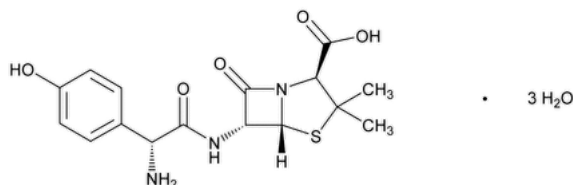


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Amoxicillin



$C_{16}H_{19}N_3O_5S \cdot 3H_2O$ 419.45

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-, trihydrate [2S-[2 α ,5 α ,6 β (S*)]]-; (2S,5R,6R)-6-[(R)-(-)-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate CAS RN[®]: 61336-70-7; UNII: 804826J2HU.

Anhydrous 365.41 CAS RN[®]: 26787-78-0; UNII: 9EM05410Q9.

DEFINITION

Amoxicillin contains NLT 900 µg/mg and NMT 1050 µg/mg of amoxicillin ($C_{16}H_{19}N_3O_5S$), 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

Diluent: 6.8 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with a 45% (w/w) solution of [potassium hydroxide](#) to a pH of 5.0 ± 0.1.

Mobile phase: Acetonitrile and Diluent (1:24)

Standard solution: 1.2 mg/mL of [USP Amoxicillin RS](#) in Diluent. [NOTE—Use this solution within 6 h.]

Sample solution: 1.2 mg/mL of Amoxicillin in Diluent. [NOTE—Use this solution within 6 h.]

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4-mm × 25-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of amoxicillin ($C_{16}H_{19}N_3O_5S$) in the portion of Amoxicillin taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = potency of amoxicillin in [USP Amoxicillin RS](#) ($\mu\text{g}/\text{mg}$)

Acceptance criteria: 900–1050 $\mu\text{g}/\text{mg}$ of amoxicillin ($\text{C}_{16}\text{H}_{19}\text{N}_3\text{O}_5\text{S}$) on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 2.72 g/L of [monobasic potassium phosphate](#). Adjust with [1 N potassium hydroxide](#) or [20% phosphoric acid](#) to a pH of 5.0 ± 0.1 .

Solution B: [Methanol](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	97	3
10	97	3
22	75	25
26	97	3

System suitability solution: 12.5 $\mu\text{g}/\text{mL}$ each of [USP Amoxicillin Related Compound A RS](#) and [USP Amoxicillin Related Compound D RS](#) in *Solution A*

Standard solution: 12.5 $\mu\text{g}/\text{mL}$ of [USP Amoxicillin RS](#) in *Solution A*

Sample solution: 1.25 mg/mL of Amoxicillin in *Solution A*. [NOTE—Store this solution at 4° and use within 4 h.]

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 10-cm; 5- μm packing [L1](#)

Temperatures

Autosampler: 4°

Column: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—Identify peaks by the relative retention times in [Table 2](#).]

Suitability requirements

Resolution: NLT 1.5 between amoxicillin related compound A and the second peak for amoxicillin related compound D, *System suitability solution*

Relative standard deviation: NMT 10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

C_S = concentration of [USP Amoxicillin RS](#) in the *Standard solution* ($\mu\text{g}/\text{mL}$)

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

F = unit conversion factor, 0.001 mg/ μg

Acceptance criteria: See [Table 2](#). [NOTE—The reporting limit is 0.03 times the amoxicillin peak from the *Standard solution*.]

Table 2