Edition: BP 2025 (Ph. Eur. 11.6 update)

Chlorpromazine Injection

General Notices

Action and use

Dopamine receptor antagonist; neuroleptic.

DEFINITION

Chlorpromazine Injection is a sterile solution of Chlorpromazine Hydrochloride in Water for Injections free from dissolved air.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of chlorpromazine hydrochloride, $C_{17}H_{19}ClN_2S,HCl$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

A. To a volume containing 0.1 g of Chlorpromazine Hydrochloride add 20 mL of *water* and 2 mL of 10M *sodium hydroxide*. Shake and extract with 25 mL of *ether*. Wash the ether layer with two 5 mL quantities of *water*, dry with *anhydrous sodium sulfate*, evaporate the ether and dissolve the residue in 1 mL of *chloroform*. The *infrared absorption spectrum* of the resulting solution, Appendix II A, is concordant with the *reference spectrum* of chlorpromazine *(RS 056)*.
B. Complies with the test for *identification of phenothiazines*, Appendix III A. For solution (1) dilute the injection with *water* to give a solution containing 0.2% w/v of Chlorpromazine Hydrochloride.

TESTS

Acidity

pH, 5.0 to 6.5, Appendix V L.

Related substances

Carry out the test for *related substances in phenothiazines*, Appendix III A, using *mobile phase A* and applying separately to the plate 20 µL of each of the following freshly prepared solutions. For solution (1) dilute a volume of the injection, if necessary, with sufficient of a mixture of 95 volumes of *methanol* and 5 volumes of *diethylamine* to produce a solution containing 0.5% w/v of Chlorpromazine Hydrochloride. For solution (2) dilute 1 volume of solution (1) to 20 volumes with

the same solvent. For solution (3) dilute 1 volume of solution (1) to 200 volumes with the same solvent. Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3).

ASSAY

Carry out the following procedure protected from light. Dilute a suitable volume with sufficient 0.1M *hydrochloric acid* to produce a solution containing 0.0005% w/v of Chlorpromazine Hydrochloride and measure the *absorbance* at the maximum at 254 nm, Appendix II B. Calculate the content of $C_{17}H_{19}ClN_2S,HCl$ taking 915 as the value of A(1%, 1 cm) at the maximum at 254 nm.

STORAGE

Chlorpromazine Injection should be protected from light.