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

Oxyclozanide Oral Suspension

General Notices

Action and use

Antihelminthic.

DEFINITION

Oxyclozanide Oral Suspension is an aqueous suspension of Oxyclozanide containing suitable suspending and dispersing agents.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.

Content of oxyclozanide, $C_{13}H_6Cl_5NO_3$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In test A for Related substances the principal spot in the chromatogram obtained with 10 µL of solution (1) corresponds to that in the chromatogram obtained with solution (3).

Related substances

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 5 volumes of *glacial acetic acid*, 20 volumes of *acetone* and 60 volumes of *petroleum spirit (boiling range, 60° to 80°)* as the mobile phase. Apply separately to the plate 40 µL and 10 µL of solution (1), 4 µL of solution (2) and 10 µL of solution (3). For solution (1) dilute the oral suspension with *acetone* to contain 1.0% w/v of Oxyclozanide, centrifuge and use the supernatant liquid. Solution (2) contains 0.050% w/v of *3,5,6-trichloro-2-hydroxybenzoic acid BPCRS* in *acetone*. Solution (3) contains 1.0% w/v of *oxyclozanide BPCRS* in *acetone*. After removal of the plate, allow it to dry in air and spray with a 3.0% w/v solution of *iron(III) chloride hexahydrate* in *methanol*. In the chromatogram obtained with 40 µL of solution (1) any spot corresponding to 3,5,6-trichloro-2-hydroxybenzoic acid is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).
B. 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* as the mobile phase, 10 volumes of *methanol* and 100 volumes of *ethyl acetate*. Apply separately to the plate 40 µL of solution (1) and 4 µL of solution (2). For solution (1) dilute the oral suspension with *acetone* to contain 1.0% w/v of Oxyclozanide, centrifuge and use the supernatant liquid. Solution (2) contains 0.050% w/v of *2-amino-4,6-dichlorophenol hydrochloride BPCRS* in *acetone*. After removal of the plate, allow it to dry in air and spray with *phosphomolybdotungstic reagent* . In the chromatogram obtained with solution (1) any spot corresponding to 2-amino-4,6-dichlorophenol is not more intense than the spot in the chromatogram obtained with solution (2) (0.4%).

ASSAY

Protect the solutions from light throughout the Assay. To a quantity of the oral suspension containing 60 mg of Oxyclozanide add 60 mL of *acidified methanol* and boil gently on a water bath. Shake continuously for 20 minutes, cool to

2° and dilute to 100 mL with *acidified methanol*. Filter, dilute 5 mL of the filtrate to 100 mL with *acidified methanol* and measure the *absorbance* of the resulting solution at the maximum at 300 nm, Appendix II B. Calculate the content of $C_{13}H_6Cl_5NO_3$ taking 254 as the value of A(1%, 1 cm) at the maximum at 300 nm.