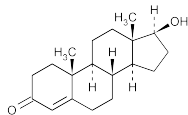


Testosterone



$C_{19}H_{28}O_2$ 288.42

Androst-4-en-3-one, 17-hydroxy-, (17 β)-.

17 β -Hydroxyandrost-4-en-3-one [58-22-0].

» Testosterone contains not less than 97.0 percent and not more than 103.0 percent of $C_{19}H_{28}O_2$, calculated on the dried basis.

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

USP Reference standards (11)—

USP Testosterone RS

Identification—

A: Infrared Absorption (197K).

B: Ultraviolet Absorption (197U)—

Solution: 10 μ g per mL.

Medium: methanol.

Melting range (741): between 153° and 157°.

Specific rotation (781S): between +101° and +105°.

Test solution: 10 mg per mL, in dioxane.

Loss on drying (731)—Dry it in vacuum over phosphorus pentoxide for 4 hours: it loses not more than 1.0% of its weight.

Assay—

Standard preparation—Prepare as directed under *Single-Steroid Assay* (511), using USP Testosterone RS.

Assay preparation—Accurately weigh about 20 mg of Testosterone, previously dried; dissolve in a sufficient quantity of a mixture of equal volumes of alcohol and chloroform to make 10.0 mL; and mix.

Procedure—Proceed as directed for *Procedure* under *Single-Steroid Assay* (511), using a solvent system consisting of a mixture of benzene and ethyl acetate (1:1), through the fourth sentence of the second paragraph under *Procedure*. Then centrifuge the tubes for 5 minutes, and determine the absorbances of the supernatant in 1-cm cells at the wavelength of maximum absorbance at about 241 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{19}H_{28}O_2$ in the portion of Testosterone taken by the formula:

$$10C(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Testosterone RS in the *Standard preparation*; and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

Testosterone Injectable Suspension

» Testosterone Injectable Suspension is a sterile suspension of Testosterone in an aqueous medium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{28}O_2$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP Reference standards (11)—

USP Endotoxin RS

USP Testosterone RS

Identification—The testosterone obtained by filtration and washing, as directed in the *Assay*, and dried at 105° to constant weight, meets the requirements for *Identification* tests A and B under *Testosterone*.

Bacterial endotoxins (85)—It contains not more than 3.5 USP Endotoxin Units per mg of testosterone.

Uniformity of dosage units (905): meets the requirements.

pH (791): between 4.0 and 7.5.

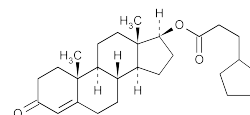
Other requirements—It meets the requirements under *Injections* (1).

Assay—Transfer an accurately measured volume of previously well-mixed Injectable Suspension, equivalent to about 100 mg of testosterone, to a fine-porosity, sintered-glass filtering crucible, previously dried at 105° for 1 hour, and filter with suction. If the filtrate is not clear, again pass it through the same filter into a second receiver. Wash the residue in the filter with several 5-mL portions of water until 2 mL of the last washing, when evaporated on a steam bath, leaves a negligible residue. [NOTE—If the Injectable Suspension is passed through the filter twice, rinse the first receiver with the portions of water before passing them through the filter.] Dry the crucible and the collected testosterone at 105° for 1 hour. Completely dissolve the testosterone with five 25-mL portions of methanol, passing each portion through the crucible under gentle suction, and transfer the combined methanol solution to a 200-mL volumetric flask. Rinse the crucible and receiver with two 25-mL portions of methanol, add the rinsings to the main solution, dilute with methanol to volume, and mix. Transfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with methanol to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of USP Testosterone RS, in the same medium having a known concentration of about 10 μ g per mL in 1-cm cells at the wavelength of maximum absorbance at about 241 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of $C_{19}H_{28}O_2$ in each mL of the Injectable Suspension taken by the formula:

$$(10C / V)(A_U / A_S)$$

in which C is the concentration, in μ g per mL, of USP Testosterone RS in the Standard solution, V is the volume, in mL, of Injectable Suspension taken, and A_U and A_S are the absorbances of the solution from the Injectable Suspension and the Standard solution, respectively.

Testosterone Cypionate



$C_{27}H_{40}O_3$ 412.60

Androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopropoxy)-, (17 β)-. Testosterone cyclopentanepropionate [58-20-8].

» Testosterone Cypionate contains not less than 97.0 percent and not more than 103.0 percent of $C_{27}H_{40}O_3$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant containers.