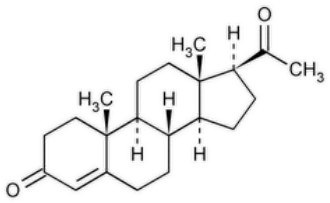
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-94DF8999-EE4E-4181-B422-A5BD17834987_2_en-US
DOI: https://doi.org/10.31003/USPNF_M69870_02_01
DOI Ref: 7ewp0

Progesterone



$C_{21}H_{30}O_2$ 314.46

Pregn-4-ene-3,20-dione.

Progesterone CAS RN®: 57-83-0; UNII: 4G7DS2Q64Y.

» Progesterone contains not less than 97.0 percent and not more than 103.0 percent of $C_{21}H_{30}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—
USP Progesterone 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: 10 µg per mL.

Medium: methanol.

Melting range ⟨741⟩**:** between 126° and 131°. It may exist also in a polymorphic modification, melting at about 121°.

Specific rotation ⟨781S⟩**:** between +175° and +183°.

Test solution: 20 mg per mL, in dioxane.

Loss on drying ⟨731⟩—Dry it in vacuum over silica gel for 4 hours: it loses not more than 0.5% of its weight.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and isopropyl alcohol (72:28). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Transfer about 66 mg of methyltestosterone to a 10-mL volumetric flask, add dilute alcohol (85 in 100) to volume, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Progesterone RS in dilute alcohol (85 in 100) to obtain a solution having a known concentration of about 2.5 mg per mL. Transfer 4.0 mL of this solution to a 10-mL volumetric flask, add 1.0 mL of *Internal standard solution,* then add dilute alcohol (85 in 100) to volume, and mix to obtain a solution having a known concentration of about 1 mg of USP Progesterone RS per mL.

Assay preparation—Transfer about 10 mg of Progesterone, accurately weighed, to a 10-mL volumetric flask, add 1.0 mL of *Internal standard solution,* then add dilute alcohol (85 in 100) to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains 10-µm packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and internal standard peaks is not less than 3.5; and the relative standard deviation for replicate injections is not more than 1.5%.

Procedure—Separately inject equal volumes (5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 2.0 for progesterone and 1.0 for

methyltestosterone. Calculate the quantity, in mg, of $C_{21}H_{30}O_2$ in the portion of Progesterone taken by the formula:

$$10C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Progesterone RS in the *Standard preparation;* and R_U and R_S are the peak response ratios 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
PROGESTERONE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(6)

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