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Eszopiclone Tablets

DEFINITION

Eszopiclone Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of eszopiclone ($C_{17}H_{17}ClN_6O_3$).

IDENTIFICATION

Change to read:

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

Standard: [USP Eszopiclone RS](#)

Sample: Nominally 37.5 mg of eszopiclone from Tablets prepared as follows. Powder a number of Tablets, and mix the resulting powder.

Transfer a portion of powder, equivalent to 37.5 mg of eszopiclone, to a suitable container, add 30 mL of [acetone](#), and shake. Dilute with [acetone](#) to 50 mL and pass the resulting solution through a suitable filter. Evaporate the filtrate to dryness on a water bath and dry the residue in an oven at 60° for 2 h.

Acceptance criteria: Meets 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

Solution A: 1.4 g/L of anhydrous dibasic [sodium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (25:75) adjusted with dilute phosphoric acid to a pH of 6.5 ± 0.05

Standard stock solution: 0.5 mg/mL of [USP Eszopiclone RS](#) prepared as follows. Transfer a suitable quantity of [USP Eszopiclone RS](#) to an appropriate volumetric flask and add 50% of the final flask volume of [acetonitrile](#). Sonication may be used to promote dissolution. Dilute with [acetonitrile](#) to volume.

Standard solution: 0.03 mg/mL of [USP Eszopiclone RS](#) from *Standard stock solution* in *Mobile phase* passed through a suitable filter of 0.45- μ m pore size. Use the filtrate.

Sample stock solution: Nominally 0.2 mg/mL of eszopiclone from Tablets prepared as follows. Transfer NLT 5 intact Tablets to a suitable volumetric flask. Add 5% of the final flask volume of *Solution A* and sonicate in cool water for 5 min with constant shaking. Add 30% of the final flask volume of [acetonitrile](#) and sonicate for 15 min. Dilute with [acetonitrile](#) to volume. Centrifuge the resulting solution and use the supernatant.

Sample solution: Nominally 0.03 mg/mL of eszopiclone from *Sample stock solution* in *Mobile phase* passed through a suitable filter of 0.45- μ m pore size. Use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 303 nm

Column: 4.6-mm $\times$ 15.0-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 50 μ L

Run time: NLT 1.9 times the retention time of eszopiclone

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 eszopiclone ($C_{17}H_{17}ClN_6O_3$) 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 Eszopiclone RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of eszopiclone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Solution A: 1.4 g/L of [anhydrous dibasic sodium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (30:70) adjusted with dilute phosphoric acid (1 in 10) to a pH of 6.5 ± 0.05

Standard stock solution: 0.1 mg/mL of [USP Eszopiclone RS](#) in [acetonitrile](#). Sonication may be used to promote dissolution.

Standard solution: ($L/500$) mg/mL of [USP Eszopiclone RS](#) from *Standard stock solution* in *Medium*, where L is the Tablet label claim in mg.

Pass the resulting solution through a suitable filter of 0.45- μ m pore size and use the filtrate.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 303 nm

Column: 4.6-mm $\times$ 15.0-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1.2 mL/min

Injection volume: 100 μ L

Run time: NLT 1.5 times the retention time of eszopiclone

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 eszopiclone ($C_{17}H_{17}ClN_6O_3$) dissolved:

$$\text{Result} = (r_u/r_s) \times C_s \times V \times (1/L) \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Acceptance criteria: NLT 80% (Q) of the labeled amount of eszopiclone ($C_{17}H_{17}ClN_6O_3$) is dissolved.

Test 2

Medium: [0.1 N hydrochloric acid VS](#); 500 mL

Apparatus 2: 50 rpm

Time: 20 min

Buffer: To each liter of [water](#) add 1.0 mL of [phosphoric acid](#) and adjust with [2 N sodium hydroxide TS](#) to a pH of 4.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (20:80)

Standard stock solution: 0.1 mg/mL of [USP Eszopiclone RS](#) in *Medium*. Sonication may be used to promote dissolution.

Standard solution: ($L/500$) mg/mL of [USP Eszopiclone RS](#) from *Standard stock solution* in *Medium*, where L is the label claim in mg/Tablet.

Pass the resulting solution through a suitable filter of 0.45- μ m pore size and use the filtrate.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size and use the filtrate.

Chromatographic system

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

Mode: LC