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Amoxicillin Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-amoxicillin-caps-20211029>.

DEFINITION

Amoxicillin Capsules contain the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$).

IDENTIFICATION

- **A.** 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

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

Mobile phase: [Acetonitrile](#) and *Buffer* (1:24)

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

Sample solution: Remove, as completely as possible, the contents of NLT 20 Capsules. Mix the combined contents, and transfer a quantity, equivalent to 200 mg of anhydrous amoxicillin, to a 200-mL volumetric flask. Add *Buffer* to volume. Sonicate if necessary to ensure complete dissolution. [NOTE—Use this solution within 6 h.]

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4-mm $\times$ 25-cm; 10- μ m packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

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 percentage of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) in the portion of Capsules taken:

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

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 = nominal concentration of amoxicillin in the *Sample solution* (mg/mL)

P = potency of amoxicillin in [USP Amoxicillin RS](#) (μ g/mg)

F = conversion factor, 0.001 mg/ μ g

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#).

Test 1

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm, for Capsules containing 250 mg

Apparatus 2: 75 rpm, for Capsules containing 500 mg

Time: 60 min

Analytical wavelength: UV 272 nm

Standard solution: [USP Amoxicillin RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution*.

Tolerances: NLT 80% (Q) of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm

Time: 90 min

Analytical wavelength: UV 272 nm

Standard solution: [USP Amoxicillin RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution*.

Tolerances: NLT 80% (Q) of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

Delete the following:

▲ (RB 1-Nov-2021)

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS (61)** and **TESTS FOR SPECIFIED MICROORGANISMS (62):** The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.
- **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

Change to read:

- **USP REFERENCE STANDARDS (11).**

[USP Amoxicillin RS](#)

▲ (RB 1-Nov-2021)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMOXICILLIN CAPSULES	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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