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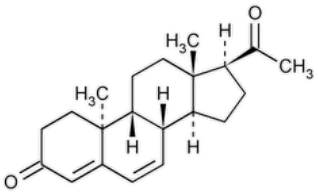
Dydrogesterone



$C_{21}H_{28}O_2$ 312.45

Pregna-4,6-diene-3,20-dione, (9β,10α)-.

9β,10α-Pregna-4,6-diene-3,20-dione CAS RN®: 152-62-5; UNII: 90I02KLE8K.

» Dydrogesterone contains not less than 98.0 percent and not more than 102.0 percent of $C_{21}H_{28}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Dydrogesterone RS

Identification—

Change to read:

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

Change to read:

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

Solution: 6 µg per mL.

Medium: methanol.

Absorptivities at 285 nm, calculated on the dried basis, do not differ by more than 2.5%.

Melting range ⟨741⟩: between 167° and 171°.

Specific rotation ⟨781S⟩: between −442° and −462°.

Test solution: 10 mg per mL, in trichloroethane.

Loss on drying ⟨731⟩—Dry it in vacuum at 50° for 1 hour: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Chromatographic purity—

Mobile phase, *System suitability preparation*, and *Chromatographic system*—Prepare as directed in the *Assay*.

Test solution—Prepare a solution of Dydrogesterone in *Mobile phase* having a concentration of about 0.1 mg per mL.

Procedure—Inject about 20 µL of the *Test solution* into the chromatograph, record the chromatograms for not less than 20 minutes, and measure the peak area responses. The sum of the areas of the secondary peaks, is not more than 2.0% of the total peak area.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water, alcohol, and acetonitrile (530:260:210). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Dydrogesterone RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer about 100 mg of Dydrogesterone, accurately weighed, to a 100-mL volumetric flask, add *Mobile phase* to volume, and mix. Transfer 10.0 mL of the resulting solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

System suitability preparation—Transfer 10 mg of dydrogesterone to a 100-mL volumetric flask, add 30 mL of alcohol, and mix to dissolve the solid. Add 1 mL of 0.2 N sodium hydroxide, and heat the mixture at 85° for 10 minutes. Cool to room temperature, neutralize with 1 mL of 0.2 N hydrochloric acid, add 20 mL of acetonitrile, dilute with water to volume, and mix. This solution contains dydrogesterone and 17 α-dydrogesterone.

Chromatographic system—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 15-cm column that contains 3-µm packing L1 and is maintained at 40°. The flow rate is about 1 mL per minute. Chromatograph 20 µL of the *System suitability preparation*, and record the peak responses as directed under *Procedure:* the resolution between the dydrogesterone and 17 α-dydrogesterone is not less than

5, and the relative standard deviation of dydrogesterone peak responses from replicate injections is not more than 1.5%. The relative retention times are about 1.0 for dydrogesterone and about 1.3 for 17 α-dydrogesterone.

Procedure—Separately inject equal volumes (about 20 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 $C_{21}H_{28}O_2$ in the portion of Dydrogesterone taken by the formula:

$$1000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dydrogesterone RS in the *Standard preparation*, and r_U and r_S are the peak responses for dydrogesterone 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
DYDROGESTERONE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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