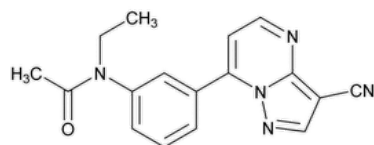


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Zaleplon



$C_{17}H_{15}N_5O$

305.33

Acetamide, N-[3-(3-cyanopyrazolo[1,5-a]pyrimidin-7-yl)phenyl]-N-ethyl-

3'-[3-(3-Cyanopyrazolo[1,5-a]pyrimidin-7-yl)-N-ethylacetanilide CAS RN®: 151319-34-5; UNII: S62U433RMH.

DEFINITION

Zaleplon contains NLT 98.0% and NMT 102.0% of zaleplon ($C_{17}H_{15}N_5O$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **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: 0.3 g/L of ammonium formate in water. Adjust with formic acid to a pH of 4.0.

Mobile phase: Acetonitrile and *Buffer* (7:18)

Diluent: Acetonitrile and water (1:1)

System suitability solution: 0.5 mg/mL of [USP Zaleplon RS](#) and 0.5 µg/mL each of [USP Zaleplon Related Compound A RS](#) and [USP Zaleplon Related Compound B RS](#) in *Diluent*

Standard solution: 50 µg/mL of [USP Zaleplon RS](#) in *Diluent*

Sample solution: 50 µg/mL of Zaleplon in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: 4-mm × 10-cm; 3-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: 2 times the retention time of zaleplon

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for zaleplon and zaleplon related compound B are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between zaleplon and zaleplon related compound B, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of zaleplon ($C_{17}H_{15}N_5O$) in the portion of Zaleplon taken:

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

r_U = peak response of zaleplon from the *Sample solution*

r_S = peak response of zaleplon from the *Standard solution*

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

C_U = concentration of Zaleplon in the *Sample solution* (µg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.2%

• ORGANIC IMPURITIES

Solution A: 1.4 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
15	60	40
25	45	55
26	80	20
35	80	20

Diluent: Acetonitrile and water (250:750)

System suitability solution: 0.5 mg/mL of [USP Zaleplon RS](#) and 0.5 µg/mL each of [USP Zaleplon Related Compound A RS](#), [USP Zaleplon Related Compound B RS](#), and [USP Zaleplon Related Compound C RS](#) in *Diluent*

Standard solution: 0.5 µg/mL of [USP Zaleplon RS](#) in *Diluent*

Sample solution: 500 µg/mL of Zaleplon in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.2 between zaleplon related compound A and zaleplon related compound C; NLT 2.0 between zaleplon and zaleplon related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Zaleplon taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any individual impurity from the *Sample solution*