the solutions from the Assay preparation and the Standard preparation, respectively.

**Testosterone Propionate**

C_{22}H_{32}O_3  344.49  
Androst-4-en-3-one, 17-(1-oxopropoxy)-, (17β)-. Testosterone propionate  [57-85-2].

Testosterone Propionate contains not less than 97.0 percent and not more than 103.0 percent of C_{22}H_{32}O_3, calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed, light-resistant containers.

**USP Reference standards** (11)—USP Testosterone Propionate RS

**Identification**—

A: Infrared Absorption (197K).

B: Ultraviolet Absorption (197U)—

Solution:  10 µg per mL.

Medium:  alcohol.

Absorptivities at 241 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: It responds to Identification test C under Testosterone Enanthate.

**Melting range** (741): between 118° and 123°.

**Specific rotation** (781S): between +83° and +90°.

**Loss on drying** (731)—Dry it in vacuum over silica gel for 4 hours: it loses not more than 0.5% of its weight.

**Assay**—Proceed with Testosterone Propionate as directed in the Assay under Testosterone Enanthate, except to use USP Testosterone Propionate RS and otherwise substitute Testosterone Propionate throughout. Calculate the quantity, in mg, of C_{22}H_{32}O_3 in the Testosterone Propionate taken by the formula given therein.

**Testosterone Propionate Injection**

Testosterone Propionate Injection is a sterile solution of Testosterone Propionate in a suitable vegetable oil. It contains not less than 88.0 percent and not more than 112.0 percent of the labeled amount of C_{22}H_{32}O_3.

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

**USP Reference standards** (11)—USP Testosterone Propionate RS

**Identification**—Dilute a suitable volume of Injection with chloroform to obtain a solution having a concentration of about 400 µg of testosterone propionate per mL. Proceed as directed in the Identification test under Testosterone Cypionate Injection, beginning with “Prepare a 20-× 20-cm thin-layer chromatographic plate,” except to use USP Testosterone Propionate RS. The Rf 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 (1).

**Assay**—

Chromatographic solvent and Isoniazid reagent—Prepare as directed in the Assay under Testosterone Enanthate Injection.

**Standard preparation**—Prepare as directed in the Assay under Testosterone Enanthate Injection, using USP Testosterone Propionate RS.

**Assay preparation**—Transfer to a 10-mL volumetric flask an accurately measured volume of Injection, equivalent to about 100 mg of testosterone propionate, 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**—Proceed as directed for Procedure in the Assay under Testosterone Enanthate Injection. Calculate the quantity, in mg, of C_{22}H_{32}O_3 in each mL of the Injection taken by the formula:

\[
2.5(C / V)(A_0 / A)
\]

in which C is the concentration, in µg per mL, of USP Testosterone Propionate RS in the Standard preparation, V is the volume, in mL, of Injection taken, and A_0 and A_1 are the absorbances of the solutions from the Assay preparation and the Standard preparation, respectively.

**Tetanus Immune Globulin**

Tetanus Immune Globulin conforms to the regulations of the FDA concerning biologics (see Biologics (1041)). It is a sterile, nonpyrogenic solution of globulins derived from the blood plasma of adult human donors who have been immunized with tetanus toxoid. It has a potency of not less than 50 antitoxin units per mL. It contains not less than 18 g of protein per 100 mL of which not less than 90 percent is gamma globulin. It contains 0.3 M glycine as a stabilizing agent, and it contains a suitable preservative.

**Packaging and storage**—Preserve at a temperature between 2° and 8°.

**Expiration date**—The expiration date for Tetanus Immune Globulin containing a 10% excess of potency is not later than 3 years after date of issue from manufacturer’s cold storage (5°, 1 year).

**Labeling**—Label it to state that it is not for intravenous injection.

**Tetracaine**

C_{15}H_{24}N_{2}O_{2}  264.36  
Benzopic acid, 4-(butylamino)-, 2-(dimethylamino)ethyl ester. 2-(Dimethylamino)ethyl p-(butylamino)benzoate  [94-24-6].
» Tetracaine contains not less than 98.0 percent and not more than 101.0 percent of C_{15}H_{24}N_{2}O_{2}, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards (11)—
USP Tetracaine Hydrochloride RS

Identification—
A: Dissolve 100 mg in 10 mL of dilute hydrochloric acid (1 in 120), and add 1 mL of potassium thiocyanate solution (1 in 4): a crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80° for 2 hours: it melts between 130° and 132° (see Melting Range or Temperature (741)).

B: Dissolve about 90 mg, accurately weighed, in 10 mL of dilute hydrochloric acid (1 in 120) in a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 2 mL of Buffer No. 6, 10 percent, pH 6.0 (see Phosphate Buffers (81)), dilute with water to volume, and mix: the UV absorption spectrum of the solution so obtained exhibits maxima and minima at the same wavelengths as that of a 1 in 100,000 solution of USP Tetracaine Hydrochloride RS in a mixture of water and Buffer No. 6 (50:1), 10 percent, pH 6.0 (see Phosphate Buffers (81)), and the respective molar absorptivities, calculated on the dried basis, at the wavelength of maximum absorbance at about 310 nm do not differ by more than 2.0%. [NOTE—The molecular weight of tetracaine hydrochloride (C_{15}H_{24}N_{2}O_{2} · HCl) is 300.82.]

Melting range, Class I (741): between 41° and 46°.

Loss on drying (731)—Dry it in vacuum over phosphorus pentoxide for 18 hours: it loses not more than 0.5% of its weight.

Residue on ignition (281): not more than 0.1%.

Chromatographic purity—Dissolve an accurately weighed separator, and dissolve in 15 mL of ether. Extract with one 20-mL portion of the test solution and the sodium carbonate TS, and extract immediately with two 50-mL portions of dilute hydrochloric acid (1 in 240) and 10 mL of Buffer No. 6, 10 percent, pH 6.0 (see Phosphate Buffers (81)), dilute with water to volume, and mix. The concentration of USP Tetracaine Hydrochloride RS in the Standard preparation is about 10 µg per mL.

Assay—Transfer about 20 mg of USP Tetracaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, dissolve in water, add water to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, add 5 mL of dilute hydrochloric acid (1 in 240) and 10 mL of Buffer No. 6, 10 percent, pH 6.0 (see Phosphate Buffers (81)), dilute with water to volume, and mix. The absorbance of the test solution with 20 mL of water, discard the washing, and extract the ether solution with two 20-mL portions and one 5-mL portion of dilute hydrochloric acid (1 in 240), collecting the acid extracts in a second separator. Render the aqueous solution alkaline by the addition of 5 mL of sodium carbonate TS, and extract immediately with two 50-mL portions of ether, collecting the ether extracts in another separator. Wash the ether solution with 20 mL of water, dry it in vacuum over phosphorus pentoxide for 18 hours: it loses not more than 0.5% of its weight.

Procedure—Concomitantly determine the absorbances of the Standard preparation and the Standard preparation in 1-cm cells at the wavelength of maximum absorbance at about 310 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of C_{15}H_{24}N_{2}O_{2} in the portion of Ointment taken by the formula:

\[
\text{quantity} = \frac{(264.37/300.83) \times (A_2 / A_1)}{C_2}
\]

in which 264.36 and 300.82 are the molecular weights of tetracaine and tetracaine hydrochloride, respectively; C is the concentration, in µg per mL, of USP Tetracaine Hydrochloride RS in the Standard preparation; and A_1 and A_2 are the absorbances of the Assay preparation and the Standard preparation, respectively.

Tetracaine Ophthalmic Ointment

» Tetracaine Ophthalmic Ointment is a sterile ointment containing not less than 0.45 percent and not more than 0.55 percent of C_{15}H_{24}N_{2}O_{2} in White Petrolatum.

Tetracaine Ointment

» Tetracaine Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of C_{15}H_{24}N_{2}O_{2} in a suitable ointment base.

Packaging and storage—Preserve in collapsible ointment tubes.

USP Reference standards (11)—
USP Tetracaine Hydrochloride RS

Identification—
A: The solution employed for measurement of absorbance in the Assay exhibits a maximum at 310 ± 2 nm.

B: Dissolve 5 g in 50 mL of ether, extract the ether solution with 5 mL of 3 N hydrochloric acid, and filter the acid extract. Add 2 mL of potassium thiocyanate solution (1 in 2) to the filtrate: a crystalline precipitate is formed, and when recrystallized from water and dried at 80° for 2 hours, it melts between 130° and 132° (see Melting Range or Temperature (741)).

Microbial enumeration tests (61) and Tests for specified microorganisms (62)—It meets the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.

Minimum fill (755): meets the requirements.

Assay—

Standard preparation—Transfer about 20 mg of USP Tetracaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, dissolve in water, add water to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, add 5 mL of dilute hydrochloric acid (1 in 240) and 10 mL of Buffer No. 6, 10 percent, pH 6.0 (see Phosphate Buffers (81)), dilute with water to volume, and mix. The concentration of USP Tetracaine Hydrochloride RS in the Standard preparation is about 10 µg per mL.

Assay procedure—Transfer an accurately weighed portion of Ointment, equivalent to about 9 mg of tetracaine, to a separator, and dissolve in 15 mL of ether. Extract with one 20-mL portion and two 10-mL portions of dilute hydrochloric acid (1 in 240), collecting the acid extracts in a second separator. Render the aqueous solution alkaline by the addition of 5 mL of sodium carbonate TS, and extract immediately with two 50-mL portions of ether, collecting the ether extracts in another separator. Wash the ether solution with 20 mL of water, dry it in vacuum over phosphorus pentoxide for 18 hours: it loses not more than 0.5% of its weight. The molecular weight of USP Tetracaine Hydrochloride RS is about 300.82.

Microbial enumeration tests (61) and Tests for specified microorganisms (62)—It meets the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.

Minimum fill (755): meets the requirements.

Assay—

Standard preparation—Transfer about 20 mg of USP Tetracaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, dissolve in water, add water to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, add 5 mL of dilute hydrochloric acid (1 in 240) and 10 mL of Buffer No. 6, 10 percent, pH 6.0 (see Phosphate Buffers (81)), dilute with water to volume, and mix. The concentration of USP Tetracaine Hydrochloride RS in the Standard preparation is about 10 µg per mL.

Assay procedure—Transfer an accurately weighed portion of Ointment, equivalent to about 9 mg of tetracaine, to a separator, and dissolve in 15 mL of ether. Extract with one 20-mL portion and two 10-mL portions of dilute hydrochloric acid (1 in 240), collecting the acid extracts in a second separator. Render the aqueous solution alkaline by the addition of 5 mL of sodium carbonate TS, and extract immediately with two 50-mL portions of ether, collecting the ether extracts in another separator. Wash the ether solution with 20 mL of water, dry it in vacuum over phosphorus pentoxide for 18 hours: it loses not more than 0.5% of its weight. The molecular weight of USP Tetracaine Hydrochloride RS is about 300.82.

Microbial enumeration tests (61) and Tests for specified microorganisms (62)—It meets the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.

Minimum fill (755): meets the requirements.