CHLORPROMAZINE HYDROCHLORIDE

Chlorpromazini hydrochloridum

C_{17}H_{20}Cl_{2}N_{2}S

M_2, 355.3

DEFINITION
Chlorpromazine hydrochloride contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of 3-(2-chloro-10H-phenothiazin-10-yl)-N,N-dimethylpropan-1-amine hydrochloride, calculated with reference to the dried substance.

CHARACTERS
A white or almost white, crystalline powder, very soluble in water, freely soluble in alcohol. It decomposes on exposure to air and light.

It melts at about 196 °C.

IDENTIFICATION
First identification: B, C, D.
Second identification: A, C, D.
A. Prepare the solutions protected from bright light and measure the absorbances immediately. Dissolve 50.0 mg in 0.1 M hydrochloric acid and dilute to 500.0 ml with the same acid. Dilute 5.0 ml of the solution to 100.0 ml with 0.1 M hydrochloric acid. Examined between 230 nm and 340 nm (2.2.25), the solution shows two absorption maxima, at 254 nm and 306 nm respectively. The specific absorbance at the maximum at 254 nm is 890 to 960.

B. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the spectrum obtained with chlorpromazine hydrochloride CRS. Examine the substances as 60 g/l solutions in methylene chloride R using a 0.1 mm cell.

C. It complies with the identification test for phenothiazines by thin-layer chromatography (2.3.3).

D. It gives reaction (b) of chlorides (2.3.1).

TESTS

pH (2.2.3). Dissolve 1.0 g in carbon dioxide-free water R and dilute to 10 ml with the same solvent. The pH of the freshly prepared solution is 3.5 to 4.5.

Related substances. Carry out the test protected from bright light.
Examine by thin-layer chromatography (2.2.27), using silica gel GF_{254} R as the coating substance.

Test solution. Dissolve 0.2 g of the substance to be examined in a mixture of 5 volumes of diethyamine R and 95 volumes of methanol R and dilute to 10 ml with the same mixture of solvents. Prepare immediately before use.

ASSAY

Dissolve 0.250 g in a mixture of 5.0 ml of 0.01 M hydrochloric acid and 50 ml of alcohol R. Carry out a potentiometric titration (2.2.20), using 0.1 M sodium hydroxide. Read the volume of 0.1 M sodium hydroxide added between the two points of inflexion.

1 ml of 0.1 M sodium hydroxide is equivalent to 35.53 mg of C_{17}H_{20}Cl_{2}N_{2}S.

STORAGE
Store in an airtight container, protected from light.

CHLORPROPAMIDE

Chlorpropamidum

C_{17}H_{15}ClN_{2}O_{3}S

M_2, 276.7

DEFINITION
Chlorpropamide contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of 1-[4-chlorophenyl]sulphonyl]3-propylurea, calculated with reference to the dried substance.

CHARACTERS
A white, crystalline powder, practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides. It shows polymorphism.

IDENTIFICATION
First identification: C, D.
Second identification: A, B, D.
A. Melting point (2.2.14): 126 °C to 130 °C.
B. Dissolve 0.10 g in methanol R and dilute to 50.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid. Dilute 10.0 ml of the solution to 100.0 ml with 0.01 M hydrochloric acid.