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Do not distribute

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.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PROMAZINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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