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Oxfendazole Oral Suspension

» Oxfendazole Oral Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of oxfendazole ($C_{15}H_{13}N_3O_3S$).

Packaging and storage—Preserve in tight containers, and protect from excessive heat.

Labeling—Label the Suspension to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Oxfendazole RS

Identification—The relative retention time of the oxfendazole peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

pH ⟨791⟩**:** between 4.3 and 4.9.

Assay—

Mobile phase—Prepare a solution of sodium acetate in water containing 2.5 mg per mL, and adjust with glacial acetic acid to a pH of 4.75 ± 0.1. Prepare a mixture of this solution and acetonitrile (800:225). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

System suitability solution—Prepare a solution in *Mobile phase* containing in each mL about 1.2 µg of methylparaben, 12 µg of sulfabenzamide, and 72 µg of USP Oxfendazole RS.

Internal standard solution—Prepare a solution of sulfabenzamide in *Mobile phase* containing about 0.3 mg per mL.

Standard preparation—Prepare a solution of USP Oxfendazole RS in methanol having a known concentration of about 900 µg per mL. Transfer 20.0 mL of this solution to a 100-mL volumetric flask, add 4.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix. This solution contains about 180 µg of USP Oxfendazole RS per mL.

Assay preparation—Transfer an accurately measured volume of the Suspension, previously well-mixed and free from air bubbles, equivalent to about 450 mg of oxfendazole, to a 500-mL volumetric flask. Add about 30 mL of water, and swirl to disperse. Add about 300 mL of methanol, and dissolve with the aid of sonication. Transfer 20.0 mL of this solution to a 100-mL volumetric flask, add 4.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector, a guard column containing packing L2, and a 4.6-mm × 25-cm analytical column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.7 for sulfabenzamide, 0.8 for methylparaben, and 1.0 for oxfendazole; the resolution, *R,* between the methylparaben peak and the oxfendazole peak is not less than 2.0; the column efficiency determined from the oxfendazole peak is not less than 2000 theoretical plates; and the relative standard deviation of replicate injections is not more than 1.5%. [Note—The detector sensitivity may be changed between the peaks to keep the responses on scale.]

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, and measure the responses for the major peaks. Calculate the quantity, in mg, of oxfendazole ($C_{15}H_{13}N_3O_3S$) in each mL of the Suspension taken by the formula:

$$2.5(C/V)(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Oxfendazole RS in the *Standard preparation; V* is the volume, in mL, of Suspension taken to prepare the *Assay preparation;* and R_U and R_S are the ratios of the oxfendazole peak response to the sulfabenzamide peak response obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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Chromatographic Database Information: Chromatographic Database

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