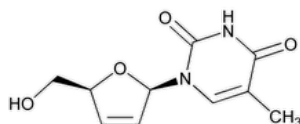


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-0FA0FB75-9AA2-427D-91BC-E4C7DABD7921_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M78160_04_01
 DOI Ref: as10z

© 2025 USPC
 Do not distribute

Stavudine



$C_{10}H_{12}N_2O_4$ 224.21

Thymidine, 2',3'-didehydro-3'-deoxy-

1-(2,3-Dideoxy-β-D-glycero-pent-2-enofuranosyl)thymine CAS RN®: 3056-17-5; UNII: B09LE4QFZF.

DEFINITION

Stavudine contains NLT 98.0% and NMT 102.0% of stavudine ($C_{10}H_{12}N_2O_4$), calculated on an anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **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

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

Solution A: 0.77 g/L of ammonium acetate

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

Standard solution: 0.02 mg/mL of [USP Stavudine RS](#) in water

Sample solution: 0.02 mg/mL of Stavudine in water

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 3.3-cm; 3-μm packing L1

Flow rate: 0.7 mL/min

Injection volume: 25 μL

System suitability

Sample: *Standard solution*

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

Suitability requirements

Column efficiency: NLT 800 theoretical plates

Tailing factor: NMT 1.6

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of stavudine ($C_{10}H_{12}N_2O_4$) in the portion of Stavudine 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 = concentration of Stavudine in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous, solvent-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%

• **ORGANIC IMPURITIES**

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

Solution B: Acetonitrile and *Solution A* (3.5:96.5)

Solution C: Acetonitrile and *Solution A* (25:75)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
10	100	0
20	0	100
30	0	100
35	100	0
40	100	0

System suitability solution: 0.50 mg/mL of [USP Stavudine System Suitability Mixture RS](#) in water

Sample solution: 0.5 mg/mL of Stavudine in water

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 2.1 mL/min

Injection volume: 10 μL

Run time: 2 times the retention time of the stavudine peak, or at least until the last impurity has eluted

System suitability

Sample: *System suitability solution*

[NOTE—The retention time of the main stavudine peak is 10.5 ± 2 min. The relative retention times for stavudine and thymine are listed in [Table 2](#).]

Suitability requirements

Resolution: NLT 1.15 between the thymidine epimer and thymidine; NLT 1.0 between stavudine and α-stavudine

Column efficiency: NLT 9500 theoretical plates

Capacity factor, k' : NLT 4

Analysis

Samples: *System suitability solution* and *Sample solution*

Calculate the percentage of thymine in the portion of Stavudine taken:

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