

Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2021
Document Type: USP Monographs
DocId: GUID-860EB43E-7AC0-4597-9D98-3845F2907004_2_en-US
DOI: https://doi.org/10.31003/USPNF_M79_02_01
DOI Ref: g3s4g

© 2025 USPC
Do not distribute

Add the following:

▲Abacavir, Lamivudine, and Zidovudine Tablets

DEFINITION

Abacavir, Lamivudine, and Zidovudine Tablets contain an amount of abacavir sulfate, lamivudine, and zidovudine equivalent to NLT 90.0% and NMT 110.0% each of the labeled amounts of abacavir ($C_{14}H_{18}N_6O$), lamivudine ($C_8H_{11}N_3O_3S$), and zidovudine ($C_{10}H_{13}N_5O_4$), respectively.

IDENTIFICATION

- **A.** The retention times of the major peaks of the *Sample solution* correspond to those of abacavir sulfate, lamivudine, and zidovudine from the *Standard solution*, as obtained in the Assay.
- **B.** The UV absorption spectra of the major peaks of the *Sample solution* correspond to those of abacavir sulfate, lamivudine, and zidovudine from the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: 1.9 g/L of [ammonium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 3.9.

Solution B: [Methanol](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	97	3
8	97	3
19	76	24
27	76	24
33	40	60
45	40	60

System suitability solution: Dissolve the contents of 1 vial of [USP Lamivudine Resolution Mixture C RS](#) in 2.5 mL of *Solution A*. [NOTE—One vial of [USP Lamivudine Resolution Mixture C RS](#) contains 0.8 mg of [USP Lamivudine Resolution Mixture C RS](#).]

Standard solution: 0.35 mg/mL of [USP Abacavir Sulfate RS](#), 0.15 mg/mL of [USP Lamivudine RS](#), and 0.30 mg/mL of [USP Zidovudine RS](#) in *Solution A*. Sonicate to dissolve prior to final dilution.

Sample stock solution: Nominally 3 mg/mL of abacavir, 1.5 mg/mL of lamivudine, and 3 mg/mL of zidovudine in *Solution A* prepared as follows. Transfer NLT 5 Tablets to a suitable volumetric flask. Add *Solution A* to about 50% of the final flask volume and shake for NLT 30 min to disperse the Tablets. Dilute with *Solution A* to volume. Pass through a suitable filter.

Sample solution: Nominally 0.30 mg/mL of abacavir, 0.15 mg/mL of lamivudine, and 0.30 mg/mL of zidovudine in *Solution A* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 270 nm. For *Identification B*, use a diode array detector in the range of 220–400 nm.

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for lamivudine-S-oxide and lamivudine-R-oxide, in relation to the lamivudine peak, are 0.36 and 0.40, respectively; the relative retention times for lamivudine diastereomer and lamivudine are 0.96 and 1.0, respectively, *System suitability solution*.]

Suitability requirements

Resolution: NLT 1.2 between lamivudine carboxylic acid and lamivudine-S-oxide; NLT 1.2 between lamivudine diastereomer and lamivudine, *System suitability solution*

Relative standard deviation: NMT 2.0% each for abacavir, lamivudine, and zidovudine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of abacavir ($C_{14}H_{18}N_6O$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of abacavir from the *Sample solution*

r_S = peak response of abacavir from the *Standard solution*

C_S = concentration of [USP Abacavir Sulfate RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of abacavir multiplied by 2, 572.66

M_{r2} = molecular weight of abacavir sulfate, 670.74

Calculate the percentage of the labeled amount of lamivudine ($C_8H_{11}N_3O_3S$) in the portion of Tablets taken:

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

r_U = peak response of lamivudine from the *Sample solution*

r_S = peak response of lamivudine from the *Standard solution*

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

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

Calculate the percentage of the labeled amount of zidovudine ($C_{10}H_{13}N_5O_4$) in the portion of Tablets taken:

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

r_U = peak response of zidovudine from the *Sample solution*

r_S = peak response of zidovudine 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% each of the labeled amounts of abacavir, lamivudine, and zidovudine

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#), degassed; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution 1: 0.35 mg/mL of [USP Abacavir Sulfate RS](#) in *Medium*. Sonicate to dissolve prior to final dilution.

Standard solution 2: 0.15 mg/mL of [USP Lamivudine RS](#) in *Medium*. Sonicate to dissolve prior to final dilution.

Standard solution 3: 0.30 mg/mL of [USP Zidovudine RS](#) in *Medium*. Sonicate to dissolve prior to final dilution.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Wavelength range: 240–320 nm

Cell: 0.05 cm

Blank: *Medium*

Analysis: The calculations of the percentages dissolved are performed using multi-component analysis software.



Documents

Document Sharing Hub