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Mibolerone Oral Solution

» Mibolerone Oral Solution contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of mibolerone ($C_{20}H_{30}O_2$).

Packaging and storage—Preserve in tight containers, protected from light.

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

USP Reference Standards ⟨11⟩—
USP Mibolerone RS

Identification—The chromatogram of the *Assay preparation* exhibits a major peak for mibolerone, the retention time of which corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Specific Gravity ⟨841⟩: between 1.030 and 1.045.

Assay—

Internal standard solution—Prepare a solution of 1,3,5-triphenylbenzene in chloroform containing about 0.25 mg per mL.

Standard preparation—Prepare a solution of USP Mibolerone RS in *Internal standard solution* having a known concentration of about 0.5 mg per mL.

Assay preparation—Transfer an accurately weighed portion of Oral Solution, equivalent to about 1000 µg of mibolerone, to a 125-mL separator containing 60 mL of water, and swirl to disperse. Add 30 mL of methylene chloride, shake gently for about 5 minutes, and allow the phases to separate. Drain the lower methylene chloride layer through a pledget of methylene chloride-washed cotton into a 50-mL conical flask. Evaporate to dryness under a current of air. Re-extract the aqueous layer remaining in the separator with an additional 30-mL portion of methylene chloride, draining the filtered methylene chloride extract into the 50-mL conical flask, and evaporating it to dryness. Add 2.0 mL of *Internal standard solution*, and swirl to dissolve.

Chromatographic system (see *Chromatography ⟨621⟩*)—The gas chromatograph is equipped with a flame-ionization detector and a 3-mm × 61-cm column packed with 1% liquid phase G6 on support S1AB. The column is maintained at about 175° and the detector at 195° to 225°. Helium is used as the carrier gas at a flow rate of about 60 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.6 for the internal standard and 1.0 for mibolerone; and the relative standard deviation for replicate injections is not more than 2.0%.

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 µg, of mibolerone ($C_{20}H_{30}O_2$) in each mL of the Oral Solution taken by the formula:

$$2000(C/W_U)(D)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Mibolerone RS in the *Standard preparation*; W_U is the weight, in g, of Oral Solution taken to prepare the *Assay preparation*; D is the specific gravity of the Oral Solution; and R_U and R_S are the ratios of the peak height response of the mibolerone peak to the internal standard peak 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
MIBOLERONE ORAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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