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	—	—
trans-Abacavir[c]	1.04	1.0	—
Any individual unspecified impurity	—	1.0	0.2

[a] *N*6-Cyclopropyl-*9H*-purine-2,6-diamine.
[b] [(1*S*,4*R*)-4-(2,6-Diamino-*9H*-purin-9-yl)cyclopent-2-enyl]methanol.
[c] {(1*R*,4*R*)-4-[2-Amino-6-(cyclopropylamino)-*9H*-purin-9-yl]-cyclopent-2-enyl}methanol. It is a process impurity and monitored in the drug substance.

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS** ⟨61⟩ and **TESTS FOR SPECIFIED MICROORGANISMS** ⟨62⟩: The total aerobic microbial count does not exceed 100 cfu/mL, and the total combined molds and yeast count does not exceed 10 cfu/mL. It also meets the requirement for absence of *Escherichia coli*.
- **PH** ⟨791⟩: 3.8–4.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Abacavir Sulfate RS
  USP Abacavir System Suitability Mixture RS
  A mixture containing abacavir sulfate and *trans*-abacavir

USP Monographs

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.