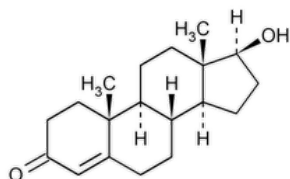


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Testosterone



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

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

17 β -Hydroxyandrost-4-en-3-one CAS RN[®]: 58-22-0; UNII: 3XMK78S470.

» 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—

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 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.

Topic/Question	Contact	Expert Committee
TESTOSTERONE	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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