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Amoxicillin and Clavulanic Acid Extended-Release Tablets

DEFINITION

Amoxicillin and Clavulanic Acid Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of amoxicillin ($C_{16}H_{19}N_3O_5S$) and clavulanic acid ($C_8H_9NO_5$).

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: 6.9 g/L of [monobasic sodium phosphate](#) adjusted with [phosphoric acid](#) to a pH of 4.2

Mobile phase: [Methanol](#) and *Buffer* (5:95)

Standard solution: 1 mg/mL of [USP Amoxicillin RS](#) and 62.5 µg/mL of [USP Clavulanate Lithium RS](#) in water. Store the solution at 4°, and inject within 10 h.

Sample solution: Equivalent to 1 mg/mL of amoxicillin and 62.5 µg/mL of clavulanic acid from finely powdered Tablets (NLT 6) in water. Stir for about 60 min. Store the solution at 4°, and inject within 12 h.

Chromatographic system

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

Mode: LC

Detector: UV 229 nm

Column: 8-mm × 10-cm; 5-µm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

Autosampler temperature: 4°

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between the amoxicillin and clavulanic acid peaks

Tailing factor: NMT 1.8 for the amoxicillin and clavulanic acid peaks

Relative standard deviation: NMT 1.0% for the amoxicillin and clavulanic acid peaks

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 = response of amoxicillin from the *Sample solution*

r_S = 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 portion of Tablets taken:

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

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

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

C_s = concentration of [USP Clavulanate Lithium RS](#) in the *Standard solution* ($\mu\text{g/mL}$)

C_u = nominal concentration of clavulanic acid in the *Sample solution* ($\mu\text{g/mL}$)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Times

Amoxicillin: 1, 3, and 5 h

Clavulanic acid: 1 h

Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard solution: [USP Amoxicillin RS](#) and [USP Clavulanate Lithium RS](#) in *Medium* at known concentrations similar to those expected in the *Sample solution*

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the amounts of amoxicillin ($\text{C}_{16}\text{H}_{19}\text{N}_3\text{O}_5\text{S}$) and clavulanic acid ($\text{C}_8\text{H}_9\text{NO}_5$) dissolved.

Tolerances

Amoxicillin: The percentage of the labeled amount of amoxicillin ($\text{C}_{16}\text{H}_{19}\text{N}_3\text{O}_5\text{S}$) dissolved at the times specified conforms to [Table 1](#).

Table 1

Time (h)	Amount Dissolved (%)
1	50–65
3	65–85
5	NLT 85

Clavulanic acid: NLT 80% (Q) of the labeled amount of clavulanic acid ($\text{C}_8\text{H}_9\text{NO}_5$) is dissolved in 1 h.

Test 2

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Times

Amoxicillin: 1, 3, and 5 h

Clavulanic acid: 45 min

Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard solution: [USP Amoxicillin RS](#) and [USP Clavulanate Lithium RS](#) in *Medium* at known concentrations similar to those expected in the *Sample solution*

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

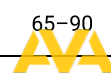
Calculate the amounts of amoxicillin ($\text{C}_{16}\text{H}_{19}\text{N}_3\text{O}_5\text{S}$) and clavulanic acid ($\text{C}_8\text{H}_9\text{NO}_5$) dissolved.

Tolerances

Amoxicillin: The percentage of the labeled amount of amoxicillin ($\text{C}_{16}\text{H}_{19}\text{N}_3\text{O}_5\text{S}$) dissolved at the times specified conforms to [Table 2](#).

Table 2

Time (h)	Amount Dissolved (%)
1	50–70
3	65–90



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