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Promazine Hydrochloride Injection

» Promazine Hydrochloride Injection is a sterile solution of Promazine 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.

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: It meets the requirements under *Identification—Organic Nitrogenous Bases ⟨181⟩*.

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

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.8 USP Endotoxin Units per mg of promazine hydrochloride.

pH ⟨791⟩: between 4.0 and 5.5.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—[Note—Use low-actinic glassware.] Transfer a volume of Injection, equivalent to about 50 mg of promazine hydrochloride, to a 100-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix. Transfer 10.0 mL of the solution to a 250-mL separator, add 20 mL of water, render alkaline with ammonium hydroxide, and extract with four 25-mL portions of ether. Extract the combined ether extracts with five 15-mL portions of 0.1 N hydrochloric acid, collecting the aqueous extracts in a 100-mL volumetric flask. Aerate to remove residual ether, dilute with 0.1 N hydrochloric acid to volume, and mix. Without delay, concomitantly determine the absorbances of this solution and of a Standard solution of USP Promazine Hydrochloride RS in the same medium having a known concentration of about 50 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 301 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_{17}H_{20}N_2S \cdot HCl$ in each mL of the Injection taken by the formula:

$$(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Promazine Hydrochloride RS in the Standard solution, V is the volume, in mL, of Injection taken, and A_U and A_S are the absorbances of the solution from the Injection 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 INJECTION	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

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