Testosterone Propionate

Testosterone Propionate, when dried, contains not less than 97.0% and not more than 103.0% of C₂₉H₄₂O₃.

Description Testosterone Propionate occurs as white to pale yellow crystals or crystalline powder. It is odorless.

It is freely soluble in methanol, in ethanol (95), in 1,4-dioxane and in diethyl ether, and practically insoluble in water.

Identification (1) To 0.03 g of Testosterone Propionate add 2 mL of a solution of potassium hydroxide in ethanol (95) (1 in 100). Heat on a water bath under a reflux condenser for 1 hour. Cool, add 10 mL of water, and filter the precipitate by suction. Wash the precipitate with water until the washings become neutral, and dry in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours: the dried precipitate melts between 151°C and 157°C.

(2) To 0.02 g of Testosterone Propionate add 3.5 mL of a solution of 0.05 g of hydroxylammonium chloride and 0.05 g of anhydrous sodium acetate in 25 mL of methanol. Heat under a reflux condenser for 1 hour. Cool, add 15 mL of water, filter the precipitate, wash with water, and recrystallize from diluted methanol (7 in 10). Dry the crystals in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours: it melts between 167°C and 170°C.

Optical rotation [α]D₁₀ 83° + 90° (after drying, 0.1 g, 1,4-dioxane, 10 mL, 100 mm).

Melting point 118°–123°C

Purity (1) Clarity and color of solution—Dissolve 0.5 g of Testosterone propionate in 10 mL of ethanol (95): the solution is clear and colorless.

(2) Other steroids—Dissolve 0.040 g of Testosterone Propionate in 2 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of this solution, add ethanol (95) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform and diethylamine (19:1) to a distance of about 15 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (0.5 g, in vacuum, phosphorus (V) oxide, 4 hours).

Residue on ignition Not more than 0.1% (0.5 g).

Assay Weigh accurately about 0.01 g of Testosterone Propionate, previously dried, and dissolve in methanol to make exactly 100 mL. To exactly 5 mL of this solution add methanol to make exactly 50 mL. Determine the absorbance A of this solution at the wavelength of maximum absorption at about 241 nm as directed under the Ultraviolet-visible Spectrophotometry.

Amount (mg) of testosterone propionate (C₂₉H₄₂O₃) = \( \frac{A}{495} \times 10,000 \)

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Testosterone Propionate Injection

Testosterone Propionate Injection is an oily solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of testosterone propionate (C₂₉H₄₂O₃: 344.49).

Method of preparation Prepare as directed under Injections, with Testosterone Propionate.

Description Testosterone Propionate Injection is a clear, colorless or pale yellow oily liquid.

Identification Measure a volume of Testosterone Propionate Injection, equivalent to 0.05 g of Testosterone Propionate according to the labeled amount, and transfer to a separator containing 40 mL of petroleum benzine. Shake well, then extract with three 20-mL portions of diluted