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Abacavir and Lamivudine Tablets

DEFINITION

Abacavir and Lamivudine Tablets contain an amount of abacavir sulfate and lamivudine equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of abacavir (C₁₄H₁₈N₆O) and NLT 90.0% and NMT 110.0% of the labeled amount of lamivudine (C₈H₁₁N₃O₃S), respectively.

IDENTIFICATION

- **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

- Diluent:** 0.1 N hydrochloric acid
Solution A: Water and trifluoroacetic acid (2000:1)
Solution B: Acetonitrile, methanol, and trifluoroacetic acid (1000:1000:1)
Mobile phase: See [Table 1](#). [NOTE—Return to original conditions and re-equilibrate the system for about 7 min.]

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
4	100	0
12	70	30
12.1	40	60
13.1	40	60
13.2	100	0

- System suitability solution:** Dissolve the contents of one vial of [USP Lamivudine Resolution Mixture C RS](#) in 2.5 mL of *Diluent*. [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](#) and 0.15 mg/mL of [USP Lamivudine RS](#) in *Diluent*. Sonicate to dissolve prior to final dilution.
Sample stock solution: Nominally 3 mg/mL of abacavir and 1.5 mg/mL of lamivudine in *Diluent* prepared as follows. Transfer NLT 5 Tablets to a suitable volumetric flask. Add *Diluent* to about 50% of the final volume and shake for NMT 30 min to disperse the Tablets. Dilute with *Diluent* to volume. Pass through a suitable filter.
Sample solution: Nominally 0.3 mg/mL of abacavir and 0.15 mg/mL of lamivudine in *Diluent* from *Sample stock solution*

Chromatographic system

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

- Mode:** LC
Detector: UV 270 nm
Column: 4.6-mm × 15-cm; 3.5-μm packing L1
Column temperature: 40°
Flow rate: 1.5 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 0.31 and 0.36, respectively; the relative retention times for lamivudine diastereomer and lamivudine are 0.88 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.0 between lamivudine-S-oxide and lamivudine-R-oxide; NLT 1.0 between lamivudine diastereomer and lamivudine, *System suitability solution*

Relative standard deviation: NMT 1.5% each for abacavir and lamivudine, *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

Acceptance criteria: 90.0%–110.0% of the labeled amount of abacavir

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)

Acceptance criteria: 90.0%–110.0% of the labeled amount of lamivudine

PERFORMANCE TESTS• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution 1: 0.79 mg/mL of [USP Abacavir Sulfate RS](#) in *Medium*. Sonicate to dissolve prior to final dilution.

Standard solution 2: 0.33 mg/mL of [USP Lamivudine 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: 240–320 nm

Cell length: 0.2 mm

Blank: *Medium*

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

Tolerances: NLT 80% (Q) of the labeled amount of abacavir and lamivudine is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements**IMPURITIES**• **ORGANIC IMPURITIES**

Diluent, Solution A, Solution B, Mobile phase, System suitability solution, Standard solution, Sample stock solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual abacavir related impurity and each unspecified impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each abacavir related impurity or unspecified impurity