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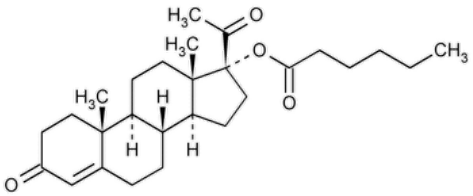
Hydroxyprogesterone Caproate



$C_{27}H_{40}O_4$ 428.60

Pregn-4-ene-3,20-dione, 17-[(1-oxohexyl)oxy]-.

17-Hydroxypregn-4-ene-3,20-dione hexanoate CAS RN®: 630-56-8; UNII: 276F2O42F5.

» Hydroxyprogesterone Caproate contains not less than 97.0 percent and not more than 103.0 percent of $C_{27}H_{40}O_4$, calculated on the anhydrous basis.

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

USP Reference standards ⟨11⟩—

USP Hydroxyprogesterone Caproate RS

Change to read:

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

Melting range ⟨741⟩**:** between 120° and 124°.

Specific rotation ⟨781S⟩**:** between +58° and +64°.

Test solution: 10 mg per mL, in chloroform.

Water Determination, *Method I* ⟨921⟩ **:** not more than 0.1%.

Free *n*-caproic acid—Dissolve 0.20 g in 25 mL of alcohol that previously has been neutralized to a faint pink color following the addition of 2 or 3 drops of phenolphthalein TS. Promptly titrate with 0.020 N sodium hydroxide: not more than 0.50 mL of 0.020 N sodium hydroxide is required (0.58%).

Ordinary impurities ⟨466⟩—

Test solution: chloroform.

Standard solution: chloroform.

Eluant: a mixture of chloroform and ethyl acetate (3:1).

Visualization: 5; then view under long-wavelength UV light.

Assay—Transfer about 50 mg of Hydroxyprogesterone Caproate, accurately weighed, to a 100-mL volumetric flask, add alcohol to volume, and mix. Dilute 2.0 mL of this solution with alcohol to volume in a second 100-mL volumetric flask, and mix. Dissolve in alcohol a suitable quantity of USP Hydroxyprogesterone Caproate RS, and dilute quantitatively and stepwise with alcohol to obtain a Standard solution having a known concentration of about 10 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 240 nm, using alcohol as the blank. Calculate the quantity, in mg, of $C_{27}H_{40}O_4$ in the Hydroxyprogesterone Caproate taken by the formula:

$$5C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Hydroxyprogesterone Caproate RS in the Standard solution; and A_U and A_S are the absorbances of the solution of Hydroxyprogesterone Caproate and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
HYDROXYPROGESTERONE CAPROATE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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