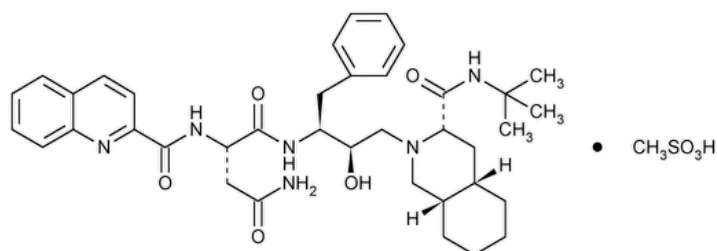


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2022
 Document Type: USP Monographs
 DocId: GUID-399A73BC-24C7-4D24-88F4-ABEB801B3EAD_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M74397_05_01
 DOI Ref: ewe6q

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Saquinavir Mesylate

Change to read:



$C_{38}H_{50}N_6O_5 \cdot CH_4O_3S$ Δ 766.96 Δ (USP 1-Dec-2022)

Butanediamide, N^1 -[3-[3-[[[1,1-dimethylethyl]amino]carbonyl]octahydro-2(1*H*)-isoquinolinyl]-2-hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)amino]-, [3*S*-[2[1*R**(*R**),2*S**],3 α ,4 α β ,8 α β]]-, monomethanesulfonate (salt); (S)-*N*-[(α S)- α -[(1*R*)-2-[(3*S*,4*aS*,8*aS*)-3-(*tert*-Butylcarbonyl)octahydro-2(1*H*)-isoquinolyl]-1-hydroxyethyl]phenethyl]-2-quinaldamidosuccinamide monomethanesulfonate (salt) CAS RN[®]: 149845-06-7; UNII: UHB9Z3841A.

DEFINITION

Saquinavir Mesylate contains NLT 98.5% and NMT 101.0% of saquinavir mesylate ($C_{38}H_{50}N_6O_5 \cdot CH_4O_3S$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K Δ or 197A Δ (USP 1-Dec-2022)

Delete the following:

Δ • **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy](#) Δ (USP 1-Dec-2022)

Change to read:

• Δ **B.** Δ (USP 1-Dec-2022) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Buffer: Transfer 10 mL of [triethylamine](#) to a 1 L flask, and dilute with [water](#) to volume. Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), and *Buffer* (5:25:70). [NOTE—Protect from light.]

System suitability solution: 0.25 mg/mL of [USP Saquinavir Mesylate RS](#) and 0.002 mg/mL of [USP Saquinavir Related Compound A RS](#) in *Mobile phase*

Standard solution: 0.25 mg/mL of [USP Saquinavir Mesylate RS](#) in *Mobile phase*

Sample solution: 0.25 mg/mL of Saquinavir Mesylate in *Mobile phase*, and mix for about 20 min

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 25-cm; packing [L1](#)

Column temperature: 20°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for saquinavir related compound A and saquinavir are 0.89 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between saquinavir related compound A and saquinavir, *System suitability solution*

▲**Tailing factor:** NMT 2.0, *Standard solution*▲ (USP 1-Dec-2022)

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of saquinavir mesylate ($C_{38}H_{50}N_6O_5 \cdot CH_4O_3S$) in the portion of Saquinavir Mesylate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of saquinavir from the *Sample solution*

r_S = peak response of saquinavir from the *Standard solution*

C_S = concentration of [USP Saquinavir Mesylate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Saquinavir Mesylate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- **ORGANIC IMPURITIES**

Buffer, Mobile phase, System suitability solution, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

▲**Sensitivity solution:** 0.125 µg/mL of [USP Saquinavir Mesylate RS](#) in *Mobile phase*▲ (USP 1-Dec-2022)

System suitability

Samples: *System suitability solution*, *Standard solution*, ▲and *Sensitivity solution*▲ (USP 1-Dec-2022)

[NOTE—The relative retention times for saquinavir related compound A and saquinavir are 0.89 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between saquinavir related compound A and saquinavir, *System suitability solution*

▲**Tailing factor:** NMT 2.0, *Standard solution*▲ (USP 1-Dec-2022)

Relative standard deviation: NMT 2.0%, *Standard solution*

▲**Signal-to-noise-ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-Dec-2022)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Saquinavir Mesylate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any individual impurity from the *Sample solution*

r_S = peak response of saquinavir from the *Standard solution*

C_S = concentration of [USP Saquinavir Mesylate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))

▲**Acceptance criteria:** See [Table 1](#). The reporting threshold is 0.05%.

Table 1