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Amoxicillin Tablets for Oral Suspension

DEFINITION

Amoxicillin Tablets for Oral Suspension contain NLT 90.0% and NMT 110.0% of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$).

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 4 mg/mL of USP Amoxicillin RS in 0.1 N hydrochloric acid. Use within 10 min of preparation.

Sample solution: An aqueous dispersion of Tablets for Oral Suspension in 0.1 N hydrochloric acid containing 4 mg/mL of amoxicillin. Use within 10 min of preparation.

Chromatographic system

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Methanol, chloroform, pyridine, and water (90:80:1:30)

Spray reagent: 3 mg/mL of ninhydrin in alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Dry the plate with the aid of a current of warm air for 10 min. Spray lightly with *Spray reagent*, and dry at 110° for 15 min.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

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). Decrease the acetonitrile concentration to increase the retention time of amoxicillin.

Standard solution: 1.2 mg/mL of USP Amoxicillin RS in *Diluent*. Use this solution within 6 h.

Sample solution: Prepare a dispersion of 20 Tablets for Oral Suspension using a suitable aliquot of water. Dilute a portion of the dispersion with *Diluent* to obtain a solution containing 1.2 mg/mL of amoxicillin. Pass a portion of the solution through a filter of 1-µm or finer pore size. 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

Capacity factor: 1.1–2.8

Column efficiency: NLT 1700 theoretical plates

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 Tablets 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 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%–110.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Medium: Water at 20 ± 5°

Time: 3 min

Acceptance criteria: Meet the requirements

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Buffer: 27.2 g of monobasic potassium phosphate in 3 L of water. Adjust with a 45% (w/w) solution of potassium hydroxide to a pH of 5.0 ± 0.1, and dilute with water to obtain 4 L of solution.

Mobile phase: Acetonitrile and *Buffer* (10:390). Pass through a filter of 0.5-µm or finer pore size.

Standard solution: 0.05 mg/mL of USP Amoxicillin RS in *Buffer*. Use this solution within 6 h.

Sample solution: Pass a portion of the sample through a filter of 0.5-µm or finer pore size. Dilute a suitable aliquot of the filtrate with water to obtain a concentration of 0.045 mg/mL of amoxicillin. Use this solution within 6 h.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Columns

Guard: 2-mm × 2-cm; packing L2

Analytical: 3.9-mm × 30-cm; packing L1

Column temperature: 40 ± 1°

Flow rate: 0.7 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor: 1.1–2.8

Column efficiency: NLT 1700 theoretical plates

Tailing factor: NMT 2.5

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times P \times F \times (1/L) \times 100$$

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)

V = volume of medium, 900 mL

D = dilution factor

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

F = conversion factor, 0.001 mg/µg

L = label claim (mg/Tablet)

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

SPECIFIC TESTS

• **Dispersion Fineness:** Place 2 Tablets for Oral Suspension in 100 mL of water, and stir until completely dispersed. A smooth dispersion that passes through a No. 25 sieve is obtained.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **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 TABLETS FOR ORAL SUSPENSION	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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