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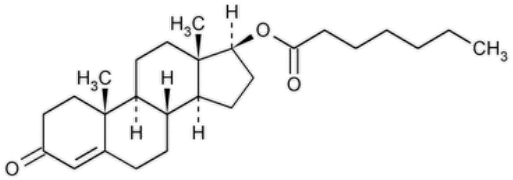
Testosterone Enanthate



$C_{26}H_{40}O_3$ 400.59

Androst-4-en-3-one, 17-(1-oxoheptyl)oxy-, (17β)-.

Testosterone heptanoate CAS RN®: 315-37-7; UNII: 7Z6522T8N9.

» Testosterone Enanthate contains not less than 97.0 percent and not more than 103.0 percent of $C_{26}H_{40}O_3$.

Packaging and storage—Preserve in well-closed containers, and store in a cool place.

USP Reference standards ⟨11⟩—

USP Testosterone Enanthate 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: alcohol.

Absorptivities at 240 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

C: Reflux 25 mg with 2 mL of a 1 in 100 solution of potassium hydroxide in methanol for 1 hour. Cool the mixture, add 10 mL of water, filter, and wash the precipitate with water until the last washing is neutral to litmus. Dry the precipitate in vacuum at 60° for 3 hours: the testosterone so obtained melts between 151° and 157°.

Melting range ⟨741⟩**:** between 34° and 39°, the initial temperature of the bath not exceeding 20°.

Specific rotation ⟨781S⟩**:** between +77° and +82°.

Test solution: 20 mg per mL, in dioxane.

Water Determination, *Method I* ⟨921⟩ **:** not more than 0.5%.

Free heptanoic acid—Dissolve 500 mg in 10 mL of alcohol that previously has been neutralized to a faint blue color following the addition of 2 or 3 drops of bromothymol blue TS, and promptly titrate with 0.01 N sodium hydroxide VS: not more than 0.6 mL of 0.01 N sodium hydroxide is required (0.16% of heptanoic acid).

Ordinary impurities ⟨466⟩—

Test solution: methanol.

Standard solution: methanol.

Eluant: a mixture of cyclohexane and ethyl acetate (2:1).

Visualization: 19.

Limits—No individual impurity exceeds 1.0%, and the total of observed impurities does not exceed 2.0%.

Assay—Dissolve about 40 mg of Testosterone Enanthate, accurately weighed, in chloroform to make 100 mL, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask, add chloroform to volume, and mix. Dissolve a suitable quantity of USP Testosterone Enanthate RS, accurately weighed, in chloroform, and dilute quantitatively and stepwise with chloroform to obtain a Standard solution having a known concentration of about 40 µg per mL. Pipet 5 mL each of the solution of Testosterone Enanthate and the Standard solution into separate, glass-stoppered, 50-mL conical flasks, and place 5.0 mL of chloroform in a similar flask to provide a blank. Treat each flask as follows. Add 10.0 mL

of a solution of 375 mg of isoniazid and 0.47 mL of hydrochloric acid in 500 mL of methanol, mix, and allow to stand for 45 minutes. Concomitantly determine the absorbances of the solutions at the wavelength of maximum absorbance at about 380 nm, with a suitable spectrophotometer, using the blank to set the instrument. Calculate the quantity, in mg, of $C_{26}H_{40}O_3$ in the Testosterone Enanthate taken by the formula:

$$C(A_U/A_S)$$

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

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

Topic/Question	Contact	Expert Committee
TESTOSTERONE ENANTHATE	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

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