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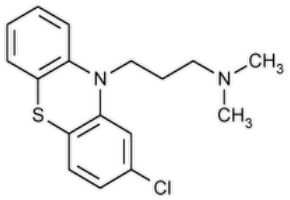
Chlorpromazine



$C_{17}H_{19}ClN_2S$ 318.86

10*H*-Phenothiazine-10-propanamine, 2-chloro-*N*,*N*- dimethyl-.

2-Chloro-10-[3-(dimethylamino)propyl]phenothiazine CAS RN®: 50-53-3; UNII: U42B7VYA4P.

» Chlorpromazine contains not less than 98.0 percent and not more than 101.0 percent of $C_{17}H_{19}ClN_2S$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

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: The IR absorption spectrum of a 1 in 100 solution in carbon disulfide, in a 1.0-mm cell between 7 µm and 15 µm, exhibits maxima only at the same wavelengths as that of a solution prepared by dissolving 55 mg of USP Chlorpromazine Hydrochloride RS in 3 mL of 1 N sodium hydroxide and extracting the resulting solution with 5.0 mL of carbon disulfide.

B: The principal spot found in the test for *Other alkylated phenothiazines* corresponds in R_F to the spot from the *Standard solution*.

Loss on drying ⟨731⟩—Dry it in vacuum at room temperature for 3 hours: it loses not more than 1.0% of its weight.

Other alkylated phenothiazines—Dissolve 45.0 mg in 10 mL of methanol. Dissolve a suitable quantity of USP Chlorpromazine Hydrochloride RS in methanol to obtain a concentration of 5 mg per mL (*Standard solution*), and dilute it quantitatively and stepwise with methanol to obtain a concentration of 25 µg per mL (*Diluted standard solution*). Apply separately 10 µL of each of the three solutions to the starting line of a thin-layer chromatographic plate coated with chromatographic silica gel mixture. 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 10 cm from the origin. Remove the plate from the chamber, and air-dry for 20 minutes. View under short-wavelength UV light: the area and intensity of any spot, other than the principal spot, from the solution of Chlorpromazine are not greater than those of the spot from the *Diluted standard solution* (0.5%).

Assay—Place about 750 mg of Chlorpromazine, accurately weighed, in a 250-mL conical flask, and dissolve in 25 mL of glacial acetic acid, warming gently on a steam bath to effect solution. Cool, add crystal violet TS, and titrate with 0.1 N perchloric acid VS to a blue endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 31.89 mg of $C_{17}H_{19}ClN_2S$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

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