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Aztreonam for Injection

DEFINITION

Aztreonam for Injection is a dry mixture of sterile Aztreonam and Arginine. It contains NLT 90.0% and NMT 105.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and arginine-free basis. Each container 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 1: Nominally 0.2 mg/mL of aztreonam in *Mobile phase* from Aztreonam for Injection prepared as follows. Weigh one container of Aztreonam for Injection, transfer the contents to a suitable container, and dilute with *Mobile phase* to the appropriate volume. Weigh the empty container, and calculate the weight, in mg, of Aztreonam for Injection used.

Sample solution 2: Nominally 0.2 mg/mL of aztreonam from Aztreonam for Injection constituted as directed below and diluted with *Mobile phase*.

Where the vial has a capacity of less than 100 mL, constitute with water using the volume of solvent specified in the labeling.

Where the vial capacity is ≥100 mL, constitute with 10 mL of water and dilute the entire withdrawable contents of the container with *Mobile phase* to obtain the final concentration.

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 about 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*, *Sample solution 1*, and *Sample solution 2*

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

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

r_U = peak response for aztreonam from *Sample solution 1*

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

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

C_U = nominal concentration of Aztreonam for Injection in *Sample solution 1* (mg/mL), corrected for water and arginine content (see *Content of Arginine*)

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–105.0% on the anhydrous and arginine-free basis

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

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

r_U = peak response for aztreonam from *Sample solution 2*

r_S = peak response for 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 *Sample solution 2* (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%

OTHER COMPONENTS

• **Content of Arginine**

Use the result of this test to calculate, on the anhydrous and arginine-free basis, the *Assay* result from *Sample solution 1*, obtained as directed in the *Assay*.

Buffer, Mobile phase, System suitability solution, Standard solution, Sample solution 1, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution 1*

Calculate the percentage of arginine ($C_6H_{14}N_4O_2$) in the portion of Aztreonam for Injection taken:

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

r_U = peak response for arginine from *Sample solution 1*

r_S = peak response for arginine from the *Standard solution*

C_S = concentration of USP L-Arginine RS in the *Standard solution* (mg/mL)

C_U = concentration of Aztreonam for Injection in *Sample solution 1* (mg/mL)

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.17 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⟩**

Sample solution: 100 mg/mL of aztreonam

Acceptance criteria: 4.5–7.5

• **Water Determination, *Method I* ⟨921⟩:** NMT 2.0%

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

• **Other Requirements:** It meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

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

• **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 FOR INJECTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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