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Do not distribute

Diazepam Tablets

» Diazepam Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of diazepam ($C_{16}H_{13}ClN_2O$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Diazepam RS
USP Nordazepam RS

7-Chloro-1,3-dihydro-5-phenyl-2*H*-1,4-benzodiazepin-2-one.

$C_{15}H_{11}ClN_2O$ 270.72

Identification—

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

B: Accurately weigh an amount of Tablet mass, equivalent to 10 mg of diazepam, place in a 50-mL centrifuge tube, and add 2 mL of acetone. Place the centrifuge tube in an ultrasonic bath for 5 minutes, and centrifuge. Using 100 µL of the supernatant as the test solution, 100 µL of a solution of USP Diazepam RS in acetone containing 5 mg per mL as the Standard solution, and a solvent system consisting of equal volumes of ethyl acetate and *n*-heptane, proceed as directed in *Identification* test *B* under *Diazepam*. The specified result is observed.

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{16}H_{13}ClN_2O$ dissolved by employing UV absorption at a wavelength of about 242 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Diazepam RS in the same *Medium*.

Tolerances—Not less than 85% *(Q)* of the labeled amount of $C_{16}H_{13}ClN_2O$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase, System suitability solution, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Diazepam*.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of diazepam, to a 100-mL volumetric flask. Add about 50 mL of methanol, sonicate for 5 minutes, shake by mechanical means for 5 minutes, dilute with methanol to volume, mix, and filter, discarding the first few mL of the filtrate.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Diazepam*. Calculate the quantity, in mg, of diazepam ($C_{16}H_{13}ClN_2O$) in the portion of Tablets taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Diazepam RS in the *Standard preparation*, and r_U and r_S are the peak responses 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 TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

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Chromatographic Database Information: Chromatographic Database

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