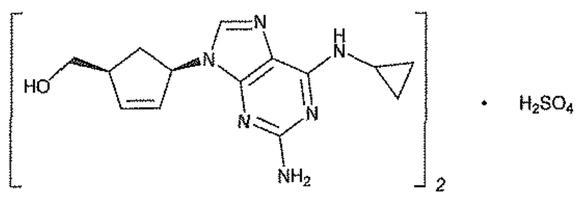
Uracil: Pyrimidine-2,4(1*H*,3*H*)-dione.
$C_4H_4N_2O_2$ 112.09
Lamivudine-uracil derivative: 1-[(2*RS*,5*SR*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]uracil.
$C_8H_{10}N_2O_4S$ 230.24
Cytosine: 4-Aminopyrimidin-2(1*H*)-one.
$C_4H_5N_3O$ 111.10
Lamivudine-*S*-sulfoxide: 1-[(2*R*,3*S*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine *S*-oxide.
$C_8H_{11}N_3O_4S$ 245.26
Lamivudine-*R*-sulfoxide: 1-[(2*R*,3*R*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine *S*-oxide.
$C_8H_{11}N_3O_4S$ 245.26
Lamivudine carboxylic acid: (2*RS*,5*SR*)-5-(Cytosine-1-yl)-1,3-oxathiolane-2-carboxylic acid.
$C_8H_9N_3O_4S$ 243.24
Lamivudine diastereomer: 1-[(2*S*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine.
$C_8H_{11}N_3O_3S$ 229.26
Salicylic acid: 2-Hydroxybenzoic acid.
$C_7H_6O_3$ 138.12

## Abacavir Sulfate




$(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$ *670.74*
2-Cyclopentene-1-methanol, 4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-, (1*S*-*cis*)-, sulfate (salt) (2:1);
(1*S*,4*R*)-4-[2-Amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1) [188062-50-2].

### 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
- **A. Infrared Absorption** ⟨197K⟩
- **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*