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Ranitidine Tablets

» Ranitidine Tablets contain an amount of ranitidine hydrochloride ($C_{13}H_{22}N_4O_3S \cdot HCl$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ranitidine ($C_{13}H_{22}N_4O_3S$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Ranitidine Hydrochloride RS

USP Ranitidine Related Compound A RS

5-[[(2-Aminoethyl)thio]methyl]-*N*,*N*-dimethyl-2-furanmethanamine, hemifumarate salt.

USP Ranitidine Related Compound C RS

N-{2-[({5-[(Dimethylamino)methyl]-2-furanyl}methyl)sulfinyl]ethyl}-*N*′-methyl-2-nitro-1,1-ethenediamine.

Identification—

A: The R_F value of the principal spot observed in the chromatogram of the *Test preparation* obtained as directed in the *Chromatographic purity* test corresponds to that obtained from the *Standard preparation.*

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

C: Shake a quantity of crushed Tablets, equivalent to about 100 mg of ranitidine, with 2 mL of water, and filter: the filtrate responds to the tests for *Chloride ⟨191⟩*.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{13}H_{22}N_4O_3S$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 314 nm using filtered portions of the solution under test, suitably diluted with water, if necessary, in comparison with a Standard solution having a known concentration of USP Ranitidine Hydrochloride RS in the same medium.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{13}H_{22}N_4O_3S$ is dissolved in 45 minutes.

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

Chromatographic purity—

Test preparation—Prepare a filtered solution in methanol containing 20 mg of ranitidine per mL (equivalent to 22.4 mg of ranitidine hydrochloride per mL) by shaking an appropriate number of Tablets in a suitable volume of methanol until the tablets have disintegrated completely.

Standard preparations—Dissolve USP Ranitidine Hydrochloride RS in methanol to obtain a solution having a known concentration of 0.22 mg per mL. Dilute portions of this *Standard preparation* quantitatively with methanol to obtain solutions having concentrations of 110 µg per mL (*Diluted standard preparation A*), 66 µg per mL (*Diluted standard preparation B*), 22 µg per mL (*Diluted standard preparation C*), and 11 µg per mL (*Diluted standard preparation D*), respectively.

Resolution preparation—Dissolve USP Ranitidine Related Compound A RS, 5-[[(2-aminoethyl)thio]methyl]-*N*,*N*-dimethyl-2-furanmethanamine, hemifumarate salt, in methanol to obtain a solution having a known concentration of 1.27 mg per mL.

Procedure—Apply separately 10 µL of the *Test preparation*, the *Standard preparation*, and *Diluted standard preparations A*, *B*, *C*, and *D* to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. In addition, apply separately 10 µL of the *Test preparation* to the same plate, and on top of this application, apply 10 µL of the *Resolution preparation*. Allow the spots to dry, and develop the chromatograms in a solvent system consisting of a mixture of ethyl acetate, isopropyl alcohol, ammonium hydroxide, and water (25:15:5:1) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent front, and air-dry. Expose the plate to iodine vapor in a closed chamber until the chromatogram is fully revealed. Examine the plate, and compare the intensities of any secondary spots observed in the chromatogram of the *Test preparation* with those of the principal spots in the chromatograms of the *Standard preparation* and *Diluted standard preparations A*, *B*, *C*,

and *D:* the system suitability requirements are met if there is complete resolution between the primary spots in the chromatogram of the combined *Test preparation* and the *Resolution preparation*, and if a spot is observed in the chromatogram of *Diluted standard preparation D*. No single secondary spot exhibits an intensity greater than that of *Diluted standard preparation A* (0.5%), and no other secondary spot exhibits an intensity greater than that of *Diluted standard preparation B* (0.3%). The sum of the intensities of all secondary spots obtained from the *Test preparation* correspond to not more than 2.0%.

Assay—

Mobile phase, Standard preparation, System suitability solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Ranitidine Injection*.

Assay preparation—Transfer 10 Tablets to a minimum of 250 mL of *Mobile phase*, accurately measured. Shake the mixture until the Tablets have disintegrated completely, and filter. Dilute the filtrate quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a concentration of ranitidine similar to that of the *Standard preparation*.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. Calculate the quantity, in mg, of $C_{13}H_{22}N_4O_3S$ in the portion of Tablets taken by the formula:

$$(314.40/350.87)(L/D)(C)(r_U/r_S)$$

in which 314.40 and 350.87 are the molecular weights of ranitidine and ranitidine hydrochloride, respectively; L is the labeled amount, in mg, of ranitidine in each tablet; D is the concentration, in mg per mL, of ranitidine in the *Assay preparation*, based on the labeled quantity per Tablet and the extent of dilution; C is the concentration, in mg per mL, of USP Ranitidine Hydrochloride RS in the *Standard preparation*; and r_U and r_S are the peak area responses 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
RANITIDINE TABLETS	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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