Probenecid tablets (Probenecidi compressi)

Category. Antigout drug.

Additional information. Available strength: 500 mg.

Requirements

Comply with the monograph for Tablets.

Probenecid tablets contain not less than 95.0% and not more than 105.0% of the amount of \( C_{13}H_{19}NO_4S \) stated on the label.

Identity tests

Either test A alone or tests B and C may be applied.

Triturate a quantity of the powdered tablets equivalent to 0.5 g of Probenecid with ethanol (~750 g/l) TS, filter, concentrate the filtrate to a small volume by evaporation, cool and filter. Recrystallize the residue from ethanol (~457 g/l) TS and use it for the following two tests:

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from probenecid RS or with the reference spectrum of probenecid.

B. Melting temperature of the residue, about 199 °C.

C. The absorption spectrum of the solution prepared for the assay, when observed between 220 nm and 248 nm; the absorbance of a 1 cm layer at the maximum of 248 nm is between 310 and 350.

Related substances

Carry out the test as described under 1.14.1 Thin-layer chromatography using silica gel R4 as the coating substance and a mixture of 15 volumes of 1-propanol R and 3 volumes of ammonia (~17 g/l) TS as the mobile phase. Apply separately to the plate 5 μl of each of the following two solutions. For solution (A) shake a quantity of the powdered tablets equivalent to 0.2 g of Probenecid with 10 mL of a mixture of 1 volume of ammonia (~17 g/l) TS and 9 volumes of ethanol (~750 g/l) TS, centrifuge and use the supernatant liquid. For solution (B) dilute 1 mL of solution A to 100 mL with the same mixture of solvents. After removing the plate from the chromatographic chamber allow it to dry in air and examine the chromatogram in ultraviolet light (254 nm).

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 0.2 g of Probenecid, accurately weighed, add 200 mL of ethanol (~750 g/l) TS and 5 mL of hydrochloric acid (1 mol/l) VS. Heat on a water-bath at 70 °C for 30 minutes, shaking the flask occasionally, cool, add sufficient ethanol (~750 g/l) TS to produce 250 mL and filter. To 5 mL of the filtrate, add 5 mL of hydrochloric acid (0.1 mol/l) VS and dilute to 250 mL with ethanol (~750 g/l) TS.

Measure the absorbance of this solution in a 1 cm layer at the maximum at about 248 nm and calculate the content of \( C_{13}H_{19}NO_4S \) using the absorptivity value of 33.2 (\( \epsilon_{1%1cm}=332 \)).

Disintegration test. Complies with the test for 5.3 Disintegration test for tablets and capsules. Time period: 30 minutes.