pH ⟨791⟩: between 2.8 and 4.0.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Propranolol Hydrochloride*.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 5 mg of propranolol hydrochloride, to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Propranolol Hydrochloride*. Calculate the quantity, in mg, of $C_{16}H_{21}NO_2 \cdot HCl$ in each mL of the Injection taken by the formula:

$$25(C / V)(r_U / r_S)$$

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

Propranolol Hydrochloride Tablets

» Propranolol Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{16}H_{21}NO_2 \cdot HCl$.

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

USP Reference standards ⟨11⟩—
USP Propranolol Hydrochloride RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for propranolol, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay*.

Dissolution ⟨711⟩—

Medium: dilute hydrochloric acid (1 in 100); 1000 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{16}H_{21}NO_2 \cdot HCl$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 289 nm of filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Propranolol Hydrochloride RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{16}H_{21}NO_2 \cdot HCl$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—Transfer 1 Tablet to a 100-mL volumetric flask, add 5 mL of dilute hydrochloric acid (1 in 100), and let stand, swirling occasionally, until it is disintegrated. Add about 70 mL of methanol, and sonicate for about 1 minute. Dilute with methanol to volume, mix, and centrifuge a portion of the solution. Dilute an aliquot of the clear solution quantitatively with methanol to provide a solution containing about 40 µg of propranolol hydrochloride per mL. Concomitantly determine the absorbances of this solution and of a solution of USP Propranolol Hydrochloride RS in methanol, at a known concentration of about 40 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 290 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of $C_{16}H_{21}NO_2 \cdot HCl$ in the Tablet by the formula:

$$(T / D)C(A_U / A_S)$$

in which T is the labeled quantity, in mg, of propranolol hydrochloride in the Tablet, D is the concentration, in µg per mL, of the solution from the Tablet, based on the labeled quantity per Tablet and the extent of dilution, C is the concentration, in µg per mL, of USP Propranolol Hydrochloride RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Tablet and the Standard solution, respectively.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Propranolol Hydrochloride*.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of propranolol hydrochloride, to a 50-mL volumetric flask, add 40 mL of methanol, shake, and sonicate for 5 minutes. Dilute with methanol to volume, mix, and filter through a 0.7-µm or finer porosity filter. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Propranolol Hydrochloride*. Calculate the quantity, in mg, of $C_{16}H_{21}NO_2 \cdot HCl$ in the portion of Tablets taken by the formula:

$$250C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Propranolol Hydrochloride 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 and Hydrochlorothiazide Extended-Release Capsules

» Propranolol Hydrochloride and Hydrochlorothiazide Extended-Release Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of propranolol hydrochloride ($C_{16}H_{21}NO_2 \cdot HCl$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Benzothiadiazine Related Compound A RS
4-Amino-6-chloro-1,3-benzenedisulfonamide.
$C_6H_8ClN_3O_4S_2$ 285.73
USP Hydrochlorothiazide RS
USP Propranolol Hydrochloride RS

Identification—

A: Transfer the contents of a number of Capsules, equivalent to about 100 mg of hydrochlorothiazide, to a 20-mesh sieve. Break up any large lumps with the aid of a spatula, and collect the powder that passes through the sieve. [NOTE—Retain the material on the screen for *Identification* test *B*.] Transfer the powder that passed through the sieve to a screw-capped, 35-mL centrifuge tube, add 5 mL of solvent hexane, and shake for 5 minutes. Centrifuge, and discard the solvent. To the residue in the centrifuge tube add 10 mL of 1 N sodium hydroxide, shake, and filter, collecting the filtrate in a separator. Wash the filter with 5 mL of water, and collect the washing in the separator. Add 50 mL of ether to the separator, shake for 2 minutes, and allow the phases to separate. Drain the aqueous