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

Acetazolamide Tablets

General Notices

Action and use

Carbonic anhydrase inhibitor; diuretic; treatment of glaucoma, ocular hypertension, mountain sickness.

DEFINITION

Acetazolamide Tablets contain Acetazolamide.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of acetazolamide, $C_4H_6N_4O_3S_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing 0.5 g of Acetazolamide with 2 mL of 1M *sodium hydroxide* and filter. Neutralise the filtrate with *glacial acetic acid*, filter and dry the resulting precipitate at 105°. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of acetazolamide *(RS 002)*.
B. Triturate a quantity of the powdered tablets containing 0.5 g of Acetazolamide with a mixture of 5 mL of *water* and 1 mL of 1M *sodium hydroxide*, transfer to a test tube, add 0.2 g of *zinc powder* and 0.5 mL of *hydrochloric acid* and immediately place a piece of *lead acetate paper* over the mouth of the tube. The paper exhibits a brownish black colour.
C. To a quantity of the powdered tablets containing 25 mg of Acetazolamide add 5 mL of *water*, 0.15 mL of 1M *sodium hydroxide* and 0.1 mL of *weak copper sulfate solution*. A greenish blue colour or precipitate is produced.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 50 mg of Acetazolamide for 20 minutes with 10 mL of a mixture of equal volumes of *ethanol (96%)* and *ethyl acetate* and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with the same solvent mixture as for solution (1).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF_{254}*.

(b) Use a mobile phase freshly prepared as described below. Use the tank without lining the walls and allow to saturate for 1 hour before development.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

20 volumes of 13.5M *ammonia*, 30 volumes of *ethyl acetate* and 50 volumes of *propan-2-ol*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 0.4 g of Acetazolamide add 90 mL of *dimethylformamide* and carry out Method II for *non-aqueous titration*, Appendix VIII A, using 0.1M *tetrabutylammonium hydroxide VS* as titrant and determining the end point potentiometrically. Each mL of 0.1M *tetrabutylammonium hydroxide VS* is equivalent to 22.22 mg of $C_4H_6N_4O_3S_2$.