

Certificate

ENTECAVIR SYSTEM SUITABILITY MIXTURE

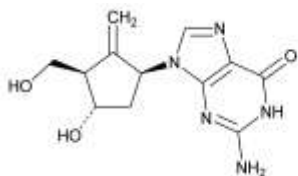
(A mixture containing entecavir 1-epimer (0.2%), entecavir (99.6%), 8-hydroxy entecavir (0.1%), and 8-methoxy entecavir (0.1%))

USP Catalog No.: 1235988

USP Lot No.: F006K1

Entecavir anhydrous

(9-[(1S,3R,4S)-4-Hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine)



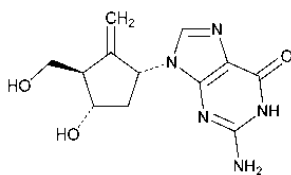
CAS No.: 142217-69-4

Molecular Formula: C₁₂H₁₅N₅O₃

Molecular Weight: 277.28

Entecavir 1-epimer

(9-[(1R,3R,4S)-4-Hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine)



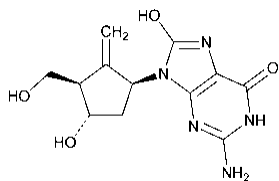
CAS No.: N/A

Molecular Formula: C₁₂H₁₅N₅O₃

Molecular Weight: 277.28

8-Hydroxy Entecavir

(8-Hydroxy-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine)



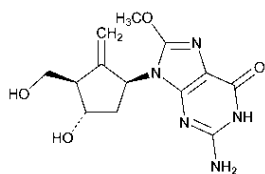
CAS No.: N/A

Molecular Formula: C₁₂H₁₅N₅O₄

Molecular Weight: 293.28

8-Methoxy Entecavir

(8-Methoxy-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine)



CAS No.: N/A

Molecular Formula: C₁₃H₁₇N₅O₄

Molecular Weight: 307.31

LABEL TEXT

USP REFERENCE STANDARD

ENTECAVIR SYSTEM SUITABILITY MIXTURE 15 mg

Warning! Harmful if swallowed. Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.

(This is a mixture containing entecavir 1-epimer (0.2%), entecavir (99.6%), 8-hydroxy entecavir (0.1%), and 8-methoxy entecavir (0.1%))

Labeled for qualitative use. This is a mixture containing entecavir 1-epimer, entecavir, 8-hydroxy entecavir, and 8-methoxy entecavir. Keep in a tightly closed container. Store in a refrigerator.

USP, 12601 Twintbrook Pkwy, Rockville, MD, +1-301-851-0666
Cat. No. 1235988 Material mfd. in United States

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

Lot: F006K1

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. 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.

LEGAL NOTICE

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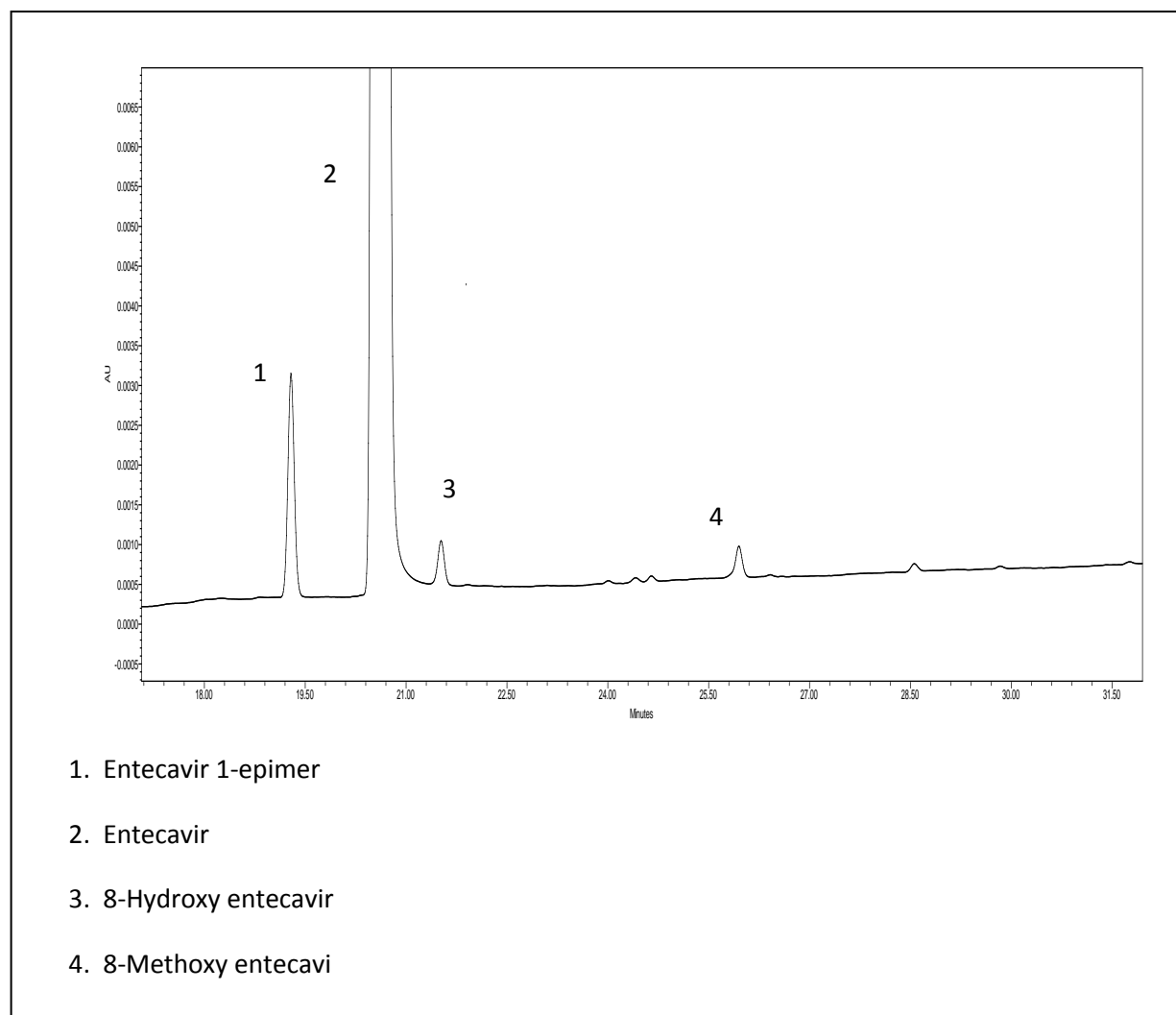
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Typical Chromatogram

Entecavir System Suitability Mixture

Catalog Number: 1235988
Lot: F006K1
Monograph: Entecavir
Publication: USP 39 / NF 34
Test: Organic Impurities
Sample: System suitability solution



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