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Thiabendazole Oral Suspension

» Thiabendazole Oral Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of thiabendazole ($C_{10}H_7N_3S$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Thiabendazole RS

Identification—

A: Mix a portion of Oral Suspension, equivalent to about 0.5 g of thiabendazole, with about 20 mL of water, and filter. Wash the residue with 20 mL of water, discard the washing, dissolve the residue in 30 mL of 0.1 N hydrochloric acid, and filter. Collect the filtrate in a separator, render it alkaline with 1 N sodium hydroxide, and extract with 10 mL of carbon disulfide. Pass the carbon disulfide layer through a dry filter, collecting the filtrate in an evaporating dish. Evaporate the solvent with the aid of gentle heat and a stream of nitrogen. [**Caution—**Do not overheat the residue.] The residue so obtained responds to *Identification* test *A* under *Thiabendazole*.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that 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 3.4 and 4.2.

Assay—

pH 3.1 Phosphate buffer—Dissolve 13.8 g of monobasic sodium phosphate in water to obtain 2000 mL of solution. Adjust this solution with phosphoric acid to a pH of 3.1 ± 0.05.

Mobile phase—Prepare a filtered and degassed mixture of *pH 3.1 Phosphate buffer* and methanol (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Thiabendazole RS in 0.1 N hydrochloric acid, and dilute quantitatively, and stepwise if necessary, with 0.1 N hydrochloric acid to obtain a solution containing about 2 mg per mL. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with water to volume, and mix to obtain a *Standard preparation* having a known concentration of about 0.2 mg of USP Thiabendazole RS per mL.

Assay preparation—Transfer an accurately measured volume of Oral Suspension, equivalent to about 0.5 g of thiabendazole, to a 250-mL volumetric flask; dilute with 0.1 N hydrochloric acid to volume; and mix. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 960 theoretical plates, the tailing factor for the analyte peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 20 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 g, of thiabendazole ($C_{10}H_7N_3S$) in each mL of the Oral Suspension taken by the formula:

$$2.5(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Thiabendazole 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 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
THIABENDAZOLE 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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