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Temazepam Capsules

DEFINITION

Temazepam Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of temazepam ($C_{16}H_{13}O_2N_2Cl$).

[CAUTION—Temazepam is a potent sedative: its powder should not be inhaled.]

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, both relative to the internal standard, as obtained in the Assay.

• **B. THIN-LAYER CHROMATOGRAPHY**

Standard solution: 5 mg/mL of [USP Temazepam RS](#) in methanol

Sample solution: Transfer a portion of Capsule contents equivalent to about 50 mg of temazepam to a 25-mL volumetric flask, add 10 mL of methanol, shake by mechanical means, and allow to settle. Use the supernatant layer.

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography.](#))

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 20 μ L

Developing solvent system: Toluene, dioxane, methanol, and ammonium hydroxide (65:30:5:1)

Analysis: Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, air-dry, and examine the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **PROCEDURE**

Buffer: 2.7 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (47:53)

Internal standard solution: 0.2 mg/mL of benzophenone in a mixture of methanol and water (9:1)

Standard solution: 0.2 mg/mL of [USP Temazepam RS](#) in *Internal standard solution*

Sample solution: Nominally 0.2 mg/mL of temazepam in *Internal standard solution*, from the weighed and mixed contents of NLT 20

Capsules. Shake mechanically for 30 min. Allow the contents of the flask to settle, and then filter, discarding the first 5 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 254 nm

Column: 4-mm \times 25-cm; packing L16

Flow rate: 2 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for temazepam and benzophenone are about 1.0 and 2.0, respectively.]

Suitability requirements

Resolution: NLT 1 between the temazepam peak and any other peak

Column efficiency: NLT 800 theoretical plates

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of temazepam ($C_{16}H_{13}O_2N_2Cl$) in the portion of Capsules taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of temazepam to the internal standard from the *Sample solution*

R_S = peak response ratio of temazepam to the internal standard from the *Standard solution*

C_S = concentration of [USP Temazepam RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of temazepam in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [Dissolution \(711\)](#)

Buffer: Dissolve 2 g of sodium hydroxide in 450 mL of water in a 1-L volumetric flask. Adjust with acetic acid to a pH of 4.0, and dilute with water to volume. Degaerate.

Medium: Buffer with 0.05% polysorbate 80; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Detector: UV 310 nm

Standard solution: [USP Temazepam RS](#) in *Medium*

Sample solution: Filter a portion of the solution under test. Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.

Tolerances: NLT 80% (Q) of the labeled amount of temazepam ($C_{16}H_{13}O_2N_2Cl$) is dissolved.

- [Uniformity of Dosage Units \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- [Packaging and Storage](#): Preserve in well-closed, light-resistant containers.

- [USP Reference Standards \(11\)](#).

[USP Temazepam RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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