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 μL 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).

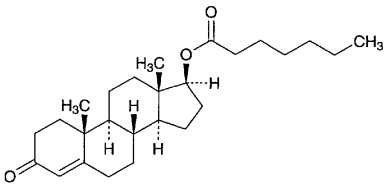
Assay Weigh accurately about 0.5 g of Terbutaline Sulfate, dissolve in 50 mL of a mixture of acetonitrile and acetic acid (100) (1:1) by stirring and warming. Allow to cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration, substituting a saturated solution of potassium chloride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

Each mL of 0.1 mol/L perchloric acid VS
= 54.87 mg of $(C_{12}H_{19}NO_3)_2.H_2SO_4$

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

Testosterone Enanthate

エナント酸テストステロン



$C_{26}H_{40}O_3$: 400.59
3-Oxoandrost-4-en-17β-yl heptanoate [*315-37-7*]

Testosterone Enanthate, when dried, contains not less than 95.0% and not more than 105.0% of $C_{26}H_{40}O_3$.

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.

Amount (mg) of testosterone enanthate ($C_{26}H_{40}O_3$)
$= \frac{A}{426} \times 100{,}000$

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 ($C_{26}H_{40}O_3$: 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

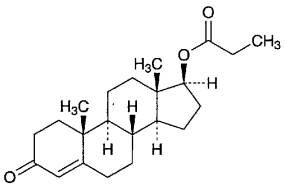
enanthate ($C_{26}H_{40}O_3$), and dissolve in chloroform to make exactly 25 mL. Pipet 3 mL of this solution, add chloroform to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.025 g of Testosterone Propionate Reference Standard, proceed in the same manner as for the sample solution, and use this solution as the standard solution. Pipet 5 mL each of the sample solution and the standard solution, add exactly 10 mL of isoniazid TS, add methanol to make exactly 20 mL, and allow to stand for 45 minutes. Determine the absorbances, A_T and A_S, of these solutions at 380 nm, respectively, as directed under the Ultraviolet-visible Spectrophotometry, using a solution obtained by proceeding with 5 mL of chloroform as the blank.

Amount (mg) of testosterone enanthate ($C_{26}H_{40}O_3$)
= amount (mg) of Testosterone Propionate Reference Standard
$\times \frac{A_T}{A_S} \times 1.163$

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

Testosterone Propionate

プロピオン酸テストステロン



$C_{22}H_{32}O_3$: 344.49
3-Oxoandrost-4-en-17β-yl propionate [*57-85-2*]

Testosterone Propionate, when dried, contains not less than 97.0% and not more than 103.0% of $C_{22}H_{32}O_3$.

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 $[\alpha]_D^{20}$: +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 Tetosterone 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 ($C_{22}H_{32}O_3$)
$= \frac{A}{495} \times 10{,}000$

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

Testosterone Propionate Injection

プロピオン酸テストステロン注射液

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 ($C_{22}H_{32}O_3$: 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 benzin. Shake well, then extract with three 20-mL portions of diluted