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# Amoxicillin Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-amoxicillin-tabs-20211029.

**DEFINITION**
Amoxicillin Tablets contain 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:** 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:** Place NLT 5 Tablets in a high-speed glass blender jar containing *Buffer* sufficient to yield a concentration of 1 mg/mL of anhydrous amoxicillin. Blend for 4 ± 1 min, allow to stand for 5 min, and centrifuge a portion of the mixture. [Note—Where the volume of *Buffer* required would exceed 500 mL, place 5 Tablets in a volumetric flask of such capacity that when finally diluted to volume, a concentration of 1 mg of anhydrous amoxicillin per milliliter would be obtained. Add a volume of *Buffer* equivalent to three-fourths of the capacity of the volumetric flask, and sonicate for 5 min. Dilute with *Buffer* to volume, add a magnetic stirring bar, and stir for 30 min. Centrifuge a portion of this solution.]

Pass a portion of the clear supernatant 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 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 percentage of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) in the portion of Tablets 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

**Acceptance criteria:** 90.0%–120.0%

**PERFORMANCE TESTS**

• **Dissolution** ⟨711⟩

**Medium:** Water; 900 mL

**Apparatus 2:** 75 rpm

**Time:** 30 min

Determine the amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) dissolved by using the following method.

**Buffer:** 27.2 g of monobasic potassium phosphate in 3 L of water. Adjust with 45% potassium hydroxide TS to a pH of 5.0 ± 0.1. Dilute with water to obtain 4 L of solution.

**Mobile phase:** Acetonitrile and *Buffer* (1:39)

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

**Sample solution:** Pass a portion of the sample through a suitable filter of 0.5-µm pore size. Quantitatively dilute a volume of the filtrate with water to obtain an estimated 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**

**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:

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

$r_U$ = 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)

$L$ = label claim (mg/Tablet)

$V$ = volume of the dissolution medium, 900 mL

$D$ = dilution factor for the *Sample solution*

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

$F$ = conversion factor, 0.001 mg/µg

**Tolerances:** NLT 75% (*Q*) of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) is dissolved.

**For products labeled as chewable Tablets:** Proceed as directed above.

**For chewable Tablets labeled to contain 200 or 400 mg**

**Time:** 20 min

**Tolerances:** NLT 70% (*Q*) of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) is dissolved.

**For chewable Tablets labeled to contain 125 or 250 mg**

**Time:** 90 min

**Tolerances:** NLT 70% (*Q*) of the labeled amount of amoxicillin ($C_{16}H_{19}N_3O_5S$) is dissolved.

**For veterinary products:** Proceed as directed above, except use *Apparatus 2* at 100 rpm.

***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:** Label chewable Tablets to indicate that they are to be chewed before swallowing. Tablets intended solely for veterinary use are so labeled.

***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 TABLETS | Documentary Standards Support | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** Chromatographic Database

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