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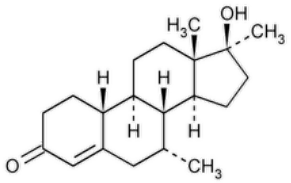
Mibolerone



$C_{20}H_{30}O_2$ 302.45

Estr-4-en-3-one, 17-hydroxy-7,17-dimethyl-, (7α,17β)-.

17β-Hydroxy-7α,17-dimethylestr-4-en-3-one CAS RN®: 3704-09-4.

» Mibolerone contains not less than 96.0 percent and not more than 106.0 percent of $C_{20}H_{30}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

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

USP Reference standards ⟨11⟩—

USP Mibolerone RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests,** ⟨197⟩, *Infrared Spectroscopy*: 197M▲ (CN 1-May-2020)

Specific rotation ⟨781S⟩: between +34° and +40°.

Test solution: 10 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry about 1 g, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.5%.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and methanol (60:25:15). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of progesterone in methanol containing 0.6 mg per mL.

Standard preparation—Prepare a solution of USP Mibolerone RS in *Internal standard solution* having a known concentration of about 0.4 mg per mL. Mix, and sonicate if necessary to achieve complete solution.

Assay preparation—Transfer about 10 mg of Mibolerone, accurately weighed, to a 25-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix. Sonicate if necessary to achieve complete solution.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-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 relative retention times are about 0.6 for mibolerone and 1.0 for progesterone; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 5 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 mg, of $C_{20}H_{30}O_2$ in the portion of Mibolerone taken by the formula:

$$25C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Mibolerone RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak responses of the mibolerone peak and the progesterone 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	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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