L = label claim (mg/Tablet)
Acceptance criteria: Meet the requirements

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**
USP Alprazolam RS

Alprazolam Extended-Release Tablets

DEFINITION
Alprazolam Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$).

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**
Mobile phase: Acetonitrile, water, and phosphoric acid (350:650:1)
Standard solution: 0.05 mg/mL of USP Alprazolam RS in methanol
Sample solution: Nominally 0.05 mg/mL of alprazolam prepared as follows. Transfer an appropriate number of Tablets to a suitable volumetric flask. Sonicate in 80% of the flask volume of methanol for 15 min, and shake mechanically for 30 min. Dilute with methanol to final volume, filter a portion of the solution, and discard the first 3 mL of filtrate.
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability.*)
Mode: LC
Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.
Column: 4.6-mm × 15-cm; 5-µm packing L7
Column temperature: 30°
Flow rate: 1 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Tailing factor: NMT 2.0
Column efficiency: NLT 3000 theoretical plates
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$) 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 Alprazolam RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of alprazolam in the *Sample solution* (mg/mL)
Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
- **DISSOLUTION ⟨711⟩**
Test 1
Medium: pH 6.0 phosphate buffer (8.0 g/L of monobasic potassium phosphate and 2.0 g/L of dibasic potassium phosphate in water. Adjust with phosphoric acid or potassium hydroxide to a pH of 6.0 ± 0.1); 500 mL
Apparatus 1: 100 rpm
Times: 1, 4, 8, and 12 h
Mobile phase: Acetonitrile, tetrahydrofuran, and *Medium* (7:1:12)
Standard stock solution: 0.5 mg/mL of USP Alprazolam RS in acetonitrile
Standard solution: (L/500) mg/mL of USP Alprazolam RS in *Medium* from the *Standard stock solution*, where L is the label claim in mg/Tablet
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: 4.6-mm × 10-cm; 5-µm packing L7
Flow rate: 1 mL/min
Injection volume: 100 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Tailing factor: NMT 2.0
Column efficiency: NLT 3000 theoretical plates
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$) dissolved:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Alprazolam RS in the *Standard solution* (mg/mL)
L = label claim (mg/Tablet)
V = volume of *Medium*, 500 mL
Tolerances: See *Table 1*.

Table 1

Time (h)	Amount Dissolved		
	0.5-mg Tablet (%)	2-mg Tablet (%)	3-mg Tablet (%)
1	NMT 25	NMT 20	NMT 20
4	40–60	30–55	30–55
8	70–90	65–90	65–90
12	NLT 85	NLT 85	NLT 85

The percentages of the labeled amount of alprazolam ($C_{17}H_{13}ClN_4$) released 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: pH 6.0 phosphate buffer (8.0 g/L of monobasic potassium phosphate and 2.0 g/L of dibasic potassium phosphate in water. Adjust with phosphoric acid or potassium hydroxide to a pH of 6.0 ± 0.1); 500 mL
Apparatus 1: 100 rpm
Times: 1, 4, 8, and 16 h
Mobile phase: Acetonitrile, tetrahydrofuran, and *Medium* (35:5:60)
Standard stock solution: 0.05 mg/mL of USP Alprazolam RS in methanol
Standard solution: (L/500) mg/mL of USP Alprazolam RS in *Medium* from the *Standard stock solution*, where L is the label claim in mg/Tablet
Sample solution: Pass a portion of the solution under test through a suitable filter.