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)-, (17*β*)-.
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°.

Test solution: 20 mg, previously dried, per mL, in dioxane.

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 R_F 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:

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

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_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

Tetanus Immune Globulin

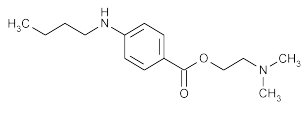
» Tetanus Immune Globulin conforms to the regulations of the FDA concerning biologics (see *Biologics* ⟨1041⟩). It is a sterile, nonpyrogenic solution of globulins derived from the blood plasma of adult human donors who have been immunized with tetanus toxoid. It has a potency of not less than 50 antitoxin units per mL based on the U.S. Standard Tetanus Antitoxin and the U.S. Control Tetanus Test Toxin, tested in guinea pigs. It contains not less than 10 g and not more 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



$C_{15}H_{24}N_2O_2$ 264.36
Benzoic 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 $C_{15}H_{24}N_2O_2$, 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 ($C_{15}H_{24}N_2O_2 \cdot HCl$) 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 quantity of Tetracaine in chloroform to obtain a test solution containing 50 mg per mL. Prepare a Standard solution of 4-(butylamino) benzoic acid in methanol containing 0.2 mg per mL. Apply separate 5-µL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the plate in a suitable chromatographic chamber containing a solvent system consisting of a mixture of chloroform, methanol, and isopropylamine (98:7:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry in a current of warm air. Examine the plate under short-wavelength UV light: any spot obtained from the test solution, other than the principal spot, is not more intense than the principal spot obtained from the Standard solution (0.4%), and the sum of the intensities of any such spots is not greater than 0.8%.

Assay—Transfer about 500 mg of Tetracaine, accurately weighed, to a suitable vessel. Add 5 mL of hydrochloric acid and 50 mL of water, cool to 15°, add about 25 g of crushed ice, and slowly titrate with 0.1 M sodium nitrite VS, stirring vigorously, until a glass rod dipped into the titrated solution produces an immediate blue ring when touched to starch iodide paper. When the titration is complete, the endpoint is reproducible after the mixture has been allowed to stand for 1 minute. Perform a blank determination, and make any necessary correction. Each mL of 0.1 M sodium nitrite is equivalent to 26.44 mg of $C_{15}H_{24}N_2O_2$.

Tetracaine Ointment

» Tetracaine Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{15}H_{24}N_2O_2$ 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 preparation—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, 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 50-mL volumetric flask. Dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 10 mL of *Buffer No. 6*, 10 percent, pH 6.0 (see *Phosphate Buffers* ⟨81⟩), dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Assay 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 $C_{15}H_{24}N_2O_2$ in the portion of Ointment taken by the formula:

$$(264.37/300.83)(C)(A_U / A_S)$$

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_U and A_S 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 $C_{15}H_{24}N_2O_2$ in White Petrolatum.