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Diazepam Injection

General Notices

Action and use

Benzodiazepine.

DEFINITION

Diazepam Injection is a sterile solution of Diazepam in Water for Injections or other suitable solvent.

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

Content of diazepam, $C_{16}H_{13}ClN_2O$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, of the solution obtained in the Assay exhibits a maximum at 368 nm.
B. Complies with test B for Identification described under Diazepam Tablets applying separately to the plate 10 µL of each of the following solutions. For solution (1) dilute a suitable volume of the injection with sufficient *methanol* to produce a solution containing 0.10% w/v of Diazepam. Solution (2) contains 0.10% w/v of *diazepam BPCRS* in *methanol*.

TESTS

Acidity or alkalinity

pH, 6.2 to 7.0, Appendix V L.

ASSAY

To a volume containing 10 mg of Diazepam add 20 mL of *mixed phosphate buffer pH 7.0* and extract with four 20 mL quantities of *chloroform*, passing each extract through the same 5 g of *anhydrous sodium sulfate*. Combine the chloroform extracts, dilute to 100 mL with *chloroform* and mix. Evaporate 10 mL to dryness in a current of nitrogen, dissolve the residue in 25 mL of 0.05M *methanolic sulfuric acid*, mix and measure the *absorbance* of the resulting solution at the maximum at 368 nm, Appendix II B. Calculate the content of $C_{16}H_{13}ClN_2O$ taking 151 as the value of A(1%, 1 cm) at the maximum at 368 nm.

STORAGE

Diazepam Injection should be protected from light.