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

Levomepromazine Injection

General Notices

Action and use

Dopamine receptor antagonist; neuroleptic.

DEFINITION

Levomepromazine Injection is a solution of Levomepromazine Hydrochloride in Water for Injections.

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

Content of levomepromazine hydrochloride, $C_{19}H_{24}N_2OS,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

To a volume of the injection containing 50 mg of Levomepromazine Hydrochloride add 2 mL of 1M *sodium hydroxide*, shake, extract with 15 mL of *ether* and allow to separate. Wash the ethereal layer with 5 mL of *water*, filter through phase-separating paper (Whatman 1 PS is suitable) containing *anhydrous sodium sulfate*, evaporate the ether to dryness and dry the residue at 100° for 3 hours. The *infrared absorption spectrum* of the dried residue, Appendix II A, is concordant with the *reference spectrum* of levomepromazine (*RS 404*).

TESTS

Acidity

pH, 4.0 to 5.0, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions protected from light.

(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 Levomepromazine Hydrochloride.
(2) Dilute 1 volume of solution (1) to 100 volumes with a mixture of 95 volumes of *methanol* and 5 volumes of *diethylamine* and further dilute 1 volume to 2 volumes with the same solvent mixture.
(3) 0.005% w/v of *levomepromazine sulfoxide BPCRS* in a mixture of 95 volumes of *methanol* and 5 volumes of *diethylamine*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *TLC silica gel GF_{254} plate*.

(b) Use the mobile phase, maintained at 35°, as described below.

(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

5 volumes of *diethylamine*, 10 volumes of *acetone* and 85 volumes of *toluene*.

LIMITS

In the chromatogram obtained with solution (1):

any spot corresponding to levomepromazine sulfoxide is not more intense than the spot in the chromatogram obtained with solution (3) (1%);

any other *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%). Disregard any spot remaining on the line of application.

ASSAY

Carry out the following procedure protected from light. Dilute a volume of the injection containing 0.1 g of Levomepromazine Hydrochloride to 100 mL with *water* and dilute 1 volume of this solution to 25 volumes with *water*. Immediately measure the *absorbance* of the solution at the maximum at 302 nm, Appendix II B, using *water* in the reference cell. Measure the absorbance of a 0.004% w/v solution of *levomepromazine maleate BPCRS* in *water* and calculate the content of $C_{19}H_{24}N_2OS,HCl$ from the absorbances obtained using the declared content of $C_{19}H_{24}N_2OS,C_4H_4O_4$ in *levomepromazine maleate BPCRS*. Each mg of $C_{19}H_{24}N_2OS,C_4H_4O_4$ is equivalent to 0.8207 mg of $C_{19}H_{24}N_2OS,HCl$.

STORAGE

Levomepromazine Injection should be protected from light.