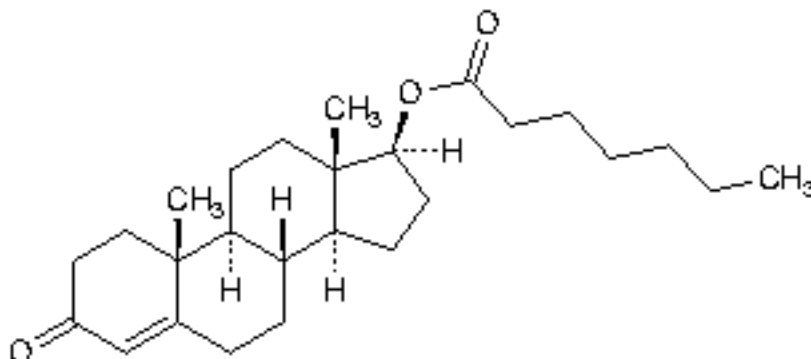


Testosterone enantate (Testosteroni enantas)

2014-01

Molecular formula. $C_{26}H_{40}O_3$ **Relative molecular mass.** 400.6**Graphic formula.****Chemical name.** 3-oxoandrost-4-en-17 β -yl heptanoate; 17 β -(heptanoyloxy)androst-4-en-3-one; testosterone heptanoate; CAS Reg. No. 315-37-7.**Description.** A white or creamy white, crystalline powder; odourless or almost odourless.**Solubility.** Practically insoluble in water; very soluble in ethanol (~750 g/L) TS, ether R and acetone R.**Category.** Androgen.**Storage.** Testosterone enantate should be kept in a tightly closed container, protected from light and stored at a temperature between 2 and 8 °C.**Additional information.** Testosterone enantate melts at about 37 °C.**Requirements****Definition.** Testosterone enantate contains not less than 97.0% and not more than 103.0% of $C_{26}H_{40}O_3$, calculated with reference to the dried substance.**Identity tests**

-Either test A alone or tests B and C may be applied.

A. Carry out the examination as described under [1.7 Spectrophotometry in the infrared region](#). The infrared absorption spectrum is concordant with the spectrum obtained from testosterone enantate RS or with the *reference spectrum* of testosterone enantate.

B. See the test described below under "Related substances". The principal spot obtained with solution C corresponds in position, appearance and intensity with that obtained with solution D.

C. Suspend 5 mg in 2.0 mL of a mixture prepared by previously cooling 2 volumes of sulfuric acid (~1760 g/L) TS and 1 volume of ethanol (~750 g/L) TS, then place it in a water-bath; a greenish yellow fluorescence develops that changes to orange, whereas the walls of the tube take on a dichroic blue colour, changing to red below a certain depth.

Specific optical rotation. Use a 10 mg/mL solution in dioxan R; $[\alpha]_D^{20} = +77^\circ$ to $+83^\circ$.

Loss on drying. Dry to constant weight at ambient temperature under reduced pressure (not exceeding 0.6 kPa or about 5 mm of mercury) over phosphorus pentoxide R; it loses not more than 5.0 mg/g.

Free heptanoic acid. Dissolve 0.5 g, accurately weighed, in 10 mL of ethanol (~750 g/L) TS, previously neutralized to bromothymol blue/ethanol TS, and titrate immediately with sodium hydroxide (0.01 mol/L) VS, using bromothymol blue/ethanol TS as indicator; not more than 0.6 mL of sodium hydroxide (0.01 mol/L) VS is required to obtain the midpoint of the indicator (green).

Related substances

Carry out the test as described under [1.14.1 Chromatography, Thin-layer chromatography](#) using silica gel R1 as the coating

substance and a mixture of 92 volumes of dichloroethane R, 8 volumes of methanol R and 0.5 volume of water as the mobile phase. Apply separately to the plate 5 µL of each of 2 solutions in a mixture of 9 volumes of chloroform R and 1 volume of methanol R containing (A) 20 mg of the test substance per mL; (B) 0.20 mg of the test substance per mL; (C) 1.0 mg of the test substance per mL and (D) 1.0 mg of testosterone enantate RS per mL. After removing the plate from the chromatographic chamber allow it to dry in air and heat it at 110 °C for 10 minutes. Spray the hot plate with sulfuric acid/ethanol TS, again heat it at 110 °C for 10 minutes and examine the chromatogram in ultraviolet light (365 nm). Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay

Dissolve about 20 mg, accurately weighed, in dehydrated ethanol R to produce 100 mL; dilute 5.0 mL of this solution to 100 mL with the same solvent. Measure the absorbance of a 1 cm layer of the diluted solution at about 241 nm and calculate the content of $C_{26}H_{40}O_3$ using the absorptivity value of 42.2 ($A_{1\%}^{1\text{cm}} = 422$).

Additional requirements for Testosterone enantate for parenteral use

Complies with the monograph for [Parenteral preparations](#).

Bacterial endotoxins. Carry out the test as described under [3.4 Test for bacterial endotoxins](#); contains not more than 3.5 IU of endotoxin RS per mg.