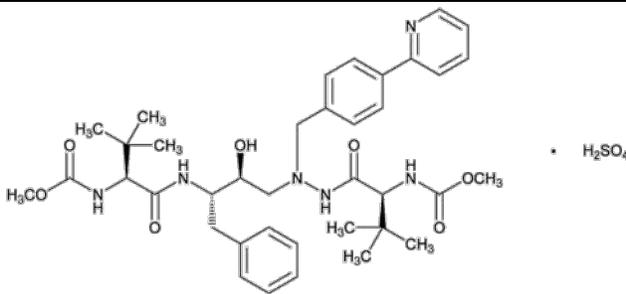
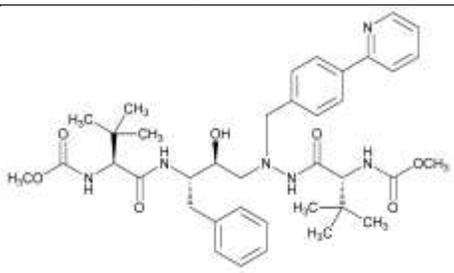
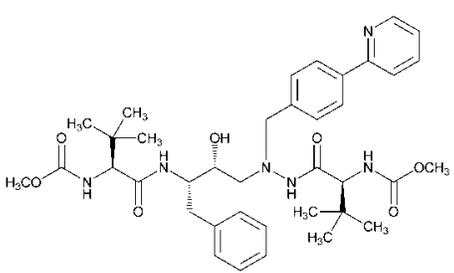


# Certificate

## ATAZANAVIR SYSTEM SUITABILITY MIXTURE

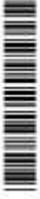
(A mixture of atazanavir sulfate, atazanavir R, S, S, S,-diastereomer and atazanavir S,R,S,S diastereomer)

USP Catalog No.:	1044345
USP Lot No.:	F015B1

<b>Component1 (ATAZANAVIR SULFATE)</b> <i>(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))</i>	
	CAS No.: 229975-97-7
	Molecular Formula: C <sub>38</sub> H <sub>52</sub> N <sub>6</sub> O <sub>7</sub> · H <sub>2</sub> SO <sub>4</sub>
	Molecular Weight: 802.93
<b>Component2 (ATAZANAVIR R, S, S, S,-DIASTEREOMER)</b> <i>(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)</i>	
	CAS No.: N/A
	Molecular Formula: C <sub>38</sub> H <sub>52</sub> N <sub>6</sub> O <sub>7</sub>
	Molecular Weight: 704.86
<b>Component3 (ATAZANAVIR S, R, S, S,-DIASTEREOMER)</b> <i>(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)</i>	
	CAS No.: N/A
	Molecular Formula: C <sub>38</sub> H <sub>52</sub> N <sub>6</sub> O <sub>7</sub>
	Molecular Weight: 704.86

**LABEL TEXT**

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



Lot: F018B1

**USP REFERENCE STANDARD**  
**ATAZANAVIR SYSTEM SUITABILITY MIXTURE 25 mg**  
(A mixture of atazanavir sulfate, atazanavir R, S, S, S-  
diastereomer and atazanavir S,R,S,S diastereomer)

**Danger!** Causes serious eye damage. Causes damage to organs (heart, liver)  
through prolonged or repeated exposure.

Do not dry. Keep container tightly closed. Protect from light. Store in a  
refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0956  
CAT No. 1044345 Material mfd. in Ireland

Wash thoroughly after handling. Wear eye/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. Get medical advice/attention if you feel  
unwell. 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](http://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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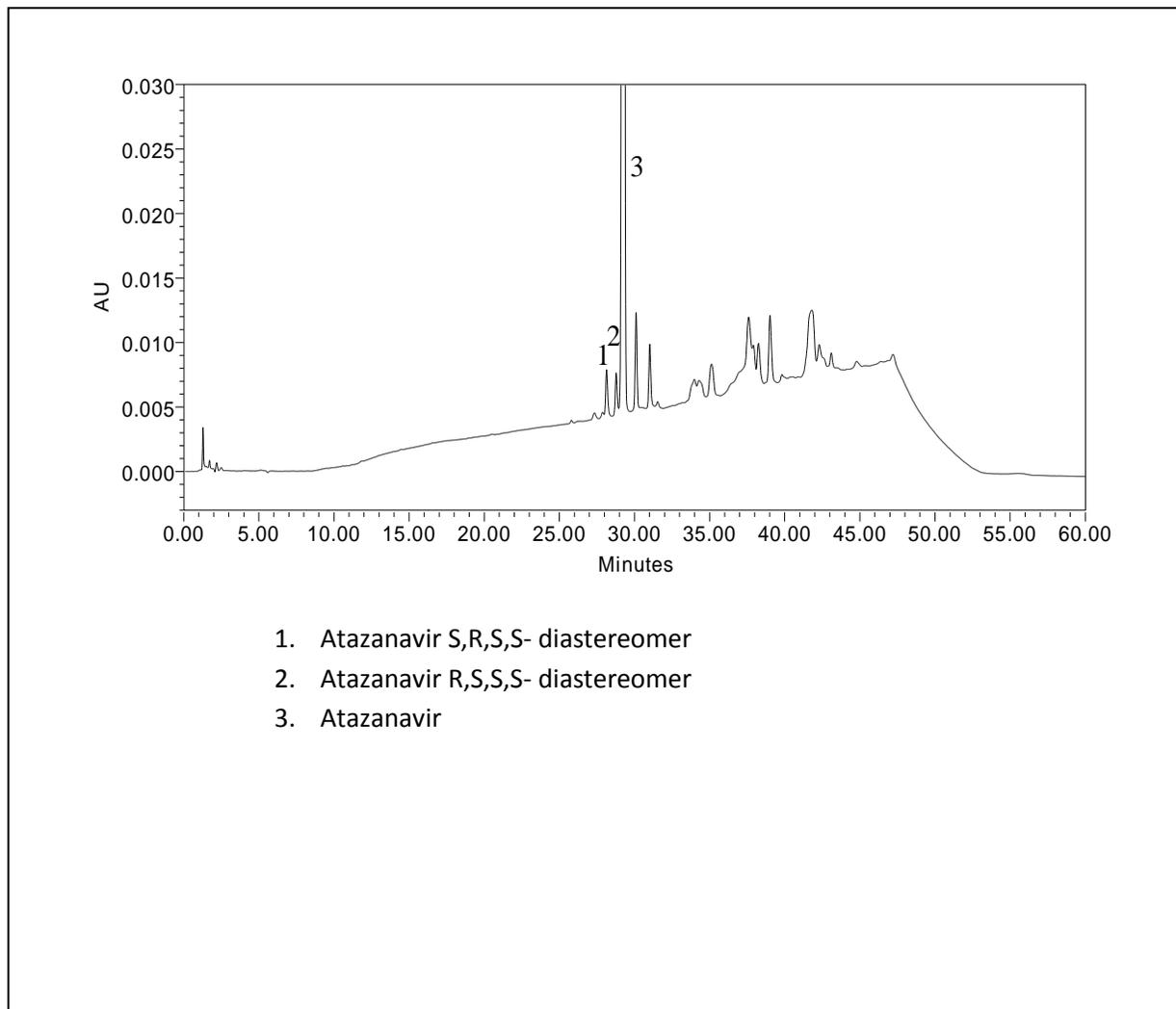
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# Typical Chromatogram

## USP Atazanavir System Suitability RS

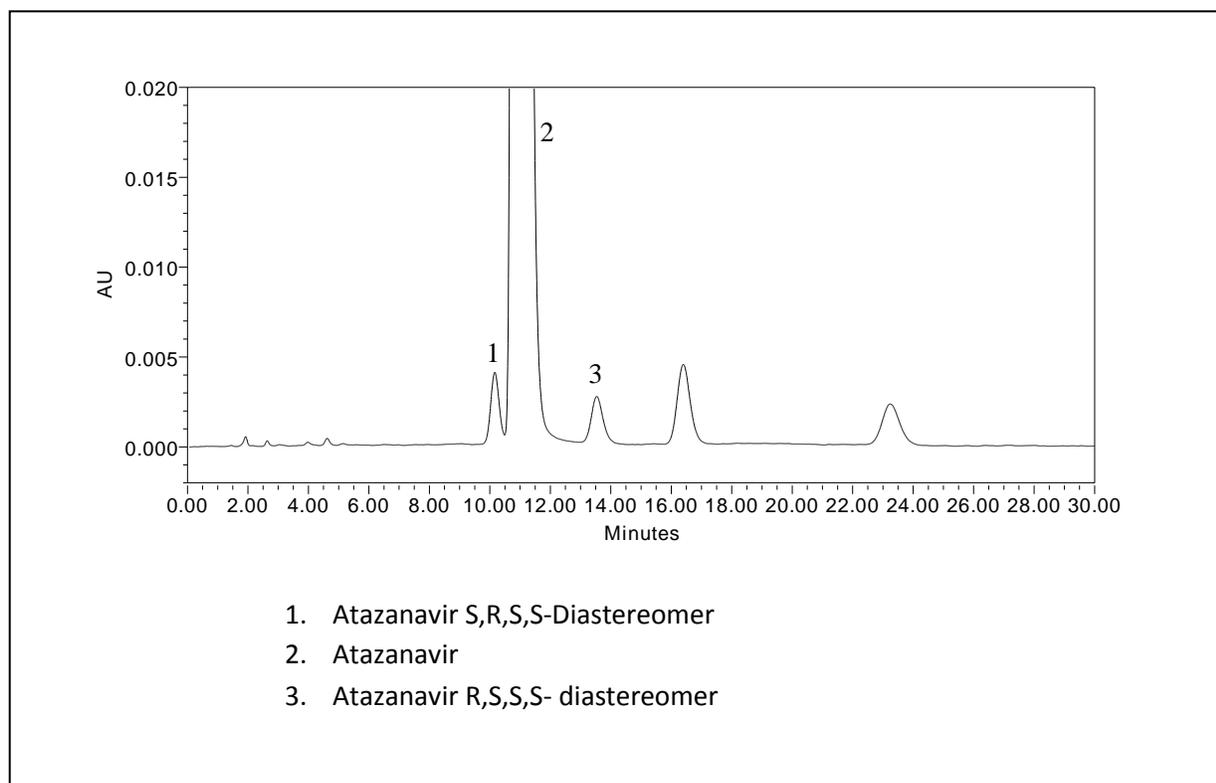
<b>Catalog Number:</b> 1044345
<b>Lot:</b> F015B1
<b>Monograph:</b> Atazanavir Sulfate
<b>Publication:</b> PF 40(2)
<b>Test:</b> Organic Impurities
<b>Sample:</b> System suitability solution



# Typical Chromatogram

## USP Atazanavir System Suitability RS

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



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