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Diazepam Injection

» Diazepam Injection is a sterile solution of Diazepam in a suitable medium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{16}H_{13}ClN_2O$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—

USP Diazepam RS

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.

B: Transfer a volume of Injection, equivalent to about 10 mg of diazepam, to a separator, add 20 mL of water, and shake. Add 20 mL of chloroform, and shake vigorously for 2 minutes. Filter the chloroform layer through about 5 g of anhydrous granular sodium sulfate into a beaker. Wash the sodium sulfate with 20 mL of chloroform, collecting the washing in the beaker. Evaporate the chloroform extract on a steam bath with the aid of a current of air to a volume of about 5 mL. Remove the beaker from the steam bath, and evaporate the chloroform extract with the aid of a current of air to dryness. Dissolve the residue in 20 mL of anhydrous ether, filter, and evaporate the filtrate to dryness using a current of air. Vigorously scrape the resulting oily film with a spatula, and dry in vacuum over phosphorus pentoxide at 60° for 4 hours: the IR absorption spectrum of a potassium bromide dispersion of the residue exhibits maxima only at the same wavelengths as that of a similar preparation of USP Diazepam RS.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 11.6 USP Endotoxin Units per mg of diazepam.

pH ⟨791⟩**:** between 6.2 and 6.9.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—[Note—Prepare fresh daily.] Prepare a solution of *p*-tolualdehyde in methanol containing about 0.3 µL per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Diazepam RS in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 1 mg per mL. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, add 5.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix to obtain a *Standard preparation* having a known concentration of about 0.2 mg of USP Diazepam RS per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 10 mg of diazepam, to a 50-mL volumetric flask. Pipet 10 mL of *Internal standard solution* into the flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.4 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative retention times are about 0.5 for *p*-tolualdehyde and 1.0 for diazepam, the tailing factor for the diazepam peak is not more than 2.5, the resolution, *R,* between the *p*-tolualdehyde and diazepam peaks is not less than 3.5, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (between 10 µL and 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{16}H_{13}ClN_2O$ in each mL of the Injection taken by the formula:

$$50(C/V)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Diazepam RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, and R_U and R_S are the ratios of the peak responses of diazepam to that of *p*-tolualdehyde obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DIAZEPAM INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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