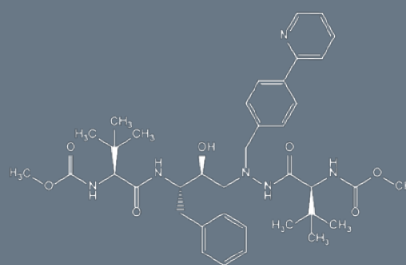


# Atazanavir

## Quality Solutions

Category: Antiviral



Authorized Distributor

USP can support your development and manufacturing activities on Atazanavir-based medicines with these existing and upcoming standards.

### Official and Proposed Documentary Standards and Associated Physical Materials

#### MONOGRAPH 2

| <b>ATAZANAVIR SULFATE</b><br>Official as of 01-Aug-2022        |                             |
|--|-----------------------------|
| USP Atazanavir System Suitability Mixture RS                   | <a href="#">USP-1044345</a> |
| USP Atazanavir Related Compound A RS                           | <a href="#">USP-1044356</a> |
| USP Atazanavir Sulfate RS                                      | <a href="#">USP-1044334</a> |
| <b>PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*</b>             |                             |
| USP Atazanavir Dipeptide Analog PAI   <b>NEW</b>               | <a href="#">USP-1A06480</a> |
| USP Dealkyl Atazanavir PAI   <b>NEW</b>                        | <a href="#">USP-1A06020</a> |
| USP Atazanavir Benzylidenehydrazine Carbamate PAI   <b>NEW</b> | <a href="#">USP-1A06160</a> |
| USP Atazanavir S,R,S,S-diastereomer PAI   <b>NEW</b>           | <a href="#">USP-1A06150</a> |
| USP Atazanavir Formyl Analog PAI   <b>NEW</b>                  | <a href="#">USP-1A06170</a> |
| USP Atazanavir amine analog PAI   <b>NEW</b>                   | <a href="#">USP-1A06510</a> |
| USP Atazanavir R,S,S,S-diastereomer PAI   <b>NEW</b>           | <a href="#">USP-1A06490</a> |
| USP Atazanavir S,S,S,R-diastereomer PAI   <b>NEW</b>           | <a href="#">USP-1A06500</a> |
| USP Atazanavir Ethyl Analog PAI   <b>NEW</b>                   | <a href="#">USP-1A06190</a> |
| USP Atazanavir Diterbutyl Analog PAI   <b>NEW</b>              | <a href="#">USP-1A06390</a> |

#### INCLUDED GENERAL CHAPTERS

##### <11> USP REFERENCE STANDARDS

Official as of 01-Nov-2020

##### <191> IDENTIFICATION TESTS—GENERAL

Official as of 01-May-2021

##### <197> SPECTROSCOPIC IDENTIFICATION TESTS

Official as of 01-Sep-2021

##### <281> RESIDUE ON IGNITION

Official as of 31-Dec-2012

##### <621> CHROMATOGRAPHY

Official as of 01-Oct-2023

##### <781> OPTICAL ROTATION

Official as of 01-Dec-2022

##### <921> WATER DETERMINATION

Official as of 01-May-2022

|                                  |                             |
|----------------------------------|-----------------------------|
| USP Sodium Tartrate Dihydrate RS | <a href="#">USP-1614909</a> |
|----------------------------------|-----------------------------|

#### INCLUDED EXCIPIENTS

##### LACTOSE MONOHYDRATE OFFICIAL AS OF 01-MAY-2020

|                            |                             |
|----------------------------|-----------------------------|
| USP Dextrose RS            | <a href="#">USP-1181302</a> |
| USP Fructose RS            | <a href="#">USP-1286504</a> |
| USP Lactose Monohydrate RS | <a href="#">USP-1356701</a> |
| USP Sucrose RS             | <a href="#">USP-1623637</a> |

##### TITANIUM DIOXIDE

Official as of 01-Jun-2023

##### MAGNESIUM STEARATE

Official as of 01-Aug-2016

|                      |                             |
|----------------------|-----------------------------|
| USP Palmitic Acid RS | <a href="#">USP-1492007</a> |
| USP Stearic Acid RS  | <a href="#">USP-1621008</a> |

##### GELATIN

Official as of 01-Nov-2020

|                |                             |
|----------------|-----------------------------|
| USP Gelatin RS | <a href="#">USP-1288485</a> |
|----------------|-----------------------------|

##### SHELLAC

Official as of 01-May-2020

|                                 |                             |
|---------------------------------|-----------------------------|
| USP Aleuritic Acid RS           | <a href="#">USP-1012799</a> |
| USP Refined Bleached Shellac RS | <a href="#">USP-1600303</a> |
| USP Regular Bleached Shellac RS | <a href="#">USP-1600314</a> |

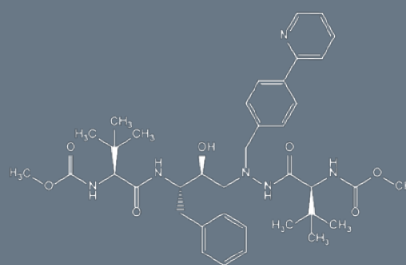
\* Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

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### Official and Proposed Documentary Standards and Associated Physical Materials

**CROSPVIDONE**

Official as of 01-May-2020

USP Crospovidone RS

[USP-1150706](#)**FERRIC OXIDE**

Official as of 01-Jun-2023

**POTASSIUM HYDROXIDE**

Official as of 01-Jan-2018

**POLYETHYLENE GLYCOL**

Official as of 01-Feb-2020

**FERROSFERRIC OXIDE**

Official as of 01-Jan-2018

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