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

Diazoxide Injection

General Notices

Action and use

Vasodilator; treatment of hypertension.

DEFINITION

Diazoxide Injection is a sterile solution of Diazoxide in Water for Injections, prepared with the aid of Sodium Hydroxide.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of diazoxide, $C_8H_7ClN_2O_2S$

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless solution.

IDENTIFICATION

To a volume containing 0.3 g of Diazoxide add 2 mL of *2M hydrochloric acid*, stir, filter the precipitate and wash the filter thoroughly with *water* until the filtrate is free from acid. The precipitate, after drying at 105°, complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of diazoxide *(RS 094)*.
B. 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.
C. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Use the injection, diluted if necessary, with *methanol* to contain 0.02% w/v of Diazoxide.
(2) 0.02% w/v of *diazoxide EPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel GF_{254}*.
(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, allow it to 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 position and colour to that in the chromatogram obtained with solution (2).

TESTS

Alkalinity

pH, 11.2 to 11.9, Appendix V L.

Related substances

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

(1) Use the injection diluted, if necessary, with 0.1M *sodium hydroxide* to contain 1.5% w/v of Diazoxide.
(2) Dilute 1 volume of solution (1) to 200 volumes with 0.1M *sodium hydroxide*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* GF_{254}.
(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, allow it to 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

To a volume containing 75 mg of Diazoxide add sufficient 0.1M *sodium hydroxide* to produce 500 mL. Dilute 5 mL to 100 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.

STORAGE

Diazoxide Injection should be protected from light.