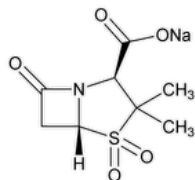


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Sulbactam Sodium

Change to read:



$C_8H_{10}NNaO_5S$ 255.22
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-, 4,4-dioxide, sodium salt, (2*S*-*cis*)-;
Sodium (2*S*,5*R*)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide CAS RN[®]: 69388-84-7; UNII: DKQ4T82YE6.
▲Sulbactam (free acid)
 $C_8H_{11}NO_5S$ 233.24 CAS RN[®]: 68373-14-8; UNII: S4TF6I2330.▲ (USP 1-Dec-2023)

DEFINITION
Sulbactam Sodium contains NLT 886 and NMT 941 µg/mg of sulbactam ($C_8H_{11}NO_5S$), calculated on the anhydrous basis.

IDENTIFICATION

Add the following:

▲ **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K▲ (USP 1-Dec-2023)

Change to read:

• **▲B.**▲ (USP 1-DEC-2023) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

• **▲C.**▲ (USP 1-DEC-2023) [IDENTIFICATION TESTS—GENERAL \(191\)](#), *Chemical Identification Tests, Sodium*: Meets the requirements

ASSAY

• **PROCEDURE**

Buffer solution: 2.7 g/L of [monobasic potassium phosphate](#), adjusted with dilute [phosphoric acid](#) to a pH of 4.0
Solution A: 5.4 g/L of [monobasic potassium phosphate](#), adjusted with dilute [phosphoric acid](#) to a pH of 4.0
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	98	2
7.5	50	50
8.5	50	50
9.0	98	

Time (min)	Solution A (%)	Solution B (%)
12.5	98	2

Standard solution: 0.7 mg/mL of [USP Sulbactam RS](#) prepared as follows. Dissolve a suitable amount of [USP Sulbactam RS](#) in [acetonitrile](#), using 2% of the final volume, and dilute with *Buffer solution* to volume.

Sample solution: 0.77 mg/mL of Sulbactam Sodium prepared as follows. Dissolve a suitable amount of Sulbactam Sodium in [acetonitrile](#), using 2% of the final volume, and dilute with *Buffer solution* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4-mm × 15-cm; 3-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in μg, of sulbactam ($C_8H_{11}NO_5S$) in each mg of Sulbactam Sodium taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = potency of sulbactam in [USP Sulbactam RS](#) (mg/mg)

F = conversion factor, 1000 μg/mg

Acceptance criteria: 886–941 μg/mg on the anhydrous basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Buffer solution, Solution A, Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Diluent: 2 mL of [acetonitrile](#) diluted with *Buffer solution* to 100 mL

System suitability solution: 0.7 μg/mL each of [USP Sulbactam Related Compound A RS](#), [USP Sulbactam Related Compound D RS](#), [USP Sulbactam Related Compound E RS](#), and [USP Sulbactam Related Compound F RS](#), prepared as follows. Dissolve suitable amounts of [USP Sulbactam Related Compound A RS](#), [USP Sulbactam Related Compound D RS](#), [USP Sulbactam Related Compound E RS](#), and [USP Sulbactam Related Compound F RS](#) in [acetonitrile](#) using 10% of the final volume, and sonicate as needed. Dilute with *Diluent* to volume. Protect this solution from light.

Standard stock solution: 0.7 mg/mL of [USP Sulbactam RS](#) prepared as follows. Dissolve a suitable amount of [USP Sulbactam RS](#) in [acetonitrile](#), using 2% of the final volume, and dilute with *Buffer solution* to volume.

Standard solution: 0.7 μg/mL of [USP Sulbactam RS](#) from the *Standard stock solution*, in *Diluent*

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between sulbactam related compound D and sulbactam related compound E,  **Documents** *System suitability solution*