sorbances of the solution from the Syrup and the Standard solution, respectively.

Promazine Hydrochloride Tablets

» Promazine Hydrochloride Tablets contain not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_{17}H_{20}N_2S \cdot HCl$.

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

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

NOTE—Throughout the following procedures, protect test or assay specimens, the Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

Identification—

A: Shake a portion of powdered Tablets, equivalent to about 50 mg of promazine hydrochloride, with 25 mL of 0.01 N hydrochloric acid for 5 minutes, and filter: the solution meets the requirements under *Identification—Organic Nitrogenous Bases* ⟨181⟩.

B: It responds to *Identification* test *B* under *Promazine Hydrochloride.*

Disintegration ⟨701⟩: 30 minutes, with disks.

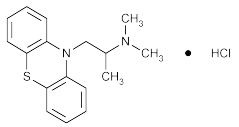
Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—[NOTE—Use low-actinic glassware.] Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of promazine hydrochloride, to a 100-mL volumetric flask. Add 50 mL of 0.1 N hydrochloric acid, and shake by mechanical means for about 1 hour. Dilute with 0.1 N hydrochloric acid to volume, mix, and centrifuge a portion of the mixture. Transfer 10.0 mL of the clear, supernatant to a 250-mL separator, and proceed as directed in the *Assay* under *Promazine Hydrochloride Injection*, beginning with "add 20 mL of water." Calculate the quantity, in mg, of $C_{17}H_{20}N_2S \cdot HCl$ in the portion of Tablets taken by the formula:

$$C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Promazine Hydrochloride RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

Promethazine Hydrochloride



$C_{17}H_{20}N_2S \cdot HCl$ 320.88

10*H*-Phenothiazine-10-ethanamine, *N*,*N*,α-trimethyl-, monohydrochloride, (±)-.

(±)-10-[2-(Dimethylamino)propyl]phenothiazine monohydrochloride [58-33-3].

» Promethazine Hydrochloride contains not less than 97.0 percent and not more than 101.5 percent of $C_{17}H_{20}N_2S \cdot HCl$, calculated on the dried basis.

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

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

Completeness and clarity of solution—Separately prepare a 1 in 10 solution of it in water and 1 in 10 solution of it in chloroform: each solution is practically clear and shows not more than a light yellow color.

NOTE—Throughout the following procedures, protect test or assay specimens, the Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

Identification—

A: *Infrared Absorption* ⟨197K⟩.

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

pH ⟨791⟩: between 4.0 and 5.0, in a solution (1 in 20).

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%.

Related substances—

Standard preparation and *Standard dilutions*—Dissolve an accurately weighed quantity of USP Promethazine Hydrochloride RS in methylene chloride to obtain a solution containing 10.0 mg per mL (*Standard preparation*). Prepare a series of quantitative dilutions of the *Standard preparation* in methylene chloride to contain 0.2, 0.1, 0.05, and 0.025 mg per mL (*Standard dilutions*) corresponding to 2.0%, 1.0%, 0.5%, and 0.25% of impurities, respectively.

Test solution—Dissolve 100 mg, accurately weighed, of Promethazine Hydrochloride in 10.0 mL of methylene chloride.

Procedure—Using a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of silica gel mixture, apply 10-µL portions of the *Test preparation*, the *Standard preparation*, and each of the *Standard dilutions* 2.5 cm from the lower edge of the plate. Develop the plate in an unsaturated tank containing a mixture of ethyl acetate, acetone, alcohol, and ammonium hydroxide (90:45:2:1). After the solvent has moved not less than 10 cm, air-dry the plate, and view under short-wavelength UV light: the R_F value of the principal spot obtained from the *Test preparation* corresponds to that from the *Standard preparation.* Estimate the concentration of any other spots observed in the lane for the *Test preparation* by comparison with the *Standard dilutions:* the sum of the impurities is not greater than 2.0%, and no single impurity is greater than 1.0%.

Assay—Dissolve about 700 mg of Promethazine Hydrochloride, accurately weighed, in a mixture of 75 mL of glacial acetic acid and 10 mL of mercuric acetate TS. Add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a blue endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 32.09 mg of $C_{17}H_{20}N_2S \cdot HCl$.

Promethazine Hydrochloride Injection

» Promethazine Hydrochloride Injection is a sterile solution of Promethazine Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_{17}H_{20}N_2S \cdot HCl$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.