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Testosterone Cypionate Injection

» Testosterone Cypionate Injection is a sterile solution of Testosterone Cypionate in a suitable vegetable oil. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{27}H_{40}O_3$. It may contain a suitable solubilizing agent.

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

USP Reference standards ⟨11⟩—

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

Identification—Dilute a suitable volume of Injection with chloroform to obtain a solution having a concentration of about 400 µg of testosterone cypionate per mL. Prepare a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography ⟨621⟩*), coated with a 0.25-mm layer of chromatographic siliceous earth, by placing it in a developing chamber containing and equilibrated with a mixture of chloroform and corn oil (90:10), and allowing the solvent front to move about three-fourths of the length of the plate. Remove the plate, and allow the chloroform to evaporate. Apply 10 µL each of the solution under test and of a solution of USP Testosterone Cypionate RS in chloroform containing about 400 µg per mL on the plate, on a line about 2.5 cm from the bottom edge and about 1.5 cm apart. Place the plate in a developing chamber that contains and has been equilibrated with a mixture of methanol and water (90:10) previously saturated with corn oil. Develop the chromatogram until the solvent front has moved to about 10 cm above the line of application. Remove the plate, and heat in an oven at 105° for a few minutes. Spray the plate with a mixture of alcohol and sulfuric acid (3:1), and heat in an oven at 105° for 1 to 2 minutes. Observe the plate under long-wavelength UV light: the R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Standard solution.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Internal standard solution and *Standard preparation*—Prepare as directed in the *Assay* under *Testosterone Cypionate.*

Assay preparation—Transfer 1 mL of Injection, accurately measured, into a glass-stoppered, 50-mL centrifuge tube. Add 30 mL of a mixture of methanol and water (9:1), insert the stopper, and shake for 15 minutes. Centrifuge, remove the dilute methanol layer without disturbing the oil, and transfer it to a 200-mL volumetric flask. Repeat the extraction with three additional 30-mL portions of the dilute methanol, collecting the combined extracts in the volumetric flask. Dilute the combined extracts with the dilute methanol to volume, mix, and chill the contents of the flask to −8°. Remove the flask from the freezer, and immediately filter a portion of the contents. Allow the filtrate to reach room temperature, transfer a portion of it, equivalent to about 3 mg of testosterone cypionate, to a suitable vial, and evaporate to dryness. Add by pipet 3 mL of *Internal standard solution*, and shake vigorously to dissolve the residue.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Testosterone Cypionate.* Calculate the quantity, in mg, of $C_{27}H_{40}O_3$ in the portion of Injection taken by the formula:

$$600(C/V)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Testosterone Cypionate RS in the *Standard preparation;* and V is the volume, in mL, of the filtrate used in the *Assay preparation.*

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

Topic/Question	Contact	Expert Committee
TESTOSTERONE CYPIONATE INJECTION	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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