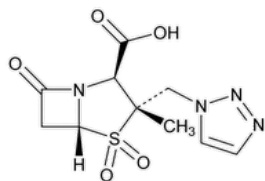


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Tazobactam



$C_{10}H_{12}N_4O_5S$ 300.29

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-, 4,4-dioxide, [2S-(2 α ,3 β ,5 α)]-; (2S,3S,5R)-3-Methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 4,4-dioxide CAS RN®: 89786-04-9; UNII: SE10G96M8W.

$C_{10}H_{12}N_4O_5S \cdot \frac{1}{2}H_2O$ 309.30 CAS RN®: 428863-55-2.

DEFINITION

Tazobactam contains NLT 98.0% and NMT 102.0% of $C_{10}H_{12}N_4O_5S$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

Mobile phase: Dissolve 1.32 g of dibasic ammonium phosphate in 750 mL of water. Adjust with 5% v/v phosphoric acid to a pH of 2.5, and dilute with water to 1000 mL. Add 30 mL of acetonitrile, mix, and pass through a filter of 0.2- μ m pore size.

System suitability solution: 16 μ g/mL of L-phenylalanine, 50 μ g/mL of [USP Tazobactam RS](#), and 8 μ g/mL of [USP Tazobactam Related Compound A RS](#) in *Mobile phase*. Maintain the *System suitability solution* at 3° until injection. Prepare fresh daily. If an autosampler is used, replace the plastic tubing connected to the injection needle with a stainless steel assembly, and maintain at 3°. If a chilled autosampler is not used, then this solution should be injected immediately after preparation.

Standard solution: 0.5 mg/mL of [USP Tazobactam RS](#) in *Mobile phase*. Cool, and maintain the *Standard solution* at 3° until injection. If an autosampler is used, replace the plastic tubing connected to the injection needle with a stainless steel assembly, and maintain at 3°. If a chilled autosampler is not used, then this solution should be injected immediately after preparation.

Sample solution: 0.5 mg/mL of Tazobactam in *Mobile phase*. Cool, and maintain the *Sample solution* at 3° until injection. If an autosampler is used, replace the plastic tubing connected to the injection needle with a stainless steel assembly, and maintain at 3°. If a chilled autosampler is not used, then this solution should be injected immediately after preparation.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L1

Flow rate: 1.5 mL/min

Injection size: 20 μ L

System suitability

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

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 6.0 between tazobactam and L-phenylalanine, *System suitability solution*

Tailing factor: NMT 1.8, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tazobactam ($C_{10}H_{12}N_4O_5S$) in the portion of Tazobactam taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

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

Blank: *Mobile phase*. Cool, and maintain the *Blank* at 3° until injection. If an autosampler is used, replace the plastic tubing connected to the injection needle with a stainless steel assembly, and maintain at 3°. If a chilled autosampler is not used, then this solution should be injected immediately after preparation.

Sample solution: Prepare as directed in the Assay. Cool, and maintain the *Sample solution* at 3° until injection. If an autosampler is used, replace the plastic tubing connected to the injection needle with a stainless steel assembly, and maintain at 3°. If a chilled autosampler is not used, then this solution should be injected immediately after preparation.

Analysis

Samples: *Blank* and *Sample solution*

Ignore any peaks of the *Sample solution* that correspond to any peaks of the *Blank*.

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

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

r_U = peak response for each impurity in the *Sample solution*

r_T = sum of all the peak responses in the *Sample solution*

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

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Tazobactam related compound A	0.29	1.0
L-Phenylalanine	0.71	—
Tazobactam	1.0	—
Any other individual impurity	—	0.1
Total impurities ^a	—	0.3