phene napsylate, respectively, *C* is the concentration, in mg per mL, of anhydrous propoxyphene napsylate in the *Standard preparation*, as determined from the concentration of USP Propoxyphene Napsylate RS corrected for moisture content by a titrimetric water determination, and R_U and R_S are the peak response ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Assay for aspirin—

Sodium hydroxide reagent—Dissolve 1 g of polyoxyethylene (23) lauryl ether in about 100 mL of hot water contained in a 1000-mL volumetric flask. Dilute with water to about 600 mL, and dissolve 10 g of sodium hydroxide in this solution. Dilute with water to volume, and mix.

Ferric nitrate reagent—Mix 70 mL of nitric acid with about 600 mL of water contained in a 1000-mL volumetric flask. Dissolve 40 g of ferric nitrate [$Fe(NO_3)_3 \cdot 9H_2O$] in this solution, dilute with water to volume, and mix.

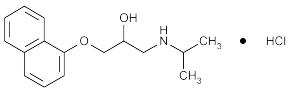
Standard preparation and *Assay preparation*—Prepare as directed in the *Assay for propoxyphene napsylate.*

Procedure—Into separate 25-mL volumetric flasks pipet 2 mL each of the *Standard preparation* and the *Assay preparation*, and 2 mL of dilute acetone (2 in 10) to provide the blank. Into each flask pipet 5 mL of *Sodium hydroxide reagent*, mix by gentle swirling, and allow to stand at room temperature for 8 minutes. Dilute with *Ferric nitrate reagent* to volume, and mix. Concomitantly determine the absorbances of both solutions against the blank in 1-cm cells at the wavelength of maximum absorbance at about 530 nm, taking care to allow the solutions to reach an equilibrium temperature in the cell compartment. The color intensity is temperature-dependent. Calculate the quantity, in mg, of $C_9H_8O_4$ in the portion taken for the *Assay preparation* by the formula:

$$100C(A_U / A_S)$$

in which *C* is the concentration, in mg per mL, of USP Aspirin RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and *Standard preparation*, respectively.

Propranolol Hydrochloride



$C_{16}H_{21}NO_2 \cdot HCl$ 295.80

2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride, (±)-.

(±)-1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol hydrochloride [318-98-9].

» Propranolol Hydrochloride contains not less than 98.0 percent and not more than 101.5 percent of $C_{16}H_{21}NO_2 \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

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

Identification—

A: *Infrared Absorption* ⟨197M⟩.

B: The retention time of the major peak for propranolol in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

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

Melting range, *Class Ia* ⟨741⟩**:** between 162° and 165°.

Specific rotation ⟨781S⟩**:** between –1.0° and +1.0°.

Test solution: 40 mg per mL, in water.

Loss on drying ⟨731⟩**—**Dry it at 105° for 4 hours: it loses not more than 0.5% of its weight.

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

Assay—

Mobile phase—Dissolve 0.5 g of sodium dodecyl sulfate in 18 mL of 0.15 M phosphoric acid, add 90 mL of acetonitrile and 90 mL of methanol, dilute with water to make 250 mL, mix, and pass through a filter having a 0.5-µm or finer porosity. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Propranolol Hydrochloride RS in methanol to obtain a stock solution having a known concentration of about 1 mg per mL. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, dilute with methanol to volume, mix, and pass through a filter having a 0.7-µm or finer porosity. This solution contains about 0.2 mg of USP Propranolol Hydrochloride RS per mL.

Resolution solution—Prepare a solution of procainamide hydrochloride in methanol containing about 0.25 mg per mL. Transfer 5 mL of this solution and 5 mL of the stock solution used to prepare the *Standard preparation* to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

Assay preparation—Transfer about 50 mg of Propranolol Hydrochloride, accurately weighed, to a 50-mL volumetric flask, add 45 mL of methanol, shake, and sonicate for 5 minutes. Dilute with methanol to volume, mix, and pass through a filter having a 0.7-µm or finer porosity. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 290-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L7. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.6 for procainamide and 1.0 for propranolol; and the resolution, *R,* between the procainamide and the propranolol peaks is not less than 2.0. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor for the propranolol peak is not more than 3.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{16}H_{21}NO_2 \cdot HCl$ in the portion of Propranolol Hydrochloride taken by the formula:

$$250C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Propranolol Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the propranolol peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Propranolol Hydrochloride Extended-Release Capsules

DEFINITION

Propranolol Hydrochloride Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of propranolol hydrochloride ($C_{16}H_{21}NO_2 \cdot HCl$).