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Saquinavir Capsules

» Saquinavir Capsules contain not less than 95.0 percent and not more than 105.0 percent of saquinavir ($C_{38}H_{50}N_6O_5$).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

USP Reference standards ⟨11⟩—

USP Saquinavir Mesylate RS
USP Saquinavir Related Compound A RS

N-tert-Butyl-decahydro-2-[2(*R*)-hydroxy-4-phenyl-3(*S*)- [[*N*-(2-quinolylcarbonyl)-D-asparaginyl]amino]butyl]-(4a*S*,8a*S*)-isoquinoline-3(*S*)-carboxamide.

$C_{38}H_{50}N_6O_5$ 670.84

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Dissolution ⟨711⟩—

Citrate buffer—Transfer 5.82 g of anhydrous dibasic sodium phosphate and 16.7 g of citric acid monohydrate to a 1-L volumetric flask. Dissolve in and dilute with water to volume.

Medium: *Citrate buffer;* 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{38}H_{50}N_6O_5$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 240 nm on filtered portions of the solution under test, suitably diluted with *Medium,* in comparison with a Standard solution having a known concentration of USP Saquinavir Mesylate RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{38}H_{50}N_6O_5$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Water Determination, *Method I* ⟨921⟩: not more than 3.0%.

Chromatographic purity—

Triethylamine phosphate solution, Mobile phase, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Saquinavir Mesylate*.

Standard solution—*Use the Standard preparation*, prepared as directed in the *Assay* under *Saquinavir Mesylate*.

Test solution—Use the *Assay preparation*.

Procedure—Separately inject equal volumes (about 20 µL) of the *Test solution* and the *Standard solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Capsules taken by the formula:

$$10{,}000F(670.86/766.96)(C/W)(r_i/r_S)$$

in which *F* is a response factor, and is equal to 2 for a peak, if present, at a retention time of 0.32 relative to saquinavir, to 0.5 for peaks, if present, at relative retention times of about 0.38 and 0.53, and to 1 for all other peaks; 670.86 and 766.96 are the molecular weights of saquinavir and saquinavir mesylate, respectively; *C* is the concentration, in mg per mL, of USP Saquinavir Mesylate RS in the *Standard solution; W* is the weight, in mg, of Capsule contents taken for the *Test solution;* r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the peak response for saquinavir obtained from the *Standard solution:* not more than 0.2% of any individual impurity is found, and not more than 1.0% of total impurities is found.

Assay—

Triethylamine phosphate solution, *Mobile phase*, *System suitability solution*, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Saquinavir Mesylate*.

Assay preparation—Empty and combine the contents of not fewer than 10 Capsules. Transfer an amount of Capsule contents, equivalent to about 22 mg of Saquinavir, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of saquinavir ($C_{38}H_{50}N_6O_5$) in the portion of Capsules taken by the formula:

$$(670.86/766.96)(100C)(r_U/r_S)$$

in which 670.86 and 766.96 are the molecular weights of saquinavir and saquinavir mesylate, respectively; C is the concentration, in mg per mL, of USP Saquinavir Mesylate RS in the *Standard preparation;* and r_U and r_S are the peaks obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SAQUINAVIR CAPSULES	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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