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 diinte-grated. 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. Concomi-tantly 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:

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25(C / V)(r_0 / r_1)
\]

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 \( r_0 \) and \( r_1 \) 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 (\( C_7H_6ClIN_2O_6S_2 \)).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards (11)—
USP Benzenothiadiazine Related Compound A RS
4-Amino-6-chloro-1,3-benzenedisulfonamide.
\( C_7H_6ClIN_2O_6S_2 \) 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