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Edition: BP 2025 (Ph. Eur. 11.6 update)

Abacavir Oral Solution

General Notices

Action and use

Nucleoside reverse transcriptase inhibitor; antiviral (HIV).

DEFINITION

Abacavir Oral Solution is a solution containing Abacavir Sulfate in a suitable flavoured vehicle.

The oral solution complies with the requirements stated under Oral Liquids and with the following requirements.

Content of abacavir, $C_{28}H_{36}N_{12}O_2$

92.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *methanol (50%)*.
(1) Dilute the oral solution to produce a solution containing the equivalent of 0.2% w/v of abacavir and filter if necessary.
(2) 0.23% w/v of *abacavir sulfate BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}* (Merck silica gel 60 F_{254} HPTLC plates are suitable). Before use, stand the plate in *methanol*, allowing the solvent front to ascend to the top of the plate, remove and heat the plate at 105° for 1 hour.
(b) Use the mobile phase described below.
(c) Apply 1 µL of each solution.
(d) Develop the plate to 7 cm.
(e) After removal of the plate, dry in a current of warm air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

5 volumes of *methanol*, 6 volumes of 13.5M *ammonia*, 34 volumes of *dichloromethane* and 55 volumes of *acetone*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to abacavir in the chromatogram obtained with solution (2).

TESTS

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Acidity

pH, 3.8 to 4.5, Appendix V L.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in 0.1% v/v of *orthophosphoric acid*.

(1) Dilute the oral solution to produce a solution containing the equivalent of 0.02% w/v of abacavir and filter if necessary.
(2) Dilute 1 volume of solution (1) to 100 volumes.
(3) Dilute 1 volume of solution (2) to 5 volumes.
(4) Dissolve 2.5 mg of *abacavir for peak identification EPCRS*(containing impurities B and D) in 10.0 mL.
(5) 0.02% w/v of a*bacavir impurity standard BPCRS*.
(6) 0.0001% w/v of *abacavir impurity 1 BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 3.9 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Waters Symmetry Shield C18 is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 0.8 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 254 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase A 0.05% v/v of *trifluoroacetic acid*.

Mobile phase B *methanol (85%)*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-20	95→70	5→30	linear gradient
20-35	70→10	30→90	linear gradient
35-40	10	90	isocratic
40-41	10→0	90→100	column wash
41-50	0	100	column wash
50-51	0→95	100→5	column wash
51-55	95	5	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4):

the chromatogram closely resembles the reference chromatogram supplied with *abacavir for peak identification EPCRS*;

the *resolution* between the peaks due to abacavir and abacavir impurity D is at least 1.5.

LIMITS

Identify any peak in the chromatogram obtained with solution (1) corresponding to impurity C using the chromatogram obtained with solution (5) and the chromatogram supplied with a*bacavir impurity standard BPCRS*.

In the chromatogram obtained with solution (1):

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the area of any peak corresponding to abacavir impurity C is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1.0%);

the area of any peak corresponding to abacavir impurity 1 is not greater than the area of the peak in the chromatogram obtained with solution (6) (0.5%);

the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.2%);

the sum of the areas of all secondary peaks is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (2.0%).

Disregard any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with solution (3) (0.1%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in 0.1% v/v of *orthophosphoric acid*.

(1) Dilute the oral solution to produce a solution containing the equivalent of 0.02% w/v of abacavir and filter if necessary.
(2) 0.023% w/v of *abacavir sulfate BPCRS*.
(3) Dissolve 2.5 mg of *abacavir for peak identification EPCRS*(containing impurities B and D) in 10.0 mL.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to abacavir and abacavir impurity D is at least 1.5.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

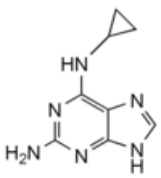
Calculate the content of $C_{28}H_{36}N_{12}O_2$ in the oral solution from the chromatograms obtained using the declared content of $C_{28}H_{36}N_{12}O_2$ in *abacavir sulfate BPCRS*.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of abacavir.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Abacavir Sulfate and the following.



1. N^6-cyclopropyl-1*H*-purine-2,6-diamine.

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