Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2020
Document Type: USP Monographs
DocId: GUID-C63A9530-6D4A-467B-9026-2982396337C4_3_en-US
DOI: https://doi.org/10.31003/USPNF_M47520_03_01
DOI Ref: inq1s

Mebendazole Oral Suspension

» Mebendazole Oral Suspension is Mebendazole in an aqueous vehicle. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of mebendazole ($C_{16}H_{13}N_3O_3$).

Packaging and storage—Preserve in tight containers at controlled room temperature.

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

USP Reference standards ⟨11⟩—
USP Mebendazole RS

Change to read:

Identification—▲Mix a quantity of Oral Suspension, equivalent to about 200 mg of mebendazole, with 20 mL of a mixture of chloroform and 96 percent formic acid (19:1). Warm the suspension on a water bath for a few minutes, cool, and filter through a medium-porosity, sintered-glass filter. Apply 10 µL of this solution and 10 µL of a *Standard solution* of USP Mebendazole RS in a mixture of chloroform and 96 percent formic acid (19:1) containing 10 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform, methanol, and 96 percent formic acid (90:5:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, allow the solvent to evaporate, and examine the plate under short-wavelength UV light: the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution*.▲ (ERR 1-Dec-2020)

pH ⟨791⟩: between 6.0 and 7.0.

Assay—

Standard preparation—Transfer about 10 mg of USP Mebendazole RS, accurately weighed, to a 100-mL volumetric flask, and add 90 mL of chloroform, 7 mL of isopropyl alcohol, and 2 mL of 96 percent formic acid. Agitate until the solid has dissolved, add isopropyl alcohol to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with isopropyl alcohol to volume, and mix to obtain a solution having a known concentration of about 5 µg per mL.

Assay preparation 1—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 1000 mg of mebendazole, to a 100-mL volumetric flask, dilute with 96 percent formic acid to volume, and mix. Transfer 10.0 mL of this mixture to a second 100-mL volumetric flask, add 40 mL of 96 percent formic acid, and heat in a water bath at a temperature of 50° for 15 minutes. Cool, add water to volume, mix, and pass through a medium-porosity, sintered-glass filter. Transfer 10.0 mL of the filtrate to a 250-mL separator, and add 50 mL of water and 50 mL of chloroform. Shake for about 2 minutes, allow the phases to separate, and transfer the chloroform layer to a second 250-mL separator. Wash the aqueous layer with two 10-mL portions of chloroform, add the chloroform washings to the second separator, and discard the aqueous layer. Wash the combined chloroform solutions with a mixture of 4 mL of 1 N hydrochloric acid and 50 mL of a 1 in 10 solution of 96 percent formic acid in water, and transfer the chloroform layer to a 100-mL volumetric flask. Extract the aqueous washing with two 10-mL portions of chloroform, add these chloroform extracts to the chloroform solution in the volumetric flask, add 2 mL of 96 percent formic acid and 7 mL of isopropyl alcohol, dilute with chloroform to volume, and mix. Transfer 5.0 mL of this solution to another 100-mL volumetric flask, dilute with isopropyl alcohol to volume, and mix.

Assay preparation 2 (where the Oral Suspension is packaged in syringes calibrated to deliver stated increments of mebendazole)—Express an increment of Oral Suspension to a volumetric flask of an appropriate nominal volume so that when diluted with 96 percent formic acid to volume a mixture containing about 10 mg of mebendazole per mL is obtained. Transfer 10.0 mL of this mixture to a 100-mL volumetric flask, add 40 mL of 96 percent formic acid, and heat in a water bath at a temperature of 50° for 15 minutes. Proceed as directed for *Assay preparation 1* beginning with “Cool, add water to volume.”

Procedure—Mix 90 mL of chloroform with 2 mL of 96 percent formic acid in a 100-mL volumetric flask, add isopropyl alcohol to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with isopropyl alcohol to volume, and mix to obtain a reagent blank. Concomitantly determine the absorbances of the relevant *Assay preparation* and the *Standard preparation* at the wavelength of maximum absorbance at about 247 nm with a spectrophotometer, using the reagent blank to set the instrument. Calculate the quantity, in mg, of mebendazole ($C_{16}H_{13}N_3O_3$) in the portion of Oral Suspension taken to prepare *Assay preparation 1* by the formula:

$$200C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Mebendazole RS in the *Standard preparation;* and A_U and A_S are the absorbances of *Assay preparation 1* and the *Standard preparation*, respectively. Where appropriate, calculate the quantity, in mg, of mebendazole ($C_{16}H_{13}N_3O_3$)

in the increment of Oral Suspension taken to prepare *Assay preparation 2* by the formula:

$$20{,}000(C/V)(A_U/A_S)$$

in which V is the volume, in mL, of the volumetric flask into which the increment of Oral Suspension was expressed; A_U is the absorbance of *Assay preparation 2;* and the other terms are as defined above.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MEBENDAZOLE ORAL SUSPENSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 32(1)

Current DocID: GUID-C63A9530-6D4A-467B-9026-2982396337C4_3_en-US
DOI: https://doi.org/10.31003/USPNF_M47520_03_01
DOI ref: inq1s