

acid are eluted in this order with the resolution between these peaks being not less than 2.0.

System repeatability: When the test is repeated 6 times with 2 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of acetic acid is not more than 3.0%.

(4) 3,5-Dihydroxy- ω -tert-butylaminoacetophenone sulfate—Dissolve 0.50 g of Terbutaline Sulfate in 0.01 mol/L hydrochloric acid TS to make exactly 25 mL, and perform the test as directed under the Ultraviolet-visible Spectrophotometry: the absorbance at a wavelength of 330 nm does not exceed 0.47.

(5) Heavy metals—Proceed with 2.0 g of Terbutaline Sulfate as directed under Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(6) Arsenic—Prepare the test solution with 1.0 g of Terbutaline Sulfate according to method 3, and perform the test using apparatus B (not more than 2 ppm).

Water Not more than 0.5% (1 g, direct titration).

Residue on ignition Not more than 0.20% (1 g).

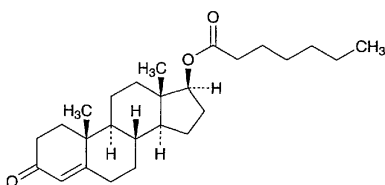
Assay Weigh accurately about 0.5 g of Terbutaline Sulfate, dissolve in 50 mL of a mixture of acetonitrile and acetic acid (100) (1:1) by stirring and warming. Allow to cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration, substituting a saturated solution of potassium chloride in methanol for the internal fluid).

$$\begin{aligned} \text{Each mL of 0.1 mol/L perchloric acid VS} \\ = 54.87 \text{ mg of } (\text{C}_{12}\text{H}_{19}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \end{aligned}$$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Testosterone Enanthate

エナント酸テストステロン



$\text{C}_{26}\text{H}_{40}\text{O}_3$: 400.59

3-Oxoandrost-4-en-17 β -yl heptanoate [315-37-7]

Testosterone Enanthate, when dried, contains not less than 95.0% and not more than 105.0% of $\text{C}_{26}\text{H}_{40}\text{O}_3$.

Description Testosterone Enanthate occurs as white to pale yellow crystals, crystalline powder or a pale yellow-brown, viscous liquid. It is odorless or has a slight, characteristic odor.

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

Melting point: about 36°C

Identification Heat 0.025 g of Testosterone Enanthate

with 2 mL of a solution of potassium hydroxide in methanol (1 in 100) under a reflux condenser on a water bath for 1 hour, cool, and add 10 mL of water. Collect the produced precipitate by suction, wash with water until the last washing is neutral, and dry the precipitate in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours: the precipitate melts between 151°C and 157°C.

Optical rotation $[\alpha]_D^{20}$: +77 – +88° (after drying, 0.1 g, 1,4-dioxane, 10 mL, 100 mm).

Purity Acid—Dissolve 0.5 g of Testosterone Enanthate in 10 mL of ethanol (95) which has previously been rendered neutral to bromothymol blue TS, and add 2 drops of bromothymol blue TS and 0.50 mL of 0.01 mol/L sodium hydroxide VS: the color of the solution is light blue.

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 0.1 g of Testosterone Enanthate, previously dried, and dissolve in ethanol (95) to make exactly 100 mL. Measure exactly 10 mL of this solution, and dilute with ethanol (95) to make exactly 100 mL. Measure exactly 10 mL of this solution, and dilute with ethanol (95) to make exactly 100 mL. Perform the test as directed under the Ultraviolet-visible Spectrophotometry with this solution. Read the absorbance A of this solution at the wavelength of maximum absorption at about 241 nm.

$$\begin{aligned} \text{Amount (mg) of testosterone enanthate } (\text{C}_{26}\text{H}_{40}\text{O}_3) \\ = \frac{A}{426} \times 100,000 \end{aligned}$$

Containers and storage Containers—Tight containers.
Storage—Light-resistant, and not exceeding 30°C.

Testosterone Enanthate Injection

エナント酸テストステロン注射液

Testosterone Enanthate Injection is an oily solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of testosterone enanthate ($\text{C}_{26}\text{H}_{40}\text{O}_3$: 400.59).

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

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

Identification Measure a volume of Testosterone Enanthate Injection, equivalent to 0.05 g of Testosterone Enanthate according to the labeled amount, add 8 mL of petroleum ether, and extract with three 10-mL portions of diluted acetic acid (31) (7 in 10). Combine the extracts, wash with 10 mL of petroleum ether, add 0.5 mL of diluted sulfuric acid (7 in 10) to 0.1 mL of the extract, and heat on a water bath for 5 minutes. Cool, and add 0.5 mL of iron (III) chloride-acetic acid TS: the color of the solution is blue.

Assay Measure accurately a volume of Testosterone Enanthate Injection, equivalent to about 0.025 g of testosterone