Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution*, and record the peak areas as directed for *Procedure:* the relative retention times are about 0.7 for fluorometholone and 1.0 for fluorometholone acetate; and the resolution, *R,* between fluorometholone and fluorometholone acetate is not less than 2.0. Chromatograph the *Standard preparation*, and record the areas as directed for *Procedure:* the capacity factor, *k'*, determined from fluorometholone acetate peak is between 1.0 and 5.0; the column efficiency is not less than 1000 theoretical plates; the tailing factor is not more than 1.35; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak areas. Calculate the quantity, in mg, of fluorometholone acetate ($C_{24}H_{31}FO_5$) in each mL of Ophthalmic Suspension taken by the formula:

$$62.5(C / V)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Fluorometholone Acetate RS in the *Standard preparation; V* is the volume, in mL, of Ophthalmic Suspension taken; and r_U and r_S are the fluorometholone acetate peak areas obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Tobramycin Sulfate

$(C_{18}H_{37}N_5O_9)_2 \cdot 5H_2SO_4$ 1425.45

D-Streptamine, *O*-3-amino-3-deoxy-α-D-glucopyranosyl-(1→6)-*O*-[2,6-diamino-2,3,6-tridoexy-α-D-*ribo*-hexopyranosyl-(1→4)]-2-deoxy-, sulfate (2:5) (salt).

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[2,6-diamino-2,3,6-trideoxy-α-D-*ribo*-hexopyranosyl-(1→6)]-2-deoxy-L-streptamine, sulfate (2:5) (salt) [79645-27-5].

» Tobramycin Sulfate has a potency of not less than 634 µg and not more than 739 µg of tobramycin ($C_{18}H_{37}N_5O_9$) per mg.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Tobramycin RS

Identification—

A: It responds to the *Identification* tests under *Tobramycin*.

B: It responds to the tests for *Sulfate* ⟨191⟩.

pH ⟨791⟩: between 6.0 and 8.0, in a solution containing 40 mg per mL.

Water, *Method I* ⟨921⟩: not more than 2.0%.

Other requirements—It meets the requirements for *Residue on ignition*, *Heavy metals*, and *Chromatographic purity* under *Tobramycin*. Where the label states that Tobramycin Sulfate is sterile, it meets the requirements for *Sterility Tests* ⟨71⟩ and for *Bacterial endotoxins* under *Tobramycin for Injection*. Where the label states that Tobramycin Sulfate must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Tobramycin for Injection.*

Assay—

Mobile phase, *2,4-Dinitrofluorobenzene reagent*, *Tris(hydroxymethyl)aminomethane reagent*, *Standard preparation, Derivatization procedure*, *Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Tobramycin.*

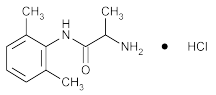
Assay preparation—Transfer an accurately weighed quantity of Tobramycin Sulfate, equivalent to about 50 mg of tobramycin ($C_{18}H_{37}N_5O_9$), to a 250-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Tobramycin*. Calculate the quantity, in µg, of tobramycin ($C_{18}H_{37}N_5O_9$) in each mg of the Tobramycin Sulfate taken by the formula:

$$250(CE / W)(r_U / r_S)$$

in which the terms are as defined therein.

Tocainide Hydrochloride



$C_{11}H_{16}N_2O \cdot HCl$ 228.72

Propanamide, 2-amino-*N*-(2,6-dimethylphenyl)-, hydrochloride, (±)-.

(±)-2-Amino-2′,6′-propionoxylidide hydrochloride.

» Tocainide Hydrochloride contains not less than 98.0 percent and not more than 101.0 percent of $C_{11}H_{16}N_2O \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Tocainide Hydrochloride RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: It responds to the tests for *Chloride* ⟨191⟩.

Loss on drying ⟨731⟩**—**Dry it at 105° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Heavy metals, *Method II* ⟨231⟩: 0.002%.

Chromatographic purity—

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture coating on a thin-layer chromatographic plate, previously washed with methanol.

Test solution: 100 mg per mL, in methanol.

Standard solutions: 1.0, 0.5, 0.25, and 0.1 mg per mL in methanol to obtain *Standard solutions A*, *B*, *C*, and *D*, respectively.

Application volume: 20 µL.

Developing solvent system: a freshly prepared mixture of toluene and alcohol (4:1) in a paper-lined equilibrated tank in an atmosphere of ammonia vapors.

Procedure—Proceed as directed for *Thin-Layer Chromatography* under *Chromatography* ⟨621⟩. Examine the plate under short-wavelength UV light. Expose the plate to iodine vapors, and observe again under white light: the chromatograms show principal spots at about the same R_F value. Estimate the concentration of any spot observed in the chromatogram of the *Test solution*, other than the principal spot and that observed at the origin (which may appear because of the presence of ammonium chloride), by comparison with the principal spots in the chromatograms of *Standard solutions B*, *C*, and *D:* the intensity of any secondary spot is not greater than that of the principal