Official Monographs for USP 41

Abacavir Oral Solution

DEFINITION
Abacavir Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of abacavir ($C_{14}H_{18}N_6O$).

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
●	95	5
●	95	5
●	95	5
●	95	5
●	95	5
●	95	5
●	95	5
●	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 $C_{14}H_{18}N_6O$ 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 mutiplied 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 mutiplied 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%