Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-ED834222-B6B3-46D6-9417-CB6F235BCAEC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M81250_01_01
DOI Ref: rv6rw

Testosterone Enanthate Injection

» Testosterone Enanthate Injection is a sterile solution of Testosterone Enanthate 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 $C_{26}H_{40}O_3$.

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

USP Reference standards ⟨11⟩—
USP Testosterone Enanthate RS

Identification—Dilute a suitable volume of Injection with chloroform to obtain a solution having a concentration of about 400 µg of testosterone enanthate per mL. Proceed as directed in the *Identification* test under *Testosterone Cypionate Injection*, beginning with "Prepare a 20- × 20-cm thin-layer chromatographic plate," but using USP Testosterone Enanthate RS. The R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Reference Standard solution.

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

Assay—

Chromatographic solvent—Equilibrate, by shaking in a separator, 95 mL of alcohol, 5 mL of water, and 50 mL of chromatographic *n*-heptane. Allow the layers to separate.

Isoniazid reagent—Dissolve 375 mg of isoniazid and 0.47 mL of hydrochloric acid in 500 mL of methanol.

Standard preparation—Dissolve a suitable quantity of USP Testosterone Enanthate RS, accurately weighed, in methanol, and dilute quantitatively and stepwise with methanol to obtain a solution having a known concentration of about 40 µg per mL.

Assay preparation—Transfer to a 10-mL volumetric flask an accurately measured volume of Injection, equivalent to about 100 mg of testosterone enanthate, add chromatographic *n*-heptane to volume, and mix. Pipet 5 mL of this solution into a 100-mL volumetric flask, add chromatographic *n*-heptane to volume, and mix.

Procedure—Mix in a beaker 3 g of silanized chromatographic siliceous earth and 3 mL of the upper layer of the *Chromatographic solvent*. Pack the mixture into a 250- × 25-mm chromatographic tube that contains a small pledget of glass wool above the stem constriction. Mix in a beaker 3 g of silanized chromatographic siliceous earth and 2.0 mL of *Assay preparation*, transfer the mixture to the tube, and pack. Dry-wash the beaker with 1 g of silanized chromatographic siliceous earth, and transfer to the tube. Place a small pad of glass wool above the column packing. Pass 35 mL of the lower layer of the *Chromatographic solvent* through the column, and collect the eluate in a 50-mL volumetric flask. Add alcohol to volume, and mix. Pipet 10 mL of the resulting solution into a glass-stoppered, 50-mL conical flask, and evaporate on a water bath to dryness. Pipet 5 mL of methanol into the flask, and swirl to dissolve the residue. Pipet 5 mL of *Standard preparation* into a similar flask. To each flask add 10.0 mL of *Isoniazid reagent*, mix, and allow to stand for about 45 minutes. Concomitantly determine the absorbances of both solutions at the wavelength of maximum absorbance at about 380 nm, with a suitable spectrophotometer, using as a blank 5 mL of methanol that has been treated similarly with *Isoniazid reagent*. Calculate the quantity, in mg, of $C_{26}H_{40}O_3$ in each mL of the Injection taken by the formula:

$$2.5(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Testosterone Enanthate RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
TESTOSTERONE ENANTHATE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(3)

Current DocID: GUID-ED834222-B6B3-46D6-9417-CB6F235BCAEC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M81250_01_01
DOI ref: rv6rw