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Rimantadine Hydrochloride Tablets

» Rimantadine Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of rimantadine hydrochloride ($C_{12}H_{21}N \cdot HCl$).

Packaging and storage—Preserve in tight, light-resistant containers, and store between 15° to 30°.

USP Reference standards ⟨11⟩—
USP Rimantadine Hydrochloride RS

Identification—

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

B: [**Caution—**Avoid contact with o-tolidine when performing this test, and conduct the test in a well-ventilated hood.] Weigh and finely powder not fewer than 5 Tablets. Transfer a portion of the powder, equivalent to 100 mg of riman tadine hydrochloride, to a 10-mL centrifuge tube, add 2 mL of 1 N sodium hydroxide, and mix. Add 2 mL of chloroform, and mix on a vortex mixer for 1 minute. Allow the layers to separate, and use the organic layer as the test solution. Separately apply 10 µL of the test solution and 10 µL of a Standard solution of USP Rimantadine Hydrochloride RS, similarly prepared, to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel. Place the plate in a low-actinic glass chromatographic chamber, and develop the chromatogram in a solvent system consisting of a mixture of ethyl acetate, methanol, and ammonium hydroxide (80:10:4) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, dry it in a stream of hot air, and then heat in an oven at 105° for 30 minutes. Allow the plate to cool to room temperature. Place the dried plate in an atmosphere of chlorine, prepared from a mixture of 1.5% potassium permanganate solution and 3 N hydrochloric acid (1:1), for about 90 minutes. Remove the plate, and allow it to air-dry for 60 minutes. Prepare a spray reagent as follows. Dissolve 160 mg of *o*-tolidine in 30 mL of glacial acetic acid, dilute with water to 500 mL, add 1 g of potassium iodide, and mix until the potassium iodide is dissolved. Locate the spots on the plate by spraying with the spray reagent: the R_F value of the principal spot in the chromatogram of the test solution corresponds to that of the principal spot obtained from the Standard solution.

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

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{12}H_{21}N \cdot HCl$ dissolved, employing the procedure set forth in the *Assay.*

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{12}H_{21}N \cdot HCl$ is dissolved in 30 minutes.

Assay—

Internal standard solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Rimantadine Hydrochloride.*

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 40 mg of rimantadine hydrochloride, to a 50-mL centrifuge tube, add 15 mL of 1 N sodium hydroxide, and mix. Add 25.0 mL of *Internal standard solution*, and shake by mechanical means for about 15 minutes. Allow the layers to separate, and filter a portion of the top hexane layer through anhydrous sodium sulfate. Use the clear filtrate as the *Assay preparation.*

Procedure—Separately inject equal volumes (about 2 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 rimantadine hydrochloride ($C_{12}H_{21}N \cdot HCl$) in the portion of Tablets taken by the formula:

$$25C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Rimantadine Hydrochloride RS in the *Standard preparation;* and R_U and R_S are the ratios

of the rimantadine peak response to the *n*-eicosane peak response 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
RIMANTADINE HYDROCHLORIDE TABLETS	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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