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Levamisole Oral Solution

General Notices

Action and use

Immunostimulant; antihelminthic.

DEFINITION

Levamisole Oral Solution is an aqueous solution of Levamisole Hydrochloride.

The oral solution complies with the requirements stated under Oral Liquids 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 1 volume of 13.5M *ammonia*, 10 volumes of *methanol* and 100 volumes of *ethyl acetate* as the mobile phase. Apply separately to the plate 1 µL of each of the following solutions. For solution (1) dilute a volume of the oral solution with *methanol* to produce a solution containing 1% w/v of Levamisole Hydrochloride. Solution (2) contains 1% w/v of *levamisole hydrochloride BPCRS* in *methanol*. 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. To a quantity of the oral solution containing 0.3 g of Levamisole Hydrochloride add 10 mL of *water* and 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 oral solution is laevorotatory.

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 50 µL of solution (1) and 10 µL of solution (2). For solution (1) dilute a volume of the oral solution to produce a solution containing 1.0% 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 oral solution containing 0.75 g of Levamisole Hydrochloride add 15 mL of 2M *sodium hydroxide*, extract with three quantities, of 25 mL, 20 mL and 15 mL, of *chloroform*, wash the combined extracts with two 10 mL quantities of

water and discard the washings. To the clear chloroform solution, after drying with *anhydrous sodium sulfate* if necessary, add 50 mL of *anhydrous acetic acid*. 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 $C_{11}H_{12}N_2S,HCl$.