factor: NMT 1.8, *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 the portion of Capsules 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 Stavudine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#)

Medium: [Water](#) 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Solution A and Mobile phase: Prepare as directed in the Assay.

Sample solution: ▲ Dilute with *Medium* to a concentration that is similar to the *Standard solution*. ▲_{2S} (USP41)

Standard solution: [USP Stavudine RS](#) in *Medium* with a concentration corresponding to that of the *Sample solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 3.3-cm; ▲3-μm ▲_{2S} (USP41) packing [L1](#)

Flow rate: 0.7 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

▲ ▲_{2S} (USP41)

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Determine the percentage of the labeled amount of stavudine ($C_{10}H_{12}N_2O_4$) dissolved, using the procedure set forth in the Assay, making any necessary modifications.

Tolerances: NLT 80% (Q) of the labeled amount of stavudine ($C_{10}H_{12}N_2O_4$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES**

Solution A, Mobile phase, System suitability solution, and Sample solution: Prepare as directed in the Assay.

Standard solution: 0.001 mg/mL of ▲ [USP Zidovudine Related Compound C RS](#). ▲_{2S} (USP41) Use sonication to dissolve before dilution.

Chromatographic system

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

Mode: LC

Detector: UV 268 nm

Column: 4.6-mm × 3.3-cm; ▲3-μm ▲_{2S} (USP41) packing [L1](#)

Flow rate: 0.7 mL/min

Injection volume: 20 μL

Run time: ▲ NLT ▲_{2S} (USP41) 2.5 times the retention time of the stavudine peak

System suitability

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