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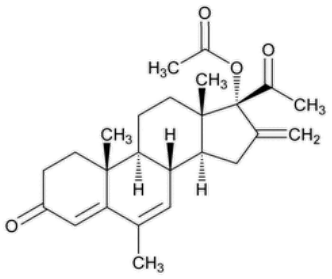
Melengestrol Acetate

Change to read:



$C_{25}H_{32}O_4$ ▲396.53▲ (ERR 1-Jul-2022)

Pregna-4,6-diene-3,20-dione, 17-(acetyloxy)-6-methyl-16-methylene-.

17-Hydroxy-6-methyl-16-methylenepregna-4,6-diene-3,20-dione acetate CAS RN®: 2919-66-6; UNII: 4W5HDS3936.

» Melengestrol Acetate contains not less than 97.0 percent and not more than 103.0 percent of $C_{25}H_{32}O_4$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

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

Change to read:

USP Reference standards ⟨11⟩—

USP Melengestrol Acetate RS

USP Melengestrol Acetate Related Compound A RS

16-Methylene-▲3,20-dioxopregn-4-en-17-yl acetate.▲ (ERR 1-Jul-2022)

USP Melengestrol Acetate Related Compound B RS

▲6,16-Dimethylene-3,20-dioxopregn-4-en-17-yl acetate.▲ (ERR 1-Jul-2022)

Identification—

A: *Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197K*.

B: *Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*

Solution: 10 µg per mL.

Medium: alcohol.

C: The retention time of the melengestrol acetate peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Melting temperature ⟨741⟩**:** between 219° and 226°.

Specific rotation ⟨781S⟩**:** between −132.0° and −122.0°, at 20°.

Test solution: 10.0 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 0.5% of its weight.

Related compounds—

Mobile phase—Prepare a mixture of acetonitrile and water (50:50).

Standard solution—Dissolve an accurately weighed quantity of USP Melengestrol Acetate RS, USP Melengestrol Acetate Related Compound A RS, and USP Melengestrol Acetate Related Compound B RS in methanol to obtain a solution having known concentrations of about 0.005 mg of each per mL.

Test solution—Use the *Assay preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a multiwavelength detector set at 240 and 262 nm and a 4.6-mm × 25-cm column that contains 5-µm packing L7. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure* [Note—Melengestrol acetate and melengestrol related compound B will generate larger peak areas at 262 nm than at 240 nm; melengestrol acetate related compound A will generate a larger peak area at 240 nm than at 262 nm]: the relative retention times are about 0.78, 1.0, and 1.05 for melengestrol acetate related compound A, melengestrol acetate, and melengestrol acetate related compound B, respectively; the resolution, *R,* between melengestrol acetate related compound A and melengestrol acetate related compound B is not less than 5.0; the column efficiency for the melengestrol acetate related compound A peak is greater than 1500 theoretical plates; the tailing factor is less than 2.0; and the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, identify the peaks, and determine which detector wavelength generates the larger peak area for each impurity. Using the larger peak area, calculate the percentage of each impurity in the portion of Melengestrol Acetate taken by the formula:

$$100(C_S/C_U)(r_i/r_S)$$

in which C_S is the concentration, in mg per mL, of either melengestrol related compound A or melengestrol related compound B in the *Standard solution* [NOTE—If using the impurity peak area generated at 240 nm, C_S is the concentration of melengestrol related compound A; if using the impurity peak area generated at 262 nm, C_S is the concentration of melengestrol related compound B]; C_U is the concentration, in mg per mL, of melengestrol acetate in the *Test solution;* r_i is the peak area of each impurity obtained from the *Test solution;* and r_S is the peak area of either melengestrol related compound A or melengestrol related compound B obtained from the *Standard solution* [NOTE—If using the impurity peak area generated at 240 nm, r_S is the peak area of melengestrol related compound A; if using the impurity peak area generated at 262 nm, C_S is the peak area of melengestrol related compound B]: not more than 0.5% of any identified impurity is found; not more than 0.2% of any unidentified impurity is found; and not more than 1.0% of total impurities is found.

Assay—

Mobile phase—Prepare a mixture of acetonitrile and water (50:50).

Standard preparation—Dissolve an accurately weighed quantity of USP Melengestrol Acetate RS in methanol to obtain a solution having a known concentration of about 0.5 mg per mL.

Assay preparation—Transfer about 50 mg of Melengestrol Acetate, accurately weighed, to a 100-mL volumetric flask, and dissolve in and dilute with methanol to volume.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 287-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L7. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation* as directed for *Procedure:* the column efficiency is not less than 1500 theoretical plates; the tailing factor is not more than 2; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* in duplicate into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of $C_{25}H_{32}O_4$ in the portion of Melengestrol Acetate taken by the formula:

$$2CW(r_U/r_S)$$

in which C is the concentration, in mg per mL, of the *Standard preparation; W* is the weight, in mg, of Melengestrol Acetate used to prepare the *Assay preparation;* r_U is the average peak area of the melengestrol acetate peak obtained from the *Assay preparation;* and r_S is the average peak area of the melengestrol acetate peak obtained from the *Standard preparation.*

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

Topic/Question	Contact	Expert Committee
MELENGESTROL ACETATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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