

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 | — |
| trans-Abacavir ^b | 1.04 | 0.2 |
| O-Pyrimidine derivative abacavir ^c | 1.33 | 0.2 |
| t-Butyl derivative abacavir ^d | 1.67 | 0.2 |
| Any unspecified impurity | — | 0.1 |

^a [(1S,4R)-4-(2,6-Diamino-9H-purin-9-yl)cyclopent-2-enyl]methanol.

^b [(1R,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-cyclopent-2-enyl]methanol.

^c N⁶-Cyclopropyl-9-[(1R,4S)-4-[(2,5-diamino-6-chloropyrimidin-4-yl-oxy)methyl]cyclopent-2-enyl]-9H-purine-2,6-diamine.

^d 9-[(1R,4S)-4-(tert-Butoxymethyl)cyclopent-2-enyl]-N⁶-cyclopropyl-9H-purine-2,6-diamine.

• PROCEDURE 2: ENANTIOMERIC PURITY

Solution A: Heptane, 2-propanol, and diethylamine (850:150:1).

Solution B: Heptane and 2-propanol (1:1)

Mobile phase: See the gradient table below.

| Time (min) | Solution A (%) | Solution B (%) | Flow Rate (mL/min) |
|------------|----------------|----------------|--------------------|
| 0 | 100 | 0 | 1.0 |
| 25 | 100 | 0 | 1.0 |
| 27 | 0 | 100 | 0.8 |
| 37 | 0 | 100 | 0.8 |
| 39 | 100 | 0 | 1.0 |
| 55 | 100 | 0 | 1.0 |

Diluent: Methanol and trifluoroacetic acid (200:1)

System suitability solution: Transfer a quantity of USP Abacavir Stereoisomers Mixture RS to a suitable volumetric flask, add a volume of *Diluent* equivalent to 30% of the final volume, and sonicate until the solid is fully dissolved. Add a volume of 2-propanol equivalent to about 30% of the final volume, mix, and dilute with heptane to volume to obtain 0.4 mg/mL of USP Abacavir Stereoisomers Mixture RS.

Sample solution: Transfer 4 mg of Abacavir Sulfate to a 10-mL volumetric flask. Add 3 mL of *Diluent*, and sonicate until the solid is fully dissolved. Add 3 mL of 2-propanol, mix, and dilute with heptane to volume.

Chromatographic system

(See *Chromatography* (621), *System Suitability*.)

Mode: LC

Detector: UV 286 nm

Column: 4.6-mm × 25-cm; 10-μm packing L51

Column temperature: 30°

Injection size: 20 μL

System suitability

[NOTE—The relative retention times for *trans*-abacavir, abacavir enantiomer, and abacavir are 0.8, 0.9, and 1.0, respectively.]

Sample: System suitability solution

Suitability requirements

Resolution: NLT 1.0 between *trans*-abacavir and abacavir enantiomer; NLT 1.5 between abacavir enantiomer and abacavir

Analysis

Sample: Sample solution

Calculate the percentage of abacavir enantiomer in the portion of Abacavir Sulfate taken:

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

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

r_T = total peak areas of abacavir and abacavir enantiomer from the *Sample solution*

Acceptance criteria

Individual impurities: NMT 0.3% of abacavir enantiomer

SPECIFIC TESTS

- **WATER DETERMINATION, Method 1c (921):** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at room temperature.

• USP REFERENCE STANDARDS (11)

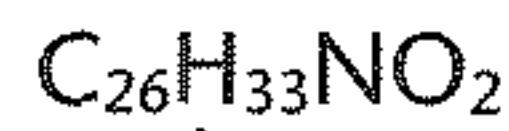
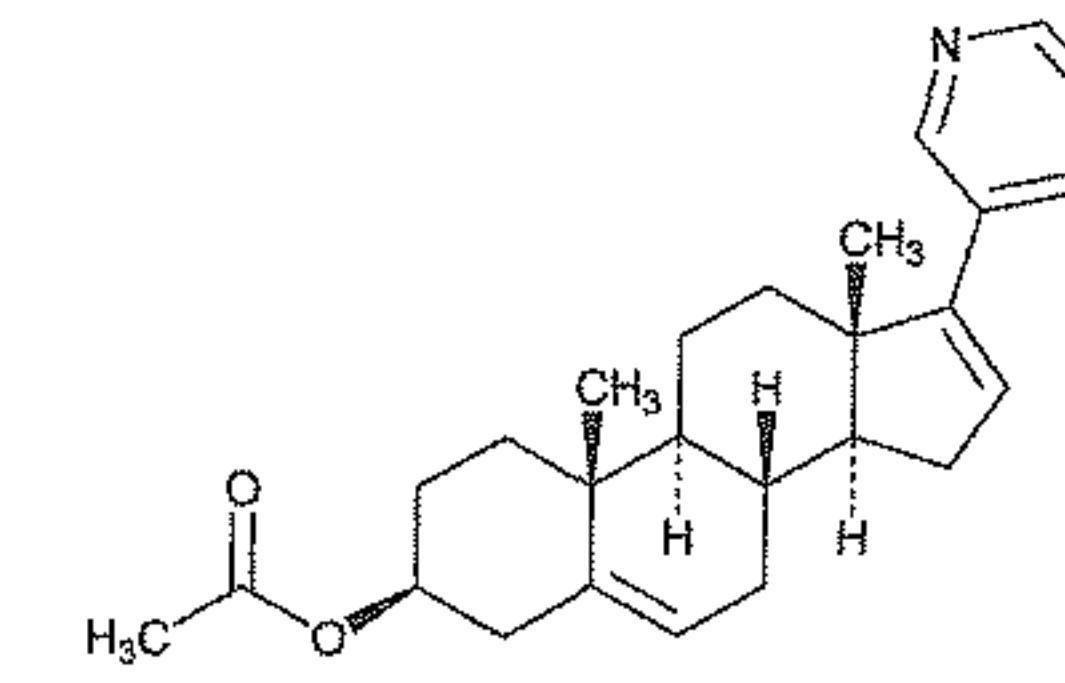
USP Abacavir Sulfate RS

USP Abacavir Stereoisomers Mixture RS

A mixture of abacavir sulfate, abacavir enantiomer, and *trans*-abacavir.

USP Abacavir Related Compounds Mixture RS

A mixture of abacavir glutarate, O-pyrimidine derivative abacavir, descyclopropyl abacavir, *trans*-abacavir, and *t*-butyl derivative abacavir.

Abiraterone Acetate

Androsta-5,16-dien-3-ol, 17-(3-pyridinyl)-, acetate (ester), (3β);

17-(Pyridin-3-yl)androsta-5,16-dien-3β-yl acetate [154229-18-2].

DEFINITION

Abiraterone Acetate contains NLT 98.0% and NMT 102.0% of abiraterone acetate ($C_{26}H_{33}NO_2$), calculated on the as-is basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION (197K):**

- **B.** 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: 10 mM of ammonium acetate in water

Mobile phase: See *Table 1*.

Table 1

| Time (min) | Solution A (%) | Acetonitrile (%) | Ethanol (%) |
|------------|----------------|------------------|-------------|
| 0 | 50 | 20 | 30 |
| 40 | 15 | 55 | 30 |
| 47 | 0 | 20 | 80 |
| 58 | 0 | 20 | 80 |