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Aztreonam Injection

DEFINITION

Aztreonam Injection is a sterile solution of Aztreonam and Arginine and a suitable osmolality-adjusting substance in Water for Injection. It contains NLT 90.0% and NMT 120.0% of the labeled amount of aztreonam ($C_{13}H_{17}N_5O_8S_2$).

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution,* as obtained in the *Assay.*

ASSAY

• **Procedure**

Buffer: 1.15 g/L of monobasic ammonium phosphate in water. Before final dilution, adjust with phosphoric acid to a pH of 2.0 ± 0.1.

Mobile phase: Acetonitrile and *Buffer* (75:25)

System suitability solution: 0.2 mg/mL each of USP Aztreonam RS and USP Open Ring Aztreonam RS in *Mobile phase*

Standard solution: 0.2 mg/mL each of USP Aztreonam RS and USP L-Arginine RS in *Mobile phase*

Sample solution: Nominally 0.2 mg/mL of aztreonam from Injection in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 206 nm

Column: 4-mm × 25-cm; 5- to 10-µm packing L20

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for aztreonam and open ring aztreonam are 0.8 and 1.0, respectively. The relative retention times for aztreonam and arginine are 0.3 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between aztreonam and open ring aztreonam

Tailing factor: NMT 2.0 for the aztreonam peak

Relative standard deviation: NMT 2.0% for the aztreonam peak

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response of aztreonam 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 = nominal concentration of aztreonam in the *Sample solution* (mg/mL)

P = potency of aztreonam in USP Aztreonam RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.25 USP Endotoxin Unit/mg of aztreonam

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **pH ⟨791⟩:** 4.5–7.5

• **Particulate Matter in Injections ⟨788⟩:** It meets the requirements for small-volume injections.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*. Maintain in the frozen state.

• **Labeling:** It meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. The label states that the Injection is to be thawed just prior to use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.

• **USP Reference Standards ⟨11⟩**

USP L-Arginine RS
USP Aztreonam RS
USP Open Ring Aztreonam RS

(2*S*,3*S*)-2-{(*Z*)-2-[2-Aminothiazol-4-yl]-2-[2-carboxypropan-2-yloxyimino]acetamido}-3-(sulfoamino)butanoic acid.
$C_{13}H_{19}N_5O_9S_2$ 453.45

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AZTREONAM INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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