



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

Diazepam Rectal Solution

[General Notices](#)

Action and use

Benzodiazepine.

DEFINITION

Diazepam Rectal Solution is a solution of Diazepam in a suitable vehicle.

The rectal solution complies with the requirements stated under Rectal Preparations and with the following requirements.

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

95.0 to 105.0% 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. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using [silica gel G](#) as the coating substance and a mixture of 10 volumes of [methanol](#) and 100 volumes of [chloroform](#) as the mobile phase. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) dilute a suitable volume of the rectal solution 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](#). After removal of the plate, spray it with a 10% v/v solution of [sulfuric acid](#) in [absolute ethanol](#), heat at 105° for 10 minutes and examine under [ultraviolet light \(365 nm\)](#). The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

TESTS

Acidity or alkalinity

pH, 6.2 to 7.2, [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 Rectal Solution should be protected from light.