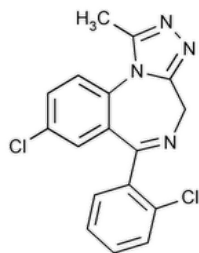


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Triazolam



$C_{17}H_{12}Cl_2N_4$ 343.21

4*H*-[1,2,4]Triazolo[4,3-*a*][1,4]benzodiazepine, 8-chloro-6-(2-chlorophenyl)-1-methyl-;

8-Chloro-6-(*o*-chlorophenyl)-1-methyl-4*H*-s-triazolo[4,3-*a*][1,4]benzodiazepine CAS RN[®]: 28911-01-5; UNII: 1HM943223R.

DEFINITION

Triazolam contains NLT 97.0% and NMT 103.0% of $C_{17}H_{12}Cl_2N_4$, calculated on the dried basis.

[**CAUTION**—Exercise care to prevent inhaling particles of triazolam and to prevent its contacting any part of the body.]

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (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

Diluent: Acetonitrile and water (45:55)

Buffer: 1.4 g/L monobasic potassium phosphate in water

Mobile phase: Acetonitrile and *Buffer* (45:55)

System suitability solution: 0.02 mg/mL each of [USP Triazolam RS](#) and [USP Alprazolam Related Compound A RS](#) in *Diluent*

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

Sample solution: 0.025 mg/mL of Triazolam in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection size: 10 μL

Run time: 3 times the retention time of triazolam

System suitability

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

[**NOTE**—The relative retention times for alprazolam related compound A and triazolam are 0.77 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between alprazolam related compound A and triazolam, *System suitability solution*

Tailing:

NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triazolam ($C_{17}H_{12}Cl_2N_4$) in the portion of Triazolam 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* (mg/mL)

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

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• **ORGANIC IMPURITIES**

Diluent, Buffer, Mobile phase, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.25 µg/mL of [USP Triazolam RS](#) in *Diluent*

Sample solution: 0.25 mg/mL of Triazolam in *Diluent*

System suitability

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

[NOTE—The relative retention times for alprazolam related compound A and triazolam are 0.77 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between alprazolam related compound A and triazolam, *System suitability solution*

Tailing: NMT 1.5, *Standard solution*

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

Analysis

Sample: *Sample solution*

Calculate the total percentage of impurities in the portion of Triazolam taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = sum of the areas of each of the minor component peaks detected

r_T = sum of all minor component peak areas and the area of the major component peak

Acceptance criteria

Total impurities: NMT 1.5%

SPECIFIC TESTS

• [LOSS ON DRYING \(731\)](#): Dry a sample at 60° and at a pressure not exceeding 5 mm of mercury for 16 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers at room temperature.

• [USP REFERENCE STANDARDS \(11\)](#).

[USP Triazolam RS](#)

[USP Alprazolam Related Compound A RS](#)

2-(2-Acetylhydrazino)-7-chloro-5-phenyl-3H-1,4-benzodiazepine.

$C_{17}H_{15}ClN_4O$ 326.78

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TRIAZOLAM	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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