

Certificate

ATAZANAVIR SYSTEM SUITABILITY MIXTURE

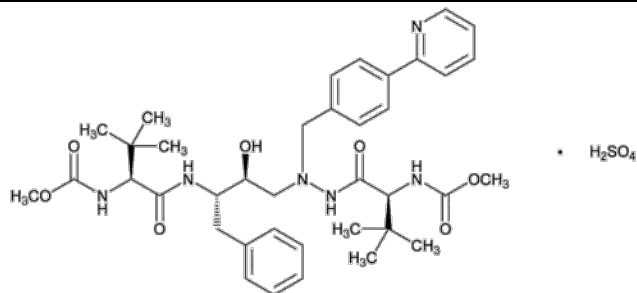
(A mixture of atazanavir sulfate, atazanavir R, S, S, S,-diastereomer and atazanavir S,R,S,S diastereomer)

USP Catalog No.: 1044345

USP Lot No.: F015B1

Component1 (ATAZANAVIR SULFATE)

(Dimethyl (3S,8S,9S,12S)-9-benzyl-3,12-di-tert-butyl-8-hydroxy-4,11-dioxo-6-(p-2-pyridylbenzyl)-2,5,6,10,13-pentaazatetradecanedioate, sulfate (1:1) (salt))



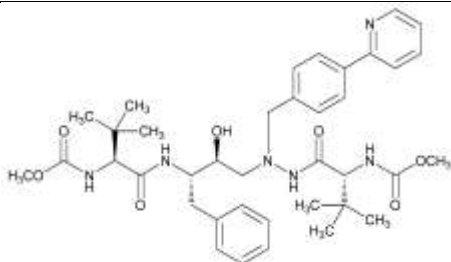
CAS No.: 229975-97-7

Molecular Formula: $C_{38}H_{52}N_6O_7 \cdot H_2SO_4$

Molecular Weight: 802.93

Component2 (ATAZANAVIR R, S, S, S,-DIASTEREOMER)

(Dimethyl (3R,8S,9S,12S)-9-benzyl-3,12-di-tert-butyl-8-hydroxy-4,11-dioxo-6-(p-2-pyridylbenzyl)-2,5,6,10,13-pentaazatetradecanedioate)



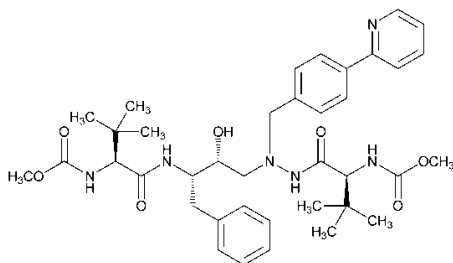
CAS No.: N/A

Molecular Formula: $C_{38}H_{52}N_6O_7$

Molecular Weight: 704.86

Component3 (ATAZANAVIR S, R, S, S,-DIASTEREOMER)

(Dimethyl (3S,8R,9S,12S)-9-benzyl-3,12-di-tert-butyl-8-hydroxy-4,11-dioxo-6-(p-2-pyridylbenzyl)-2,5,6,10,13-pentaazatetradecanedioate)



CAS No.: N/A

Molecular Formula: $C_{38}H_{52}N_6O_7$

Molecular Weight: 704.86

LABEL TEXT



Jeri L. Toth

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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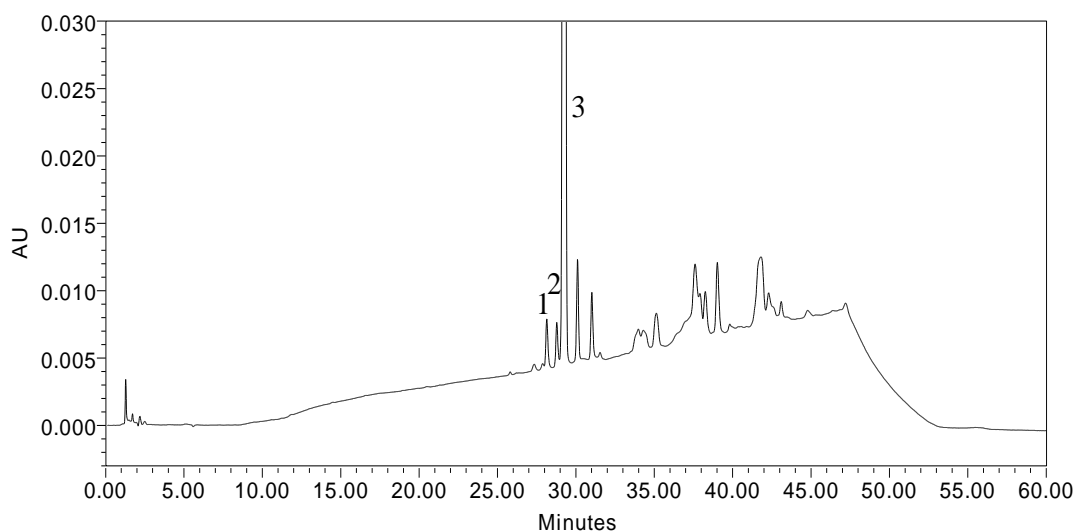
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Typical Chromatogram

USP Atazanavir System Suitability RS

Catalog Number: 1044345
Lot: F015B1
Monograph: Atazanavir Sulfate
Publication: PF 40(2)
Test: Organic Impurities
Sample: System suitability solution

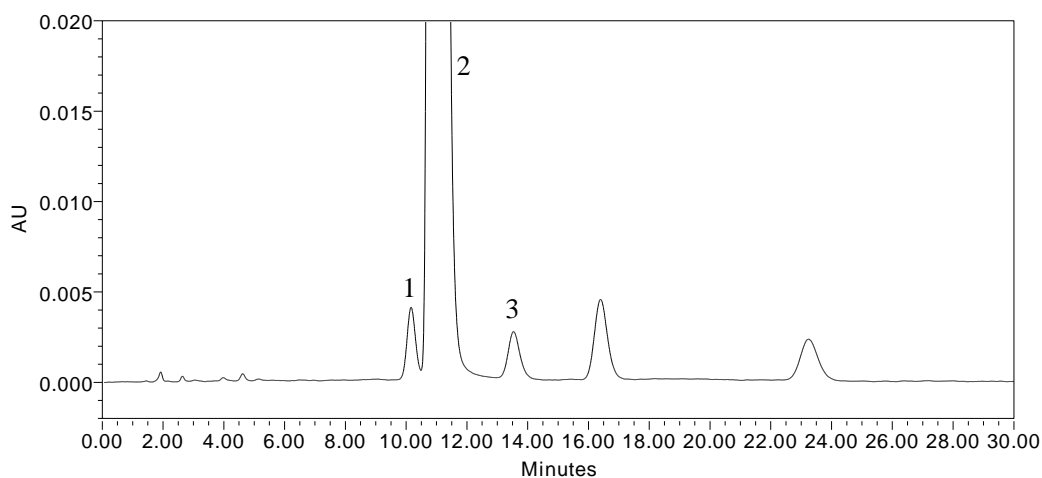


1. Atazanavir S,R,S,S- diastereomer
2. Atazanavir R,S,S,S- diastereomer
3. Atazanavir

Typical Chromatogram

USP Atazanavir System Suitability RS

Catalog Number: 1044345
Lot: F015B1
Monograph: Atazanavir Capsules
Publication: PF 40(2)
Test: Assay
Sample: System suitability solution



1. Atazanavir S,R,S,S-Diastereomer
2. Atazanavir
3. Atazanavir R,S,S,S- diastereomer

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