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Lamivudine and Zidovudine Tablets

DEFINITION

Lamivudine and Zidovudine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of lamivudine ($C_8H_{11}N_3O_3S$) and zidovudine ($C_{10}H_{13}N_5O_4$).

IDENTIFICATION

- **A.** The retention times of the lamivudine and zidovudine peaks of the *Sample solution* correspond to those 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-May-2022)

ASSAY

Change to read:

• **PROCEDURE**

- Solution A:** 25 mM of ammonium acetate. Adjust with glacial acetic acid to a pH of 4.0.
- Solution B:** Methanol
- Solution C:** Acetonitrile
- Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	95	5	0
15.0	95	5	0
30.0	70	30	0
38.0	70	30	0
38.1	0	0	100
45.0	0	0	100
45.1	95	5	0
60.0	95	5	0

- Diluent:** *Solution A* and *Solution B* (19:1)
- System suitability solution:** 0.17 mg/mL of [USP Lamivudine Resolution Mixture B RS](#) in *Diluent*
- Standard solution:** 0.15 mg/mL of [USP Lamivudine RS](#) and 0.30 mg/mL of [USP Zidovudine RS](#) in *Diluent*
- Sample stock solution:** Transfer a counted number of Tablets, equivalent to 1500 mg of zidovudine and 750 mg of lamivudine, to a 500-mL volumetric flask. Add 250 mL of water and disintegrate the Tablets completely by shaking for a minimum of 15 min. Dilute with water to volume, and mix.
- Sample solution:** Pass a portion of the *Sample stock solution* through a filter of 0.45-µm pore size, discarding the first 2–3 mL. Further dilute the filtrate to obtain 0.15 mg/mL of lamivudine and 0.30 mg/mL of zidovudine in *Diluent*.
- 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 200–400 nm. ▲ (USP 1-May-2022)

Column: 3-mm × 25-cm; packing L1

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—The relative retention times for lamivudine diastereomer and lamivudine are 0.50 and 0.52, respectively.]

Suitability requirements

Resolution: NLT 1.5 between lamivudine diastereomer and lamivudine, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lamivudine ($C_8H_{11}N_3O_3S$) and 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 or lamivudine from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Test 1

Medium: 0.1 N hydrochloric acid; 900 mL, deaerated

Apparatus 2: 75 rpm

Time: 15 min

Lamivudine ▲standard ▲ (USP 1-May-2022) **solution:** 0.167 mg/mL of [USP Lamivudine RS](#) in *Medium*. [NOTE—Prepare in duplicate.]

Zidovudine ▲standard ▲ (USP 1-May-2022) **solution:** 0.333 mg/mL of [USP Zidovudine RS](#) in *Medium*. [NOTE—Prepare in duplicate.]

Sample solution: Pass a portion of the solution under test through a suitable filter (PTFE, PVDF, or equivalent) of 0.45-µm pore size.

Detector: UV 240–300 nm

Blank: *Medium*

Cell: 0.02 cm, flow-cell

Analysis: The calculations of the percentages dissolved are done using a multicomponent analysis software.

Tolerances: NLT 85% (Q) of the labeled amount of zidovudine and lamivudine is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Buffer solution: 7.7 g/L of ammonium acetate in water

Mobile phase: Acetonitrile and *Buffer solution* (1:9)

Standard stock solution: 1.4 mg/mL of [USP Lamivudine RS](#) and 2.8 mg/mL of [USP Zidovudine RS](#) in *Medium*. A small amount of methanol, NMT 20% of the final volume, can be used to dissolve both compounds.

Standard solution: 0.168 mg/mL of lamivudine and 0.336 mg/mL of zidovudine in *Medium* from the *Standard stock solution*

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

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 15-cm; packing L1

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements