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Amoxicillin and Clavulanate Potassium for Oral Suspension

DEFINITION

Amoxicillin and Clavulanate Potassium for Oral Suspension contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) and the equivalent of NLT 90.0% and NMT 125.0% of the labeled amount of clavulanic acid ($C_8H_9NO_5$). It contains one or more suitable buffers, colors, flavors, preservatives, stabilizers, sweeteners, and suspending agents.

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 7.8 g of monobasic sodium phosphate in 900 mL of water. Adjust with phosphoric acid or 10 N sodium hydroxide to a pH of 4.4 ± 0.1, and dilute with water to 1000 mL.

Mobile phase: Methanol and *Buffer* (1:19). Pass through a suitable filter.

Standard solution: 0.5 mg/mL of USP Amoxicillin RS and 0.2 mg/mL of USP Clavulanate Lithium RS in water

Sample solution: Nominally 0.5 mg/mL of amoxicillin in water, prepared as follows. Constitute Amoxicillin and Clavulanate Potassium for Oral Suspension with water using the volume specified in the labeling. Stir by mechanical means for 10 min, and filter. Use within 1 h.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 30-cm; 3- to 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for clavulanic acid and amoxicillin are about 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.5 between the amoxicillin and clavulanic acid peaks

Tailing factor: NMT 1.5 for each analyte peak

Relative standard deviation: NMT 2.0% for each analyte peak

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 Amoxicillin and Clavulanate Potassium 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 of amoxicillin 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* (mg/mL)

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

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

F = conversion factor, 0.001 mg/µg

Calculate the percentage of the labeled amount of clavulanic acid ($C_8H_9NO_5$) in the Amoxicillin and Clavulanate Potassium for Oral Suspension taken:

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

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r_U = peak response of clavulanic acid from the *Sample solution*

r_S = peak response of clavulanic acid from the *Standard solution*

C_S = concentration of USP Clavulanate Lithium RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of clavulanic acid in the *Sample solution* (mg/mL)

P = potency of clavulanic acid in USP Clavulanate Lithium RS (mg/mg)

Acceptance criteria: 90.0%–120.0% of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) and 90.0%–125.0% of the labeled amount of clavulanic acid ($C_8H_9NO_5$)

PERFORMANCE TESTS

• **Deliverable Volume** ⟨698⟩

For powder packaged in multiple-unit containers: Meets the requirements

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

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

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: Constitute as directed in the labeling, and perform the test immediately after constitution.

Acceptance criteria: 3.8–6.6

• **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, at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Amoxicillin RS

USP Clavulanate Lithium RS

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

Topic/Question	Contact	Expert Committee
AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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