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Zolpidem Tartrate Extended-Release Tablets

DEFINITION

Zolpidem Tartrate Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$).

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample: 25 µg/mL of zolpidem tartrate in 0.01 M [hydrochloric acid](#) from a suitable quantity of powder obtained by grinding 1 Tablet

Acceptance criteria: Meet the requirements

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 3.3 mL of [phosphoric acid](#) in 1 L of water. Adjust with [triethylamine](#) to a pH of 5.5.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (4:5:11)

Standard stock solution: 0.5 mg/mL of [USP Zolpidem Tartrate RS](#) in a mixture of alcohol and 0.01 M [hydrochloric acid](#) (4:1)

Standard solution: 0.1 mg/mL of [USP Zolpidem Tartrate RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: Finely powder NLT 8 Tablets. Transfer the powder quantitatively to a suitable volumetric flask to obtain nominally 0.5 mg/mL of zolpidem tartrate. Add 70% of the flask volume of a mixture of [alcohol](#) and 0.01 M [hydrochloric acid](#) (5:2), and stir on a magnetic stirrer for 1 h. Dilute with alcohol to volume. Allow solid particles to settle, and pass the supernatant through a suitable filter (Whatman 40 or equivalent).

Alternatively, the *Sample stock solution* can be prepared as follows. Transfer NLT 20 Tablets to a suitable volumetric flask to obtain a nominal concentration of 0.5 mg/mL of zolpidem tartrate. Add 10% of the flask volume of [alcohol](#) and stir for 30 min or until the Tablets have completely disintegrated. Add another 10% of the flask volume of [alcohol](#) and stir for another 90 min. Add 10% of the flask volume of 0.01 M [hydrochloric acid](#) followed by 40% of the flask volume of a mixture of [alcohol](#) and 0.01 M [hydrochloric acid](#) (5:2). Continue to stir for another 30 min. Remove the stirrer bar and rinse with alcohol. Dilute with alcohol to volume.

Sample solution: Nominally 0.1 mg/mL of zolpidem tartrate from filtered *Sample stock solution* in *Mobile phase*. If the *Sample stock solution* is prepared using the alternative procedure, dilute the required volume of the *Sample stock solution* with *Mobile phase* and centrifuge instead of filtering before use.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 3.0 for zolpidem

Relative standard deviation: NMT 2.0% for zolpidem

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) in the portion of Tablets taken.

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.01 N [hydrochloric acid](#); 500 mL

Apparatus 1: 100 rpm

Times: 30, 90, and 240 min

Standard solution: Solution of [USP Zolpidem Tartrate RS](#) in *Medium* containing (L/500) mg/mL, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Detector: UV 295 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

Tolerances: See [Table 1](#).

Table 1

Time (min)	Amount Dissolved
30	50%–70%
90	70%–85%
240	NLT 90%

The percentages of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) dissolved at the times specified conform to [Dissolution \(711\)](#).

[Acceptance Table 2](#).

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium, Apparatus, and Times: Proceed as directed in *Test 1*.

Standard solution: Solution of [USP Zolpidem Tartrate RS](#) in *Medium* containing (L/500) mg/mL, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Analytical wavelength: 295 nm

Blank: *Medium*

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 500 mL**Tolerances:** See [Table 2](#).**Table 2**

Time (min)	Amount Dissolved
30	55%–75%
90	70%–90%
240	NLT 85%

The percentages of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) dissolved at the times specified conform to [Dissolution \(711\)](#).[Acceptance Table 2](#).**Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.**Medium:** 0.01 N [hydrochloric acid](#); 500 mL**Apparatus 1:** 100 rpm**Times:** 30, 90, and 120 min**Standard solution:** Solution of [USP Zolpidem Tartrate RS](#) in *Medium* containing ($L/500$) mg/mL, where L is the label claim in mg/Tablet**Sample solution:** Pass a portion of the solution under test through a suitable filter.**Instrumental conditions****Mode:** UV**Analytical wavelength:** 237 nm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of zolpidem tartrate ($C_{42}H_{48}N_6O_8$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 500 mL**Tolerances:** See [Table 3](#).**Table 3**