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Chlorpromazine Hydrochloride Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-notice-chlorpromazine-hcl-tabs-20241122.

DEFINITION

Chlorpromazine Hydrochloride Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$).

[NOTE—Throughout the following analyses, protect sample 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 principal spot found in the test for *Other Alkylated Phenothiazines* corresponds in R_f to the spot of the *Standard solution*.

• **B.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), *Chloride*

Sample stock solution: Digest a quantity of powdered Tablets, equivalent to about 25 mg of chlorpromazine hydrochloride, with 25 mL of [water](#). Pass the resulting solution through a suitable filter.

Sample solution: A solution (1 in 10) using the *Sample stock solution*

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Standard solution: 8 µg/mL of [USP Chlorpromazine Hydrochloride RS](#) in 0.1 N [hydrochloric acid](#)

Sample stock solution: Nominally 0.2 mg/mL of chlorpromazine hydrochloride prepared as follows. Transfer a portion of finely powdered Tablets (NLT 20), equivalent to 100 mg of chlorpromazine hydrochloride, to a 500-mL volumetric flask. Add 200 mL of [water](#) and 5 mL of [hydrochloric acid](#), insert the stopper, and shake for about 10 min. Dilute with [water](#) to volume, and mix. Pass a portion of the resulting solution through a suitable filter, discarding the first 50 mL of the filtrate.

Sample solution: Nominally 8 µg/mL of chlorpromazine hydrochloride prepared as follows. Pipet 10.0 mL of the *Sample stock solution* into a 250-mL separator, add 20 mL of [water](#), render alkaline with [ammonium hydroxide](#), and extract with four 25-mL portions of [ethyl ether](#). Extract the combined [ethyl 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 [ethyl ether](#), and dilute with 0.1 N [hydrochloric acid](#) to volume.

Instrumental conditions

Mode: UV-Vis

Analytical wavelengths: 254 and 277 nm

Cell: 1 cm

Blank: 0.1 N [hydrochloric acid](#)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = [(A_{U1} - A_{U2}) / (A_{S1} - A_{S2})] \times (C_S / C_U) \times 100$$

A_{U1} = absorbance of the *Sample solution*, 254 nm

A_{U2} = absorbance of the *Sample solution*, 277 nm

A_{S1} = absorbance of the *Standard solution*, 254 nm

A_{S2} = absorbance of the *Standard solution*, 277 nm

C_s = concentration of [USP Chlorpromazine Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_u = nominal concentration of chlorpromazine hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 0.1 N [hydrochloric acid](#) solution; 900 mL

Apparatus 1: 50 rpm

Time: 30 min

Standard solution: [USP Chlorpromazine Hydrochloride RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about 254 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$) dissolved.

Tolerances: NLT 80% (Q) of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#) solution; 500 mL, deaerated

Apparatus 1: 75 rpm

Time: 15 min

Standard solution: 0.055 mg/mL of [USP Chlorpromazine Hydrochloride RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: UV 254 nm

Cell: 1.0 mm

Blank: *Medium*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times D \times (1/L) \times 100$$

A_u = absorbance of chlorpromazine from the *Sample solution*

A_s = absorbance of chlorpromazine from the *Standard solution*

C_s = concentration of [USP Chlorpromazine Hydrochloride RS](#) in the *Standard solution* (µg/mL)

V = volume of *Medium*, 500 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S \cdot HCl$) is dissolved.

▲**Test 4:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*



Documents

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