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Levamisole Injection

General Notices

Action and use

Immunostimulant; antihelminthic.

DEFINITION

Levamisole Injection is a sterile solution of Levamisole Hydrochloride in Water for Injections. It may contain suitable colouring matter.

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

Content of levamisole hydrochloride, $C_{11}H_{12}N_2S,HCl$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 100 volumes of *ethyl acetate*, 10 volumes of *methanol* and 1 volume of 13.5M *ammonia* as the mobile phase. Apply separately to the plate 1 µL of each of the following solutions in *methanol*. For solution (1) dilute a volume of the injection to produce a solution containing 1% w/v of Levamisole Hydrochloride. Solution (2) contains 1% w/v of *levamisole hydrochloride BPCRS*. After removal of the plate, allow it to dry in air and spray with *potassium iodoplatinate solution*. The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).
B. Dilute a volume of the injection containing 0.75 g of Levamisole Hydrochloride to 20 mL with *water* and add 6 mL of 1M *sodium hydroxide*. Extract with 20 mL of *dichloromethane*, discard the aqueous layer and wash the dichloromethane layer with 10 mL of *water*. Shake with *anhydrous sodium sulfate*, filter and evaporate the dichloromethane at room temperature. The *melting point* of the residue, after drying over *phosphorus pentoxide* at a pressure of 1.5 to 2.5 kPa at a temperature not exceeding 40°, is about 59°, Appendix V A.
C. The injection is laevorotatory.
D. Yields reaction B characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH, 3.0 to 4.0, Appendix V L.

2,3-Dihydro-6-phenylimidazo[2,1-*b*]thiazole hydrochloride

Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 8 volumes of *glacial acetic acid*, 16 volumes of *methanol* and 90 volumes of *toluene* as the mobile phase. Apply

separately to the plate 10 µL of each of the following two solutions. For solution (1) dilute a volume of the injection with *methanol* to produce a solution containing 5.0% w/v of Levamisole Hydrochloride. Solution (2) contains 0.021% w/v of *2,3-dihydro-6-phenylimidazo[2,1-*b*]thiazole BPCRS* in *methanol*. After removal of the plate, allow it to dry in air and spray with *potassium iodoplatinate solution*. Any spot in the chromatogram obtained with solution (1) corresponding to 2,3-dihydro-6-phenylimidazo[2,1-*b*]thiazole is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).

ASSAY

To a volume of the injection containing 0.75 g of Levamisole Hydrochloride add 50 mL of *water* and 15 mL of 2M *sodium hydroxide*, extract with three quantities, of 25, 20 and 15 mL, of *chloroform* and wash the combined extracts with two 10 mL quantities of *water*. To the combined extracts add 50 mL of *anhydrous acetic acid* and carry out Method I for *non-aqueous titration*, Appendix VIII A, using *1-naphtholbenzein solution* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 24.08 mg of $C_{11}H_{12}N_2S,HCl$.

STORAGE

Levamisole Injection should be protected from light.