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Pyrantel Pamoate Oral Suspension

» Pyrantel Pamoate Oral Suspension is a suspension of Pyrantel Pamoate in a suitable aqueous vehicle. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of pyrantel ($C_{11}H_{14}N_2S$).

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

USP Reference standards ⟨11⟩—

USP Pyrantel Pamoate RS

Identification—[See *Note* in the *Assay*.]

A: Dilute a suitable volume of Oral Suspension with 0.05 N methanolic ammonium hydroxide to obtain a solution having a concentration of about 8 mg of pyrantel pamoate per mL. Similarly prepare a Standard solution of USP Pyrantel Pamoate RS. Shake both solutions by mechanical means, and centrifuge to obtain clear solutions. Apply a 100-µL portion of each solution to a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.50-mm layer of silica gel mixture. Develop the plate in a suitable chromatographic chamber containing the upper phase obtained by shaking together methyl isobutyl ketone, formic acid, and water (2:1:1). Develop the plate until the solvent front is about 2 cm from the top edge of the plate. Remove the plate, allow the solvent to evaporate, and examine the plate under UV light at about 365 nm: the R_F value of the principal spot from the test solution corresponds to that obtained from the Standard solution.

B: [Note—Prepare 0.05 N methanolic ammonium hydroxide by transferring 0.8 mL of ammonium hydroxide to a 250-mL volumetric flask containing 100 mL of methanol, diluting with methanol to volume, and mixing.] Dilute a suitable volume of Oral Suspension with 0.05 N methanolic ammonium hydroxide to obtain a solution having a concentration of about 16 mg of pyrantel pamoate per mL. Similarly prepare a Standard solution of USP Pyrantel Pamoate RS. Shake both solutions by mechanical means, and centrifuge to obtain clear solutions. Apply a 20-µL portion of each solution to an 18- × 24-cm sheet of chromatographic paper (Whatman No. 1 or equivalent) that previously has been prepared as follows. Impregnate the paper with a freshly prepared solution obtained by mixing 7 volumes of acetone and 3 volumes of glycine-sodium chloride-hydrochloric acid buffer solution (prepared by mixing 3 volumes of a solution that is 0.3 M with respect to both glycine and sodium chloride with 7 volumes of 0.3 M hydrochloric acid). Press the impregnated paper uniformly between white, nonfluorescent blotters to remove the excess solvent. Place the spotted chromatographic paper in a suitable chromatographic chamber, and develop by descending chromatography (see *Chromatography ⟨621⟩*), using as the solvent system the upper phase obtained by mixing ethyl acetate, butanol, and water (10:1:1). After developing for 20 hours, remove the paper from the chamber, air-dry for 10 minutes, transfer to an air-circulating oven, and dry at 60° for 30 minutes: the R_F value of the principal spot from the solution under test corresponds to that obtained from the Standard solution.

C: The retention times of the major peaks due to pyrantel base and pamoic acid in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Uniformity of dosage units ⟨905⟩—

FOR ORAL SUSPENSION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩—

FOR ORAL SUSPENSION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

pH ⟨791⟩: between 4.5 and 6.0.

Assay—[Note—Use low-actinic glassware in preparing solutions of pyrantel pamoate, and otherwise protect the solutions from unnecessary exposure to bright light. Complete the assay without prolonged interruption.]

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Pyrantel Pamoate*.

Assay preparation—Transfer by means of a pipet an accurately measured volume of Oral Suspension, equivalent to about 200 mg of pyrantel pamoate, into a 100-mL volumetric flask, disperse, and dilute with water to volume. While stirring the dispersion with a magnetic stirrer, transfer 1.0 mL of the aliquot to a 25-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, mix, and filter.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms obtained for a period of not less than 2.5 times the retention times of pyrantel base, and measure the responses for the major peaks. The relative retention times for pamoic acid and pyrantel base are about 0.6 and 1.0, respectively. Calculate the quantity,

in mg, of pyrantel ($C_{11}H_{14}N_2S$) in each mL of the Oral Suspension taken by the formula:

$$2500(0.347)(C/V)(r_U/r_S)$$

in which 0.347 is the ratio of the molecular weight of pyrantel to that of pyrantel pamoate; *C* is the concentration, in mg per mL, of USP Pyrantel Pamoate RS in the *Standard preparation; V* is the volume, in mL, of Oral Suspension taken; and r_U and r_S are the peak responses for pyrantel base 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
PYRANTEL PAMOATE ORAL SUSPENSION	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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