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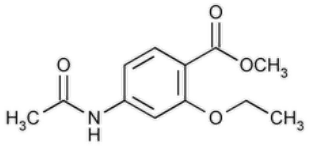
Ethopabate



$C_{12}H_{15}NO_4$ 237.25

Benzoic acid, 4-(acetylamino)-2-ethoxy-, methyl ester.

Methyl 4-acetamido-2-ethoxybenzoate CAS RN®: 59-06-3; UNII: F4X3L6068O.

» Ethopabate contains not less than 96.0 percent and not more than 101.0 percent of $C_{12}H_{15}NO_4$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers, protected from light.

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

USP Reference standards ⟨11⟩—

USP Ethopabate RS

USP Ethopabate Related Compound A RS

Methyl-4-acetamido-2-hydroxybenzoate.

$C_{10}H_{11}NO_4$ 209.20

Identification—

Change to read:

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

Change to read:

B: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)* —

Solution: 10 µg per mL.

Medium: methanol.

Loss on drying ⟨731⟩—Dry 1.0 g of it in vacuum at 60° for 2 hours: it loses not more than 1.0% of its weight.

Melting range ⟨741⟩: between 146° and 151°.

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

Chromatographic purity—Examine the chromatogram of the *Assay preparation*, as obtained in the *Assay*, for peaks that elute at the following retention times in relation to ethopabate: 0.33, *p*-aminosalicylic acid (ethopabate related compound B); 0.64, methyl 2-ethoxy-4-aminobenzoate (ethopabate related compound C); 0.68, methyl 2-hydroxy-4-aminobenzoate (ethopabate related compound D); 0.9, methyl 4-acetamido-2-hydroxybenzoate (ethopabate related compound A); and 1.6, ethyl 4-acetamido-2-ethoxybenzoate (ethopabate related compound E). Calculate the percentage of diazotizable substances, represented by peaks for ethopabate related compounds B, C, and D, if present, by the formula:

$$(0.72r_B + 0.68r_C + 0.74r_D)/0.01r_U$$

in which 0.72, 0.68, and 0.74 are the response factors of ethopabate related compounds B, C, and D, respectively, relative to that of ethopabate, r_B, r_C, and r_D are the responses of the peaks observed for ethopabate related compounds B, C, and D, respectively, and r_U is the ethopabate peak response obtained from the *Assay preparation:* not more than 0.5% of diazotizable substances is found. Calculate the percentage of any other impurities by the formula:

$$100 - A_E - A_s$$

in which A_E is the percentage of total peak area represented by the main ethopabate peak in the chromatogram obtained from the *Assay preparation*, and A_s is the percentage of peak area represented by the sum of the peaks for ethopabate related compounds B, C, and D: not more than 2.0% of other impurities is found. [Note—Exclude from the total peak area the responses of any minor peaks that are 0.01% or less than that of the main ethopabate peak.]

Assay—

Mobile phase—Dissolve 3 g of sodium 1-hexanesulfonate in 1 L of water, and adjust with phosphoric acid to a pH of 2.5. Prepare a filtered and degassed mixture of this solution, methanol, and acetonitrile (450:150:30). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluent—Prepare a mixture of methanol and water (50:50).

Standard preparation—Prepare a solution of USP Ethopabate RS in *Diluent* having a known concentration of about 0.4 mg per mL. If necessary, filter this solution through a filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Standard preparation*. Use this solution on the day prepared.

Assay preparation—Transfer about 40 mg of Ethopabate, accurately weighed, to a 100-mL volumetric flask, add about 80 mL of *Diluent*, and dissolve with the aid of sonication. Mix and dilute to volume with *Mobile phase.* If necessary, filter this solution through a filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Assay preparation*. Use this solution on the day prepared.

Resolution solution—Prepare a solution in *Diluent* containing about 0.4 mg of USP Ethopabate RS and 0.1 mg of USP Ethopabate Related Compound A RS per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 268-nm detector and a 3.9-mm × 30-cm column that contains packing L11 and is maintained at about 40°. The flow rate is about 1 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed under *Procedure:* the relative retention times are about 0.9 for methyl 4 acetamido-2-hydroxybenzoate (ethopabate related compound A) and 1.0 for ethopabate, the column efficiency is not less than 4000 theoretical plates, the resolution, *R,* between the ethopabate related compound A peak and the ethopabate peak is not less than 1.2, and the tailing factor is not more than 1.5. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas of the responses for the major peaks. Calculate the quantity, in mg, of $C_{12}H_{15}NO_4$ in the portion of Ethopabate taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Ethopabate RS in the *Standard preparation*, and r_U and r_S are the ethopabate 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
ETHOPABATE	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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

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