Allopurinol tablets (Allopurinoli compressi)

Category. Drug used for the treatment of gout.

Additional information. Strengths in the current WHO Model list of essential medicines: 100 mg, 300 mg. Strengths in the current WHO Model list of essential medicines for children: 100 mg, 300 mg.

Requirements

Comply with the monograph for *Tablets*.

Allopurinol tablets contain not less than 90.0% and not more than 110.0% of the amount of $C_5H_4N_4O$ stated on the label.

Identity tests

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

A. Triturate a quantity of the powdered tablets equivalent to about 0.1 g of Allopurinol with 10 mL of sodium hydroxide (0.1 mol/l) VS. Filter, acidify the filtrate with acetic acid (~60 g/l) TS and allow to stand for 10–15 minutes. Separate the precipitate, wash it with 3 mL of dehydrated ethanol R and 4 mL of ether R. Allow to dry in air for 15 minutes then dry at 105 °C for 3 hours. Keep half of the residue for test C. Carry out the examination with the residue as described under *1.7 Spectrophotometry in the infrared region*. The infrared absorption spectrum is concordant with the spectrum obtained from allopurinol RS or with the *reference spectrum* of allopurinol.

B. The absorption spectrum of the solution obtained in the "Assay", when observed between 230 nm and 350 nm, exhibits a maximum at about 250 nm.

C. To the residue obtained in test A add 5 mL of sodium hydroxide (50 g/l) TS, 1.0 mL of alkaline potassiomercuric iodide TS, heat to boiling and allow to stand; a yellow precipitate is produced.

Related substances

Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R4 as the coating substance and a mixture of 6 volumes of 2-butanol R, 2 volumes of ammonia (~260 g/l) TS and 2 volumes of ethylene glycol monomethyl ether R as the mobile phase. Apply separately to the plate 10 µl of each of the following 2 solutions. For solution (A) shake a quantity of the powdered tablets equivalent to about 0.25 g of Allopurinol with a mixture of 1.0 mL of diethylamine R and 9ml of water, filter and use the filtrate. For solution (B) use 0.05 mg of aminopyrazole-4-carboxamide hemisulfate RS per mL of ammonia (~260 g/l) TS. After removing the plate from the chromatographic chamber allow it to dry in a current of 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 0.1 g of Allopurinol add 20 mL of sodium hydroxide (0.05 mol/l) VS and shake for 20 minutes. Then add 80 mL of hydrochloric acid (0.1 mol/l) VS and shake for 10 minutes. Dilute to 250 mL with hydrochloric acid (0.1 mol/l) VS, filter and dilute 10 mL of the filtrate to 250 mL with the same acid. Measure the absorbance of a 1 cm layer at the maximum at about 250 nm against a solvent cell containing hydrochloric acid (0.1 mol/l) VS.

Calculate the percentage content of $C_5H_4N_4O$ using the absorptivity value of 56.3 ($A^{1\%}_{1cm} = 563$).