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

Diazoxide Tablets

General Notices

Action and use

Vasodilator; treatment of hypertension.

DEFINITION

Diazoxide Tablets contain Diazoxide.

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

Content of diazoxide, $C_8H_7ClN_2O_2S$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 0.2 g of Diazoxide with 50 mL of *absolute ethanol*, filter and evaporate the filtrate to dryness at a pressure of 2 kPa. The residue complies with the following tests.

A. The *light absorption*, Appendix II B, in the range 230 to 350 nm of a 0.001% w/v solution in 0.1M *sodium hydroxide* exhibits a maximum only at 280 nm.
B. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) 0.02% w/v of the residue in *methanol*.
(2) 0.02% w/v of *diazoxide EPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use *silica gel GF_{254}* as the coating.
(b) Use the mobile phase as described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air until the solvent has evaporated, examine under *ultraviolet light (254 nm)* and then treat the plate by *Method I* and examine again.

MOBILE PHASE

20 volumes of *acetone*, 30 volumes of *ether*, and 50 volumes of *toluene*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in colour and intensity to that in the chromatogram obtained with solution (2).

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 0.75 g of Diazoxide with 40 mL of 0.1M *sodium hydroxide* for 30 minutes, filter and dilute the filtrate to 50 mL with 0.1M *sodium hydroxide*.
(2) Dilute 1 volume of solution (1) to 200 volumes with 0.1M *sodium hydroxide*.

CHROMATOGRAPHIC CONDITIONS

(a) Use *a TLC silica gel GF_{254} plate*.
(b) Use the mobile phase as described below.
(c) Apply 5 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

7 volumes of 18M *ammonia*, 25 volumes of *methanol* and 68 volumes of *chloroform*.

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) (0.5%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 50 mg of Diazoxide add 70 mL of *methanol*, shake for 1 hour, add sufficient *methanol* to produce 100 mL, mix and filter. Dilute 5 mL of the filtrate to 250 mL with 0.1M *sodium hydroxide* and measure the *absorbance* of the resulting solution at the maximum at 280 nm, Appendix II B. Calculate the content of $C_8H_7ClN_2O_2S$ taking 585 as the value of A(1%, 1 cm) at the maximum at 280 nm.