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Nizatidine Capsules

» Nizatidine Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of nizatidine ($C_{12}H_{21}N_5O_2S_2$).

Packaging and storage—Preserve in tight, light-resistant containers. Store at controlled room temperature.

USP Reference standards ⟨11⟩—

USP Nizatidine RS

Identification—

A: Empty the contents of 2 Capsules into a beaker, add 20 mL of methanol, and swirl for approximately 2 minutes. Filter through a filter paper, and evaporate the methanol solution with a current of cool air to dryness: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Nizatidine RS.

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

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{12}H_{21}N_5O_2S_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 314 nm using filtered portions of the solution under test, diluted with water if necessary, in comparison with a Standard solution having a known concentration of USP Nizatidine RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{12}H_{21}N_5O_2S_2$ is dissolved in 30 minutes.

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

Chromatographic purity—[Note—Use peak areas where peak responses are indicated.]

Buffer solution and *Mobile phase*—Prepare as directed in the *Assay* under *Nizatidine*.

Standard solution—Dissolve an accurately weighed quantity of USP Nizatidine RS in *Mobile phase* and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 40 µg per mL.

Test solution—Remove as completely as possible the contents of not less than 20 Capsules, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 200 mg of nizatidine, to a 100-mL volumetric flask, add 50 mL of *Mobile phase*, and sonicate for about 3 minutes. Dilute with *Mobile phase* to volume, mix, and filter.

System suitability solution—Prepare a solution of nizatidine and phenol in *Mobile phase* containing 40 µg of each per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed under *Procedure:* the resolution, *R,* between the nizatidine and phenol peaks is not less than 1.5, the tailing factor for the nizatidine peak is not greater than 1.5, and the relative standard deviation of the nizatidine peak for replicate injections is not more than 2%.

Procedure—Chromatograph about 10 µL of the *Standard solution* and the *Test solution*, and run the chromatograph for twice the elution time of nizatidine. Record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Capsules taken by the formula:

$$2(r_i/r_s)$$

in which r_i is the response of each impurity peak in the *Test solution*, and r_s is the response of the nizatidine peak in the *Standard solution:* not more than 0.5% of any individual impurity and not more than 1.5% of total impurities is found.

Assay—[Note—Use peak areas where peak responses are indicated.]

Buffer solution and *Mobile phase*—Prepare as directed in the *Assay* under *Nizatidine*.

Internal standard solution—Prepare a solution of phenol in *Mobile phase* having a concentration of 0.1 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Nizatidine RS in *Internal standard solution* to obtain a solution having a known concentration of 0.1 mg per mL.

Assay preparation—Weigh accurately not less than 10 Capsules. Remove as completely as possible the contents of the Capsules, and mix the combined contents. Clean and accurately weigh the Capsule shells, and calculate the net weight of the Capsule contents. Transfer an accurately weighed portion of the mixed Capsule contents equivalent to about 500 mg of nizatidine to a 500-mL volumetric flask, add 200 mL of *Internal standard solution*, and sonicate for a few minutes. Cool, dilute with *Internal standard solution* to volume, and mix. Filter a portion of the solution, transfer 1.0 mL of the filtered solution to a 10-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between nizatidine and the internal standard phenol, is not less than 3; the tailing factor, *T*, for the nizatidine peak is not more than 1.6; and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.7 for phenol and 1.0 for nizatidine. Calculate the quantity, in mg, of $C_{12}H_{21}N_5O_2S_2$ in the portion of Capsules taken by the formula:

$$5000C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Nizatidine RS in the *Standard preparation*, and R_U and R_S are the ratios of the peak response of the nizatidine to that of the internal standard for 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
NIZATIDINE CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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