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Zolpidem Tartrate Tablets

DEFINITION

Zolpidem Tartrate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$.

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **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: 3.4 g/L of [monobasic potassium phosphate](#) in [water](#), adjusted with [ammonium hydroxide](#) to a pH of 5.5

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (30:20:50)

Standard stock solution: 0.8 mg/mL of [USP Zolpidem Tartrate RS](#) in [0.01 N hydrochloric acid TS](#)

Standard solution: 0.16 mg/mL of [USP Zolpidem Tartrate RS](#) in *Mobile phase*, from the *Standard stock solution*

Sample stock solution: Nominally 0.4 mg/mL of zolpidem tartrate from NLT 20 Tablets prepared as follows. Transfer the Tablets to a suitable volumetric flask and add 40% of the flask volume of [0.125 N hydrochloric acid TS](#). Mix well until the Tablets disintegrate, and add 50% of the flask volume of *Mobile phase*. Dilute with [water](#) to volume, and stir for 30 min using a magnetic stirrer. Allow solid particles to settle, and pass the supernatant through a suitable filter.¹

Sample solution: Nominally 0.16 mg/mL of zolpidem tartrate in *Mobile phase*, from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

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

Flow rate: 1.2 mL/min

Injection volume: 10 μL

Run time: NLT 2.5 times the retention time of zolpidem tartrate

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 $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ 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 zolpidem tartrate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS**Change to read:**

- [DISSOLUTION \(711\)](#).

Test 1**Medium:** [0.01 N hydrochloric acid TS](#); 900 mL, deaerated**Apparatus 2:** 50 rpm**Time:** 15 min▲ Perform the analysis by using either the *Spectrophotometric procedure* or the *Chromatographic procedure*.**Spectrophotometric procedure** ▲ (USP 1-Aug-2020)**Standard solution:** $(L/1000)$ mg/mL of [USP Zolpidem Tartrate RS](#) in *Medium*, where L is the label claim in mg/Tablet**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.**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 $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ 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 [USP Zolpidem Tartrate RS](#) in the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 900 mL▲ **Chromatographic procedure****Solution A:** 5.6 g/L of [phosphoric acid](#) in [water](#), adjusted with [triethylamine](#) to a pH of 5.5**Mobile phase:** [Acetonitrile](#), [methanol](#), and *Solution A* (18:23:59)**Standard solution:** $(L/900)$ mg/mL of [USP Zolpidem Tartrate RS](#) in *Medium*, where L is the label claim of zolpidem tartrate in mg/Tablet.

Sonicate as needed.

Sample solution: Pass a portion of the solution under test through a suitable filter.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 254 nm**Column:** 3.9-mm $\times$ 15-cm; 4- μ m packing [L1](#)**Column temperature:** 30°**Flow rate:** 1.5 mL/min**Injection volume:** 20 μ L**Run time:** NLT 1.5 times the retention time of zolpidem tartrate**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ dissolved:

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