

Certificate

ABACAVIR SYSTEM SUITABILITY MIXTURE

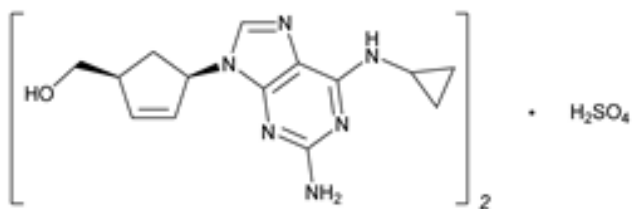
(A mixture containing abacavir sulfate and trans-abacavir)

USP Catalog No.: 1000500

USP Lot No.: R066P0

Abacavir Sulfate

((1S,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1))



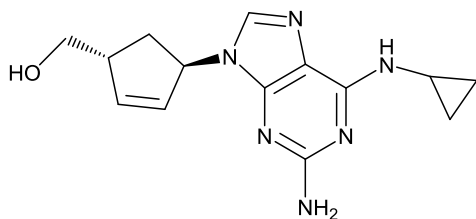
CAS No.: 188062-50-2

Molecular Formula: $(C_{14}H_{18}N_6O)_2 \cdot H_2SO_4$

Molecular Weight: 670.74

trans-Abacavir

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



CAS No.: 1443421-67-7

Molecular Formula: $C_{14}H_{18}N_6O$

Molecular Weight: 286.33

LABEL TEXT

For use with specified USP compendial tests.
Not for use as a drug. See USP prior to use
at www.usp.org/sds.



USP REFERENCE STANDARD

ABACAVIR SYSTEM SUITABILITY MIXTURE 15 mg

(A mixture containing abacavir sulfate and trans-abacavir)

Danger! May cause an allergic skin reaction. Causes serious eye damage. Suspected of causing genetic defects. May cause cancer. Suspected of damaging fertility or the unborn child.

Do not dry. See USP certificate for description of the mixture components and the chromatographic profile. Keep container tightly closed. Protect from light. Store in a refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
Cat. No. 1000500 Material mfd. in United Kingdom

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth
Quality Assurance

Calculation Value

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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Typical Chromatogram

USP Abacavir System Suitability Mixture RS

Catalog Number: 1000500

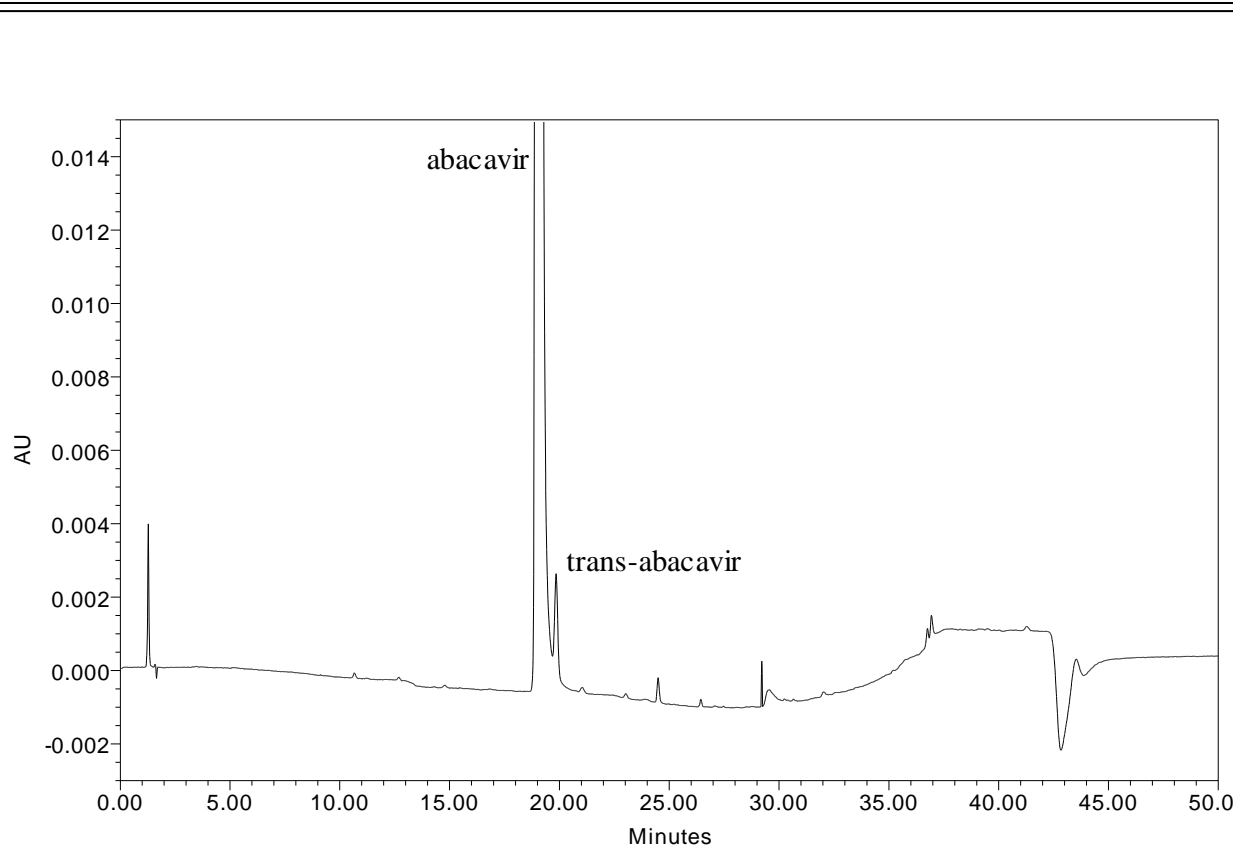
Lot: R066P0

Monograph: Abacavir Tablets

Publication: USP-NF

Test: Organic Impurities

Sample: System Suitability Solution



This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.