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Amoxicillin for Oral Suspension

DEFINITION

Amoxicillin for Oral Suspension contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$). It contains one or more suitable buffers, colors, flavors, preservatives, stabilizers, sweeteners, and suspending agents.

IDENTIFICATION

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 a 45% (w/w) solution of potassium hydroxide 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: Dilute a measured volume of Amoxicillin for Oral Suspension, constituted as directed in the labeling, freshly mixed and free from air bubbles, quantitatively and stepwise in *Buffer* to obtain a solution containing nominally 1 mg/mL of anhydrous amoxicillin. Pass a portion of this solution through a suitable filter. [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;10-µm packing L1

Flow rate: 1.5 mL/min

Injection size: 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 percentage of $C_{16}H_{19}N_3O_5S$ in the Amoxicillin for Oral Suspension 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 anhydrous amoxicillin in the *Sample solution* (mg/mL)

P = potency of amoxicillin in USP Amoxicillin RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For solids packaged in single-unit containers: Meets the requirements

• **Deliverable Volume ⟨698⟩:** Meets the requirements

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.0–7.5, in the suspension constituted as directed in the labeling

• **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.

• **USP Reference Standards** ⟨11⟩

USP Amoxicillin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMOXICILLIN FOR ORAL SUSPENSION	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

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