

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2017
Document Type: USP Monographs
DocId: GUID-DC878AD8-5B46-439D-A80B-D0420EF50485_1_en-US
DOI: https://doi.org/10.31003/USPNF_M3328_01_01
DOI Ref: ttb1d

© 2025 USPC
Do not distribute

Zaleplon Capsules

DEFINITION
Zaleplon Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of zaleplon ($C_{17}H_{15}N_5O$).

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

ASSAY

• **PROCEDURE**

Solution A: 0.3 g/L of [ammonium formate](#) in [water](#)

Solution B: Acetonitrile

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
30	50	50
31	95	5

Diluent: Acetonitrile and [water](#) (20:80)

Standard solution: 0.1 mg/mL of [USP Zaleplon RS](#) in *Diluent*

Sample solution: Nominally 0.1 mg/mL of zaleplon from NLT 5 Capsules in *Diluent*. Pass through a filter of 0.45-µm pore size. [NOTE—Use the entire Capsule with its contents. Shake for 10 min.]

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

Mode: LC

Detector: UV 240 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 1.4 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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 Zaleplon RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• DISSOLUTION

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 75 rpm, with sinkers if necessary

Time: 20 min

Determine the percentage of zaleplon dissolved using one of the following procedures.

Spectrophotometric procedure

Standard stock solution: 0.044 mg/mL of [USP Zaleplon RS](#) prepared as follows. Transfer a suitable quantity of [USP Zaleplon RS](#) to an appropriate volumetric flask. Add 10.0% of the total flask volume of methanol to dissolve. Dilute with *Medium* to volume. [NOTE—This solution is stable for 7 days.]

Standard solution: $(L/1000)$ mg/mL of [USP Zaleplon RS](#) from *Standard stock solution* in *Medium*, where L is the label claim in mg/Capsule. [NOTE—This solution is stable for 7 days.]

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

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: About 333 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of zaleplon ($C_{17}H_{15}N_5O$) 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/Capsule)

V = volume of *Medium*, 900 mL

Chromatographic procedure

Buffer: 0.77 g/L of [ammonium acetate](#) in [water](#)

Mobile phase: Methanol and *Buffer* (33:67)

Standard stock solution: 0.22 mg/mL of [USP Zaleplon RS](#) prepared as follows. Dissolve first in methanol using 5% of total flask volume and dilute with *Medium* to volume.

Standard solution: $(L/900)$ mg/mL of [USP Zaleplon RS](#) from *Standard stock solution* in *Medium*, where L is the label claim in mg/Capsule

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

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm $\times$ 5-cm; 3- μ m packing [L1](#)

Column temperature: 35°

Flow rate: 2.0 mL/min