

Certificate

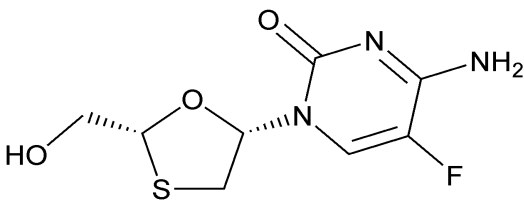
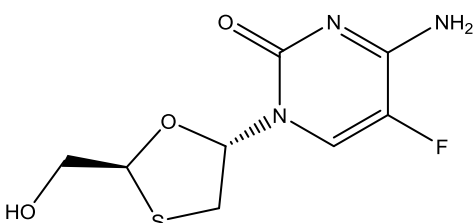
EMTRICITABINE SYSTEM SUITABILITY MIXTURE A

(A mixture consisting of about 98% emtricitabine and about 2% emtricitabine 1st 5-epimer)

USP Catalog No.: 1235128

USP Lot No.: R039Y0

Only compendial components as listed in the monograph are shown below

<u>Emtricitabine</u> (5-Fluoro-1-[(2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine)	
	CAS No.: 143491-57-0
	Molecular Formula: C ₈ H ₁₀ FN ₃ O ₃ S
	Molecular Weight: 247.25
<u>Emtricitabine 1st 5-Epimer</u> (5-Fluoro-1-[(2S,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine)	
	CAS No.: 145416-34-8
	Molecular Formula: C ₈ H ₁₀ FN ₃ O ₃ S
	Molecular Weight: 247.25

LABEL TEXT

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

USP REFERENCE STANDARD

EMTRICITABINE SYSTEM SUITABILITY MIXTURE A 15 mg

This is a mixture consisting of about 98% emtricitabine and about 2% emtricitabine 1st 5-epimer. Do not dry. See USP Certificate for additional information. Keep container tightly closed. Protect from light. Store in a refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT. NO. 1235128

Material mfd. in India

LOT: R039Y0



Jeri L. Ioth

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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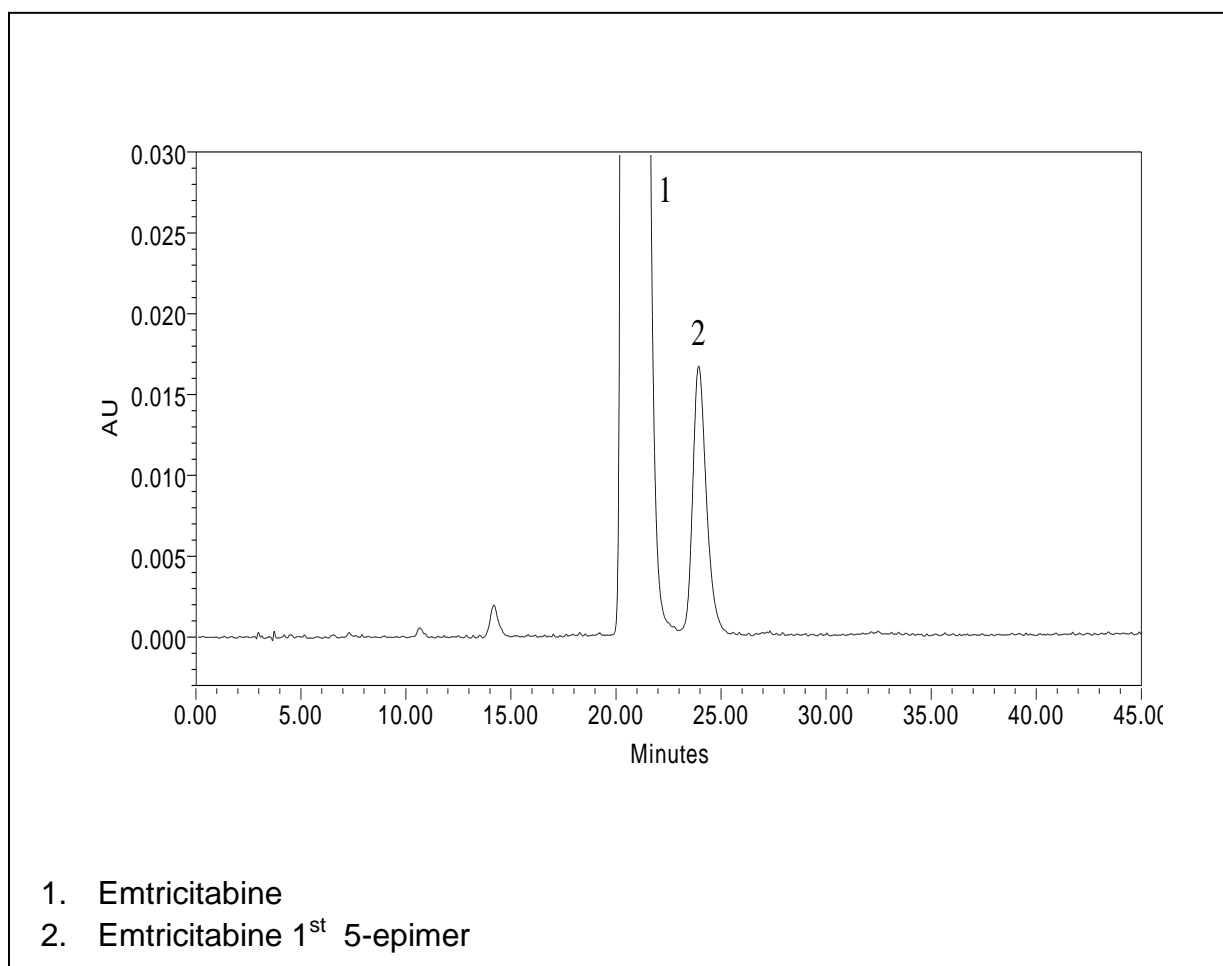
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Typical Chromatogram

USP Emtricitabine System Suitability Mixture A RS

Catalog Number: 1235128
Lot: R039Y0
Monograph: Emtricitabine
Publication: USP Authorized Pending Monograph, Version 1
Test: Organic Impurities , Procedure 1
Sample: System Suitability Solution



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