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Chlorpromazine Hydrochloride Injection

» Chlorpromazine Hydrochloride Injection is a sterile solution of Chlorpromazine Hydrochloride in Water for Injection. It contains, in each mL, not less than 23.75 mg and not more than 26.25 mg of $C_{17}H_{19}ClN_2S \cdot HCl$.

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 Chlorpromazine 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: Transfer a volume of Injection, equivalent to about 25 mg of chlorpromazine hydrochloride, to a 10-mL volumetric flask, dilute with methanol to volume, and mix (test solution). Dissolve a suitable quantity of [USP Chlorpromazine Hydrochloride RS](#) in dilute methanol (9 in 10) to obtain a Standard solution having a known concentration of 2.5 mg per mL. Apply separately 5-μL portions of each of the two solutions to the starting line of a thin-layer chromatographic plate (see [Chromatography \(621\)](#)) coated with chromatographic silica gel mixture. Develop the chromatogram in a solvent system consisting of a freshly prepared mixture of equal volumes of ether and ethyl acetate saturated with ammonium hydroxide until the solvent front has moved about 10 cm from the origin. Remove the plate from the developing chamber, air-dry for 20 minutes, then view under short-wavelength UV light: the R_f value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

B: It responds to the tests for [Chloride \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 6.9 USP Endotoxin Units per mg of chlorpromazine hydrochloride.

pH (791): between 3.4 and 5.4.

Limit of chlorpromazine sulfoxide—[NOTE—Conduct this test without exposure to daylight, and with the minimum necessary exposure to artificial light.]

Test preparation—Pipet 4 mL of the test solution prepared with methanol as directed in *Identification* test A into a 10-mL volumetric flask, dilute with methanol to volume, and mix.

Standard preparation—Dissolve a suitable quantity of [USP Chlorpromazine Hydrochloride RS](#) in methanol to obtain a solution having a concentration of 50 μg per mL.

Procedure—Apply separate 10-μL portions of the *Standard preparation* and the *Test preparation* to the starting line of a thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture. Dry the applied solutions with the aid of a stream of nitrogen. Develop the chromatogram, using as the solvent system a freshly prepared mixture of equal volumes of ether and ethyl acetate saturated with ammonium hydroxide, until the solvent front has moved about 13 cm from the origin. Remove the plate from the chamber, and air-dry for 30 minutes. Examine under short-wavelength UV light: the area and intensity of the only other spot in the test specimen chromatogram, other than the principal spot, are not greater than those of the spot from the *Standard preparation* (5.0%).

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer an accurately measured volume of Injection, equivalent to about 100 mg of chlorpromazine hydrochloride, to a 500-mL volumetric flask, add 0.1 N hydrochloric acid to volume, and mix. Pipet 10 mL of the solution into a 250-mL separator, add about 20 mL of water, render alkaline with ammonium hydroxide, and extract with four 25-mL portions of ether. Extract the combined ether extracts with four 25-mL portions of 0.1 N hydrochloric acid, collecting the aqueous extracts in a 250-mL volumetric flask. Aerate to remove residual ether, add 0.1 N hydrochloric acid to volume, and mix. Dissolve a suitable quantity, accurately weighed, of [USP Chlorpromazine Hydrochloride RS](#) in 0.1 N hydrochloric acid, and dilute quantitatively and stepwise with the same acid to obtain a Standard solution having a known concentration of about 8 μg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 254 nm and at 277 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_{17}H_{19}ClN_2S \cdot HCl$ in each mL of the Injection taken by the formula:

$$12.5C(A_{254} - A_{277})_U / V(A_{254} - A_{277})_S$$

in which *C* is the concentration, in µg per mL, of [USP Chlorpromazine Hydrochloride RS](#) in the Standard solution, *V* is the volume, in mL, of Injection taken, and the parenthetic expressions are the differences in the absorbances of the two solutions at the wavelengths indicated by the subscripts, for the solution from the Injection (*U*) and the Standard solution (*S*), respectively.

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

Topic/Question	Contact	Expert Committee
CHLORPROMAZINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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