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Do not distribute

Promethazine Hydrochloride Suppositories

» Promethazine Hydrochloride Suppositories 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, and store in a cold place.

USP REFERENCE STANDARDS (11)—
[USP Promethazine 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—Transfer a number of Suppositories, equivalent to about 50 mg of promethazine hydrochloride, to a 250-mL separator. Add 75 mL of solvent hexane and 25 mL of 0.01 N hydrochloric acid; shake to dissolve the solids. Using the aqueous phase, filtered through paper if necessary, proceed as directed under [Identification—Organic Nitrogenous Bases \(181\)](#), beginning with “Transfer the liquid to a separator.”

Assay—

Palladium chloride solution—Add 5 mL of hydrochloric acid to a beaker containing 500 mg of palladium chloride. Warm on a steam bath to obtain a complete solution. Slowly add 200 mL of hot water. (If necessary, continue warming and add additional hydrochloric acid to maintain complete solution.) Transfer the solution to a 500-mL volumetric flask, and dilute with water to volume. To 50 mL of this solution add 250 mL of 2 M sodium acetate, and adjust with hydrochloric acid to a pH of 4.0. Transfer the solution to a 500-mL volumetric flask, dilute with water to volume, and mix.

Standard preparation—Using an accurately weighed quantity of [USP Promethazine Hydrochloride RS](#), prepare a solution in 0.05 N hydrochloric acid containing about 0.1 mg in each mL. Protect the solution from light.

Assay preparation—Weigh 10 Suppositories and calculate the average. Carefully melt them, avoiding the use of excessive heat, and mix. Add 30 mL of hexanes to an accurately weighed portion, equivalent to about 50 mg of promethazine hydrochloride. Warm gently to dissolve, and transfer to a low-actinic separator. Rinse the transfer container with several small portions of the hexanes and 0.05 N hydrochloric acid, and add the rinsings to the separator. Extract with five 20-mL portions of 0.05 N hydrochloric acid shaking gently to avoid emulsions. Drain through glass wool prewashed with 0.05 N hydrochloric acid. Collect in a 500-mL low-actinic volumetric flask. Rinse the glass wool with additional 0.05 N hydrochloric acid, dilute the combined filtrate with 0.05 N hydrochloric acid to volume, and mix.

Procedure—Pipet 2.0 mL of the *Standard preparation*, *Assay preparation*, and 0.05 N hydrochloric acid into separate test tubes. Add 3.0 mL of *Palladium chloride solution* to each, and mix. Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* in 1-cm cells at the wavelength of maximum absorbance at about 450 nm, with a suitable spectrophotometer, using the hydrochloric acid-palladium chloride solution as the reagent blank in the reference cell. Calculate the quantity, in mg, of $C_{17}H_{20}N_2S \cdot HCl$ in the portion of Suppositories taken by the formula:

$$500C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of [USP Promethazine Hydrochloride RS](#) in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PROMETHAZINE HYDROCHLORIDE SUPPOSITORIES	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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