

Assay—Place not fewer than 10 Suppositories in a 250-mL beaker, reduce the mass to the consistency of a paste by crushing with a spatula, and mix. Weigh accurately a portion of the mass, equivalent to about 50 mg of chlorpromazine, place in a beaker, and dissolve in about 40 mL of ether. Transfer to a 250-mL separator with the aid of three 25-mL portions of ether, and extract with four 75-mL portions of 0.1 N hydrochloric acid, collecting the aqueous extracts in a 500-mL volumetric flask. Add 0.1 N hydrochloric acid to volume, and mix. Transfer 10.0 mL of this solution to a 200-mL volumetric flask, add 0.1 N hydrochloric acid to volume, and mix. Dissolve an accurately weighed quantity of USP Chlorpromazine Hydrochloride RS in 0.1 N hydrochloric acid, and dilute quantitatively and stepwise with the same solvent to obtain a Standard solution having a known concentration of about 5.5 µg of chlorpromazine hydrochloride 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 chlorpromazine ($C_{17}H_{19}ClN_2S$) in the portion of Suppositories taken by the formula:

$$10(0.897C)(A_{254} - A_{277})_U / (A_{254} - A_{277})_S$$

in which 0.897 is the ratio of the molecular weight of chlorpromazine to that of chlorpromazine hydrochloride; C is the concentration, in µg per mL, of USP Chlorpromazine Hydrochloride RS in the Standard solution; and the parenthetical expressions are the differences in the absorbances of the two solutions at the wavelengths indicated by the subscripts, for the solution from the Suppositories (U) and the Standard solution (S), respectively.

Chlorpromazine Hydrochloride

$C_{17}H_{19}ClN_2S \cdot HCl$ 355.33

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

2-Chloro-10-[3-(dimethylamino)propyl]phenothiazine monohydrochloride [69-09-0].

» Chlorpromazine Hydrochloride contains not less than 98.0 per cent and not more than 101.5 per cent of $C_{17}H_{19}ClN_2S \cdot HCl$, 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: *Infrared Absorption* (197K).

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

C: A solution (1 in 10) responds to the tests for *Chloride* (191).

Melting range (741): between 195° and 198°.

Loss on drying (731)—Dry it at 105° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition (281): not more than 0.1%.

Other alkylated phenothiazines—Dissolve 50 mg, previously dried, in methanol to make 10 mL, and mix. Proceed as directed in the test for *Other alkylated phenothiazines* under *Chlorpromazine*, beginning with "Dissolve a suitable quantity of USP Chlorpromazine Hydrochloride RS." The area and intensity

of any spot, other than the principal spot, from the solution of Chlorpromazine Hydrochloride are not greater than those of the spot from the *Diluted standard solution* (0.5%).

Assay—Transfer to a beaker about 700 mg of Chlorpromazine Hydrochloride, accurately weighed, and dissolve in 75 mL of glacial acetic acid. Add 10 mL of mercuric acetate TS, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Each mL of 0.1 N perchloric acid is equivalent to 35.53 mg of $C_{17}H_{19}ClN_2S \cdot HCl$.

Chlorpromazine Hydrochloride Oral Concentrate

» Chlorpromazine Hydrochloride Oral Concentrate contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of $C_{17}H_{19}ClN_2S \cdot HCl$.

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

Labeling—Label it to indicate that it must be diluted prior to administration.

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: It responds to *Identification test A* under *Chlorpromazine Hydrochloride Syrup*.

B: Dilute a portion of the Oral Concentrate with an equal volume of water: the resulting solution responds to the tests for *Chloride* (191).

Microbial enumeration tests (61) and **Tests for specified microorganisms** (62)—It meets the requirements of the tests for the absence of *Escherichia coli*.

pH (791): between 2.3 and 4.1.

Limit of chlorpromazine sulfoxide—Proceed as directed in the test for *Chlorpromazine sulfoxide* under *Chlorpromazine Hydrochloride Syrup*.

Assay—Transfer an accurately measured volume of Oral Concentrate, previously diluted if necessary, equivalent to about 10 mg of chlorpromazine hydrochloride, to a 50-mL volumetric flask, add 0.1 N hydrochloric acid to volume, and mix. Proceed as directed in the *Assay* under *Chlorpromazine Hydrochloride Injection*, beginning with "Pipet 10 mL of the solution." Calculate the quantity, in mg, of $C_{17}H_{19}ClN_2S \cdot HCl$ in each mL of the Oral Concentrate taken by the formula:

$$1.25C(A_{254} - A_{277})_U / V(A_{254} - A_{277})_S$$

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 Oral Concentrate taken; and the parenthetical expressions are the differences in the absorbances of the two solutions at the wavelengths indicated by the subscripts, for the solution from the Oral Concentrate (U) and the Standard solution (S), respectively.

Chlorpromazine Hydrochloride Injection

» Chlorpromazine Hydrochloride Injection is a sterile solution of Chlorpromazine Hydrochloride