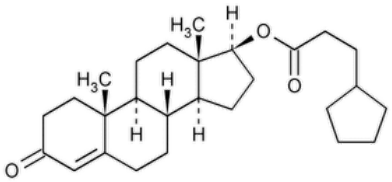
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-F4EC4D12-8386-4CDB-BBA7-220FB9259465_2_en-US
DOI: https://doi.org/10.31003/USPNF_M81180_02_01
DOI Ref: gzk6g

Testosterone Cypionate



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

Androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopropoxy)-, (17β)-.

Testosterone cyclopentanepropionate CAS RN®: 58-20-8; UNII: M0XW1UBI14.

» 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.

USP Reference standards ⟨11⟩—

USP Cholesteryl Caprylate RS	$C_{35}H_{60}O_2$	512.86
USP Testosterone Cypionate RS		

Change to read:

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

Melting range ⟨741⟩**:** between 98° and 104°.

Specific rotation ⟨781S⟩**:** between +85° and +92°.

Test solution: 20 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it in vacuum over silica gel for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.2%.

Free cyclopentanepropionic 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 0.70 mL of 0.01 N sodium hydroxide is required (0.20% of cyclopentanepropionic acid).

Assay—

Internal standard solution—Dissolve 80 mg of USP Cholesteryl Caprylate RS in a mixture of methanol and chloroform (4:1) in a 100-mL volumetric flask, then add the same solvent mixture to volume.

Standard preparation—Weigh accurately about 10 mg of USP Testosterone Cypionate RS into a suitable vial, add by pipet 10 mL of *Internal standard solution*, and mix.

Assay preparation—Prepare as directed for *Standard preparation*, using an accurately weighed portion of about 10 mg of Testosterone Cypionate instead of the Reference Standard.

Procedure—Inject 1 µL of the *Assay preparation* and the *Standard preparation*, successively, into a suitable gas chromatograph fitted with a flame-ionization detector. Under typical conditions, the instrument contains a 3-mm × 1.2-m glass column packed with 1% (w/w) phase G6 on packing S1AB. The column temperature is maintained at 260° and the helium carrier gas flows at 50 mL per minute. In a suitable chromatogram, the resolution factor, *R* (see *Chromatography* ⟨621⟩), is not less than 3 between the internal standard and testosterone cypionate peaks, and five replicate injections of a single *Standard preparation* show a coefficient of variation of not more than 2% in the peak area ratio of testosterone cypionate to internal standard. Measure the areas under the peaks for testosterone cypionate and cholesteryl caprylate in each chromatogram. Calculate the ratio, R_U, of the area of the testosterone cypionate peak to the area of the internal standard peak in the chromatogram from the *Assay preparation*, and similarly calculate the ratio, R_S, in the chromatogram from the *Standard preparation*. Calculate the quantity, in mg, of $C_{27}H_{40}O_3$ in the portion of Testosterone Cypionate taken by the formula:

$$W(R_U/R_S)$$

in which *W* is the weight, in mg, of USP Testosterone Cypionate RS in the *Standard preparation*, and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
TESTOSTERONE CYPIONATE	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(2)

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