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Triazolam Tablets

DEFINITION
Triazolam Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of triazolam ($C_{17}H_{12}Cl_2N_4$).

IDENTIFICATION
Change to read:
• **▲A.▲** (USP 1-Aug-2023) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. **▲** (USP 1-Aug-2023)
Add the following:
▲• B. The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. **▲** (USP 1-Aug-2023)

ASSAY
Change to read:
• **PROCEDURE**
▲Solution A: 0.1% (v/v) formic acid in [water](#)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	78	22
2.0	78	22
20.0	10	90
25.0	10	90
25.1	78	22
30.0	78	22

Diluent: [Acetonitrile](#) and [water](#) (45:55)
Standard solution: 5 µg/mL of [USP Triazolam RS](#) in *Diluent*. Sonicate to dissolve if necessary.
Sample solution: Nominally 5 µg/mL of triazolam from Tablets prepared as follows. Transfer an appropriate quantity of triazolam from finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add 10% of the flask volume of [water](#), mix by swirling, and allow to stand for 10 min. Vortex for 10 s, add 45% of flask volume of [acetonitrile](#), shake using mechanical shaker for 10 min, dilute with [water](#) to volume, and mix well. Centrifuge and use the clear supernatant.

Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 257 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 10-cm; 3.5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.2 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of triazolam ($C_{17}H_{12}Cl_2N_4$) in the portion of Tablets taken:

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

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

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

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

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

▲ (USP 1-Aug-2023)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: [Water](#); 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.025 mg/mL of [USP Triazolam RS](#) in [methanol](#)

Standard solution: ($L/500$) mg/mL of [USP Triazolam RS](#), where L is the label claim of triazolam in ▲mg/Tablet▲ (ERR 1-Aug-2023), prepared as follows. For each 0.125 mg of the labeled amount of triazolam/Tablet, add 2.0 mL of *Standard stock solution* to a 200-mL volumetric flask. Dilute with [water](#) to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Mobile phase: [Acetonitrile](#) and [water](#) (40:60)

Chromatographic system

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

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 10-cm ▲ (USP 1-Aug-2023); packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 200 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 500 theoretical plates

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of triazolam▲ (USP 1-Aug-2023) ($C_{17}H_{12}Cl_2N_4$) dissolved:

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