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Abacavir Oral Solution

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DEFINITION

Abacavir Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of abacavir (C₁₄H₁₈N₆O).

IDENTIFICATION

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**

Solution A: [Trifluoroacetic acid](#) and [water](#) (0.05:99.95)

Solution B: [Methanol](#) and [water](#) (17:3)

Diluent: 1 mL of [phosphoric acid](#) diluted with [water](#) to 1000 mL

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	95	5
20	70	30
35	10	90
40	10	90
41	0	100
50	0	100
51	95	5
55	95	5

System suitability solution: 0.2 mg/mL of [USP Abacavir System Suitability Mixture RS](#) in *Diluent*

Standard solution: 0.46 mg/mL of [USP Abacavir Sulfate RS](#) in *Diluent*

Sample solution: Equivalent to 0.4 mg/mL of abacavir in *Diluent*, from Oral Solution. [NOTE—Sonicate, if necessary.]

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; 5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 0.8 mL/min

Injection size: 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 abacavir (C₁₄H₁₈N₆O) in the portion of Oral Solution taken:

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

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

r_S = peak area 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%

PERFORMANCE TESTS

- **DELIVERABLE VOLUME (698):** Meets the requirements

IMPURITIES

ORGANIC IMPURITIES

PROCEDURE

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

Sensitivity solution: 0.2 µg/mL of [USP Abacavir Sulfate RS](#) in *Diluent*, from the *Standard solution*. [NOTE—The concentration of this solution is 0.05% of the nominal concentration of the *Sample solution*.]

Analysis

Samples: *Diluent, Standard solution, Sample solution, and Sensitivity solution.* [NOTE—In the *Sample solution* disregard any peaks corresponding to peaks identified in the *Diluent* and any peak with a peak area less than the abacavir peak area in the *Sensitivity solution*.]

Calculate the percentage of each impurity in the portion of Oral Solution 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 area of abacavir from the *Sample solution*

r_S = peak area 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 from [Impurity Table 1](#)

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

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

Acceptance criteria

Individual impurities: See [Impurity Table 1](#).

Total impurities: NMT 2.0%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cyclopropyldiaminopurine abacavir ^a	0.57	1.4	0.3
Descyclopropyl abacavir ^b	0.68	1.0	0.8
Abacavir	1.00	—	—