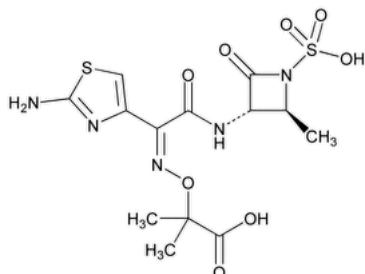


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Aztreonam



$C_{13}H_{17}N_5O_8S_2$ 435.43

Propanoic acid, 2-[[[1-(2-amino-4-thiazolyl)-2-[(2-methyl-4-oxo-1-sulfo-3-azetidinyl)amino]-2-oxoethylidene]amino]oxy]-2-methyl-, [2S-[2 α ,3 β (Z)]]-; (Z)-2-({[(2-Amino-4-thiazolyl){[(2S,3S)-2-methyl-4-oxo-1-sulfo-3-azetidinyl]carbamoyl}methylene]amino}oxy)-2-methylpropionic acid CAS RN®: 78110-38-0; UNII: G2B4VE5GH8.

DEFINITION

Aztreonam, which may be anhydrous or hydrated, contains NLT 92.0% and NMT 105.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

• **A.** ▲ **SPECTROSCOPIC IDENTIFICATION TESTS** (197), **Infrared Spectroscopy: 197K** ▲ (CN 1-MAY-2020) : If a difference appears in the IR spectra of the analyte and the standard, dissolve equal portions of the test specimen and the Reference Standard in equal volumes of [methanol](#). [NOTE—To achieve a complete dissolution, it is suggested to use about 25 mL of [methanol](#) for each 50 mg of material, and stir the mixture for 40 min at room temperature.]

Evaporate the solutions to dryness under vacuum, and dry at 40° for 4 h under vacuum. Perform the test on the residues.

• **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

[NOTE—Store the *System suitability solution*, *Standard solution*, and *Sample solution* at 5°, and protect from light to prevent isomerization of aztreonam Z-isomer to aztreonam E-isomer.]

Buffer: 6.8 mg/mL of [monobasic potassium phosphate](#) in [water](#). Adjust with 1 M [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Methanol](#) and *Buffer* (1:4)

System suitability solution: 1 mg/mL of [USP Aztreonam RS](#) and 1 mg/mL of [USP Aztreonam E-Isomer RS](#) in *Mobile phase*

Standard solution: 1 mg/mL of [USP Aztreonam RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Aztreonam in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10- μ m packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

System suitability

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

[NOTE—The relative retention times for aztreonam and aztreonam E-isomer are 1.0 and 1.8, respectively.]

Suitability requirements

Resolution: NLT 2.0 between aztreonam and aztreonam E-isomer, *System suitability solution*

Tailing factor: NMT 2 for aztreonam, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aztreonam ($C_{13}H_{17}N_5O_8S_2$) in the portion of Aztreonam taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = potency of [USP Aztreonam RS](#) (µg/mg)

F = unit conversion factor, 0.001 mg/µg

Acceptance criteria: 92.0%–105.0% on the anhydrous and solvent-free basis

IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.1%, the charred residue being moistened with 2 mL of [nitric acid](#) and 5 drops of [sulfuric acid](#)

• **ORGANIC IMPURITIES**

[NOTE—Store the *System suitability solution*, *Standard solution*, and *Sample solution* at 5°, and protect from light to prevent isomerization of aztreonam Z-isomer to aztreonam E-isomer.]

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Aztreonam taken:

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

r_U = peak response of each impurity from the *Sample solution*

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

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

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

P = potency of [USP Aztreonam RS](#) (µg/mg)

F = unit conversion factor, 0.001 mg/µg

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Open-ring aztreonam ^a and open-ring desulfated aztreonam ^{b,c}	0.55	1.0
Aztreonam (Z-isomer)	1.0	—
Desulfated aztreonam ^d	1.6	1.5
Aztreonam E-isomer ^e	1.8	0.5
Aztreonam ethyl ester ^f	3.9	1.5
Any individual unspecified impurity	—	0.1
Total impurities	—	3.0

^a (2S,3S)-2-[(Z)-2-[2-Aminothiazol-4-yl]-2-[2-carboxypropan-2-yloxyimino]acetamido]-3-(sulfoamino)butanoic acid.