

Chlorpromazine Hydrochloride Injection

塩酸クロルプロマジン注射液

Chlorpromazine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$: 355.33).

Method of preparation Prepare as directed under Injections, with Chlorpromazine Hydrochloride.

Description Chlorpromazine Hydrochloride Injection is a clear, colorless or pale yellow liquid.

pH: 4.0 – 6.5

Identification (1) Proceed with a volume of Chlorpromazine Hydrochloride Injection, equivalent to 5 mg of Chlorpromazine Hydrochloride according to the labeled amount, as directed in the Identification (1) under Chlorpromazine Hydrochloride.

(2) Proceed with a volume of Chlorpromazine Hydrochloride Injection, equivalent to 0.1 g of Chlorpromazine Hydrochloride according to the labeled amount, as directed in the Identification (2) under Chlorpromazine Hydrochloride.

Assay Transfer an exactly measured volume of Chlorpromazine Hydrochloride Injection, equivalent to about 0.15 g of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$) to a separator, add 30 mL of water and 10 mL of a solution of sodium hydroxide (1 in 5), and extract with two 30-mL portions and three 20-mL portions of diethyl ether. Wash the combined diethyl ether extracts with successive 10-mL portions of water until the last washing shows no red color upon the addition of phenolphthalein TS. Concentrate the diethyl ether extracts on a water bath to 20 mL, add 5 g of anhydrous sodium sulfate, allow to stand for 20 minutes, and filter through a pledget of absorbent cotton. Wash with diethyl ether, combine the washings with the filtrate, and evaporate the diethyl ether on a water bath. Dissolve the residue in 50 mL of acetone and 5 mL of acetic acid (100), and titrate with 0.05 mol/L perchloric acid VS until the color of the solution changes from red-purple to blue-purple (indicator: 3 drops of bromocresol green-methylrosaniline chloride TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 17.767 mg of $C_{17}H_{19}ClN_2S.HCl$

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Chlorpromazine Hydrochloride Tablets

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Chlorpromazine Hydrochloride Tablets contain not less than 93% and not more than 107% of the labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$: 355.33).

Method of preparation Prepare as directed under Tablets, with Chlorpromazine Hydrochloride.

Identification (1) Shake a quantity of powdered Chlorpromazine Hydrochloride Tablets, equivalent to 0.2 g of Chlorpromazine Hydrochloride according to the labeled amount, with 40 mL of 0.1 mol/L hydrochloric acid TS, and filter. To 1 mL of the filtrate add 4 mL of water and 1 drop of iron (III) chloride TS: a red color develops.

(2) To 20 mL of the filtrate obtained in (1) add 10 mL of 2,4,6-trinitrophenol TS dropwise, and proceed as directed in the Identification (2) under Chlorpromazine Hydrochloride.

Dissolution test Perform the test with 1 tablet of Chlorpromazine Hydrochloride Tablet at 75 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of diluted pH 6.8 phosphate buffer solution (1 in 2) as the test solution. Take 20 mL or more of the dissolved solution after 60 minutes from the start of the dissolution test, and filter through a membrane filter with pore size of not more than 0.8 μm . Discard the first 10 mL of the filtrate, pipet the subsequent V mL, add diluted pH 6.8 phosphate buffer solution (1 in 2) to make exactly V' mL so that each mL of the filtrate contains about 5.6 μg of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 0.09 g of chlorpromazine hydrochloride for assay, previously dried at 105°C for 2 hours, dissolve in diluted pH 6.8 phosphate buffer solution (1 in 2) to make exactly 200 mL. Pipet 5 mL of this solution, add diluted pH 6.8 phosphate buffer solution (1 in 2) to make exactly 100 mL, further pipet 5 mL of this solution, add diluted pH 6.8 phosphate buffer solution (1 in 2) to make exactly 20 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , of the sample solution and the standard solution at 254 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Chlorpromazine Hydrochloride Tablets in 60 minutes should be not less than 75%.

Dissolution rate (%) with respect to labeled amount of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$)

$$= W_S \times \frac{A_T}{A_S} \times \frac{V'}{V} \times \frac{1}{C} \times \frac{45}{8}$$

W_S : Amount (mg) of chlorpromazine hydrochloride for assay.

C : Labeled amount (mg) of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$) in 1 tablet.

Assay Weigh accurately, and powder not less than 20 Chlorpromazine Hydrochloride Tablets. Weigh accurately a portion of the powder, equivalent to about 0.15 g of chlorpromazine hydrochloride ($C_{17}H_{19}ClN_2S.HCl$), transfer to a