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Promazine Hydrochloride Oral Solution

» Promazine Hydrochloride Oral Solution 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 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: Dilute a volume of Oral Solution, equivalent to about 50 mg of promazine hydrochloride, with 0.01 N hydrochloric acid to 25 mL, and proceed as directed under *Identification—Organic Nitrogenous Bases ⟨181⟩*, beginning with "Transfer the liquid to a separator": the Oral Solution meets the requirements of the test.

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

pH ⟨791⟩: between 5.0 and 5.5.

Assay—[Note—Use low-actinic glassware.] Transfer an accurately measured volume of Oral Solution, or a quantitative dilution of it in water, equivalent to about 10 mg of promazine hydrochloride, to a 250-mL separator. Add water to adjust the volume to about 45 mL, add 3 mL of sodium hydroxide solution (1 in 10), mix, and extract the promazine with five 25-mL portions of ether. Wash the combined ether extracts with 25 mL of water, and discard the aqueous washings. Extract the combined ether extract with one 50-mL and four 25-mL portions of 0.1 N hydrochloric acid. Filter the acid extracts through a pledget of cotton washed with 0.1 N hydrochloric acid into a 250-mL volumetric flask, dilute with the same 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 40 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 Oral Solution taken by the formula:

$$(0.25C/V)(A_U/A_S)$$

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 Oral Solution taken, and A_U and A_S are the absorbances from the assay solution 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 ORAL SOLUTION	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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