Diloxanide furoate tablets (Diloxanidi furoatis compressi)

Category. Antiamoebic drug.

Additional information. Strength in the current WHO Model list of essential medicines: 500mg.

Requirements

Comply with the monograph for "Tablets".

Diloxanide furoate tablets contain not less than 90.0% and not more than 110.0% of the amount of $C_{14}H_{11}CI_2NO_4$ stated on the label.

Identity tests

To a quantity of the powdered tablets equivalent to about 0.2g of Diloxanide furoate add 20ml of dichloromethane R and shake. Filter, evaporate the filtrate to dryness, and use the dried residue for the following tests.

A. Carry out the examination with the residue as described under <u>1.7 Spectrophotometry in the infrared region</u>. The infrared absorption spectrum is concordant with the spectrum obtained from diloxanide furoate RS or with the *reference spectrum* of diloxanide furoate.

B. Melting temperature of the residue, about 115°C.

Related substances. Carry out the test as described under <u>1.14.1 Chromatography</u>, Thin-layer chromatography, using silica gel R2 as the coating substance and a mixture of 96 volumes of dichloromethane R and 4 volumes of methanol R as the mobile phase. Apply separately to the plate 5 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.5g of Diloxanide furoate with 5ml of chloroform R, centrifuge, and use the supernatant liquid. For solution (B) dilute 1 volume of solution A to 20 volumes of chloroform R, further dilute 1 volume of this solution to 20 volumes with the same solvent. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay. Weigh and powder 20 tablets. To a quantity of the powder equivalent to about 0.04g of Diloxanide furoate add 150ml of ethanol (~750g/l) TS and shake for 30 minutes. Add sufficient ethanol (~750g/l) TS to produce 200ml, mix, and filter. Dilute 10ml of the filtrate to 250ml with the same solvent. Measure the absorbance of a 1-cm layer at the maximum at about 258nm against a solvent cell containing ethanol (~750g/l) TS.

Calculate the percentage content of $C_{14}H_{11}Cl_2NO_4$ using the absorptivity value of 70.5 ($A_{10}m$ = 705).