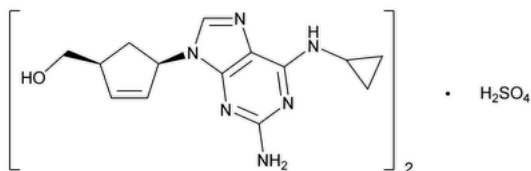


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Abacavir Sulfate



$(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$ 670.74

2-Cyclopentene-1-methanol, 4-[2-amino-6-(cyclopropyl amino)-9H-purin-9-yl]-, (1S-cis)-, sulfate (salt) (2:1);

(1S,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1) CAS RN®: 188062-50-2; UNII: J220T4J9Q2.

DEFINITION

Abacavir Sulfate contains NLT 97.0% and NMT 102.0% of $(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$, calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *System suitability solution*, obtained as directed in the test for *Organic Impurities, Procedure 2*.
- **C.** [IDENTIFICATION TESTS—GENERAL, Sulfate \(191\)](#).

Sample solution: 5 mg/mL

ASSAY

PROCEDURE

Mobile phase: Acetonitrile, phosphoric acid, and water (20:1:180)

Standard solution: 0.04 mg/mL of [USP Abacavir Sulfate RS](#) in water

Sample solution: 0.04 mg/mL of Abacavir Sulfate in water

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 5-cm; 5-μm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection size: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$ in the portion of Abacavir Sulfate taken:

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

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 = concentration of Abacavir Sulfate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

INORGANIC IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.2%

ORGANIC IMPURITIES

• PROCEDURE 1: RELATED COMPOUNDS

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

Solution B: Methanol and water (17:3)

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	95	5
20	70	30
35	10	90
35.1	95	5
50	95	5

System suitability solution: 0.25 mg/mL of [USP Abacavir Related Compounds Mixture RS](#) in water

Sample solution: 0.25 mg/mL of Abacavir Sulfate in water

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: 1 mL/min

Injection size: 20 μL

System suitability

Sample: System suitability solution

Suitability requirements

Resolution: NLT 1.5 between abacavir and *trans*-abacavir

Analysis

Sample: Sample solution

Calculate the percentage of each impurity in the portion of Abacavir Sulfate taken:

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

r_U = peak area of each impurity from the Sample solution

r_T = sum of the areas of all the peaks from the Sample solution

Acceptance criteria

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

Total impurities: NMT 0.8%

Impurity Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Descyclopropyl abacavir ^a	0.65	0.2
Abacavir	1.00	—
<i>trans</i> -Abacavir ^b	1.04	0.2