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Abacavir Oral Solution

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-abacavir-os-20220225.

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
20	70	30
35	10	90
40	10	90
41	0	100
50	0	100
51	95	5
55	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 abacavir ($C_{14}H_{18}N_6O$) 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%

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	—	—

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
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*.

Change to read:

• **pH ⟨791⟩:** 3.8–▲4.8▲ (RB 1-Mar-2022)

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ABACAVIR ORAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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