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Abacavir Tablets

DEFINITION
Abacavir Tablets contain Abacavir Sulfate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of abacavir ($C_{14}H_{18}N_6O$).

IDENTIFICATION
• **A.** 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**

Diluent: 1.0 mL of phosphoric acid in 1 L of water

Solution A: Trifluoroacetic acid and water (0.05:99.95)

Solution B: Methanol and water (85:15)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
20	70	30
35	10	90
40	10	90
41	95	5
50	95	5

System suitability solution: 0.2 mg/mL of USP Abacavir System Suitability Mixture RS in *Diluent*

Standard solution: 0.21 mg/mL of abacavir sulfate in *Diluent* (equivalent to 0.18 mg/mL of abacavir), from USP Abacavir Sulfate RS

Sample stock solution: Transfer the equivalent to 1500 mg of abacavir, from a portion of Tablets, into a 250-mL volumetric flask. Add 150 mL of *Diluent*. Shake mechanically for 45 min. Dilute with *Diluent* to volume. Pass a portion through a suitable filter of 0.45-µm or finer pore size. Discard the first 3 mL of the filtrate.

Sample solution: 0.18 mg/mL of abacavir in *Diluent* using the filtrate obtained in the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between abacavir and *trans*-abacavir, *System suitability solution*

Relative standard deviation: NMT 2.0%, *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 abacavir sulfate 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%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 15 min

Standard solution: 0.39 mg/mL of USP Abacavir Sulfate RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Instrumental conditions

Mode: UV

Analytical wavelength: 254 nm

Blank: *Medium*

Calculate the percentage of the labeled amount of abacavir ($C_{14}H_{18}N_6O$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_{r1}/M_{r2}) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

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

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

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of abacavir ($C_{14}H_{18}N_6O$) 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 solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Analysis

[Note—Record the chromatograms for 2.5 times the retention time of abacavir.]

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each impurity 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)

F = relative response factor for each impurity (see *Table 2*)

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

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

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cyclopropyldiaminopurine abacavir[a]	0.57	1.4	0.2
Descyclopropyl abacavir[b]	0.68	1.0	0.2
Abacavir	1.0	—	—
trans-Abacavir[c,d]	1.04	—	—
O-Pyrimidine derivative abacavir[d,e]	1.24	—	—
Any other individual impurity	—	1.0	0.2
Total impurities	—	—	1.0

[a] N^6-Cyclopropyl-9*H*-purine-2,6-diamine.

[b] [(1*S*,4*R*)-4-(2,6-Diamino-9*H*-purin-9-yl)-cyclopent-2-enyl]methanol.

[c] {(1*R*,4*R*)-4-[2-Amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-cyclopent-2-enyl}methanol.

[d] Process impurity monitored in the drug substance and not included in the total impurities.

[e] N^6-Cyclopropyl-9-{(1*R*,4*S*)-4-[(2,5-diamino-6-chloropyrimidin-4-yloxy)methyl]cyclopent-2-enyl}-9*H*-purine-2,6-diamine.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.

• **USP Reference Standards** ⟨11⟩

USP Abacavir Sulfate RS

USP Abacavir System Suitability Mixture RS

—A mixture of abacavir sulfate and *trans*-abacavir.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ABACAVIR TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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