

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Aug-2016
 Document Type: USP Monographs
 DocId: GUID-2066A25D-F5B5-4274-911B-5A6EF3A31C62_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M17995_01_01
 DOI Ref: 4ua05

© 2025 USPC
 Do not distribute

Clarithromycin Tablets

DEFINITION

Clarithromycin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of clarithromycin ($C_{38}H_{69}NO_{13}$).

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

Mobile phase: [Methanol](#) and 0.067 M [monobasic potassium phosphate](#) (13:7). Adjust with [phosphoric acid](#) to a pH of 4.0, and pass through a suitable filter.

System suitability stock solution: 625 µg/mL of [USP Clarithromycin Related Compound A RS](#) in [methanol](#)

System suitability solution: 125 µg/mL of [USP Clarithromycin RS](#) from the *Standard stock solution* and 125 µg/mL of [USP Clarithromycin Related Compound A RS](#) from the *System suitability stock solution* in *Mobile phase*

Standard stock solution: 625 µg/mL of clarithromycin from [USP Clarithromycin RS](#) dissolved in [methanol](#). Shake, and sonicate to facilitate dissolution.

Standard solution: 125 µg/mL of clarithromycin from *Standard stock solution* in *Mobile phase*. Pass through a suitable filter.

Sample stock solution: Nominally 4 mg/mL of clarithromycin from finely powdered Tablets in [methanol](#). Shake by mechanical means for 30 min to disperse, and allow any insoluble matter to settle.

Sample solution: 120 µg/mL of clarithromycin from the *Sample stock solution* in *Mobile phase*. Pass through a filter of 0.5-µm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

[NOTE—A guard column containing packing [L1](#) may be added.]

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 20–50 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for clarithromycin and clarithromycin related compound A are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between clarithromycin and clarithromycin related compound A, *System suitability solution*

Tailing factor: 0.9–1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clarithromycin ($C_{38}H_{69}NO_{13}$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of clarithromycin in the *Standard solution* ($\mu\text{g/mL}$)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Buffer: Prepare a solution containing 13.61 mg/mL of [sodium acetate trihydrate](#) in water. Prepare another solution by diluting 5.7 mL of [glacial acetic acid](#) with water to 1 L. Combine portions of the two solutions to obtain a pH of 5.0.

Medium: *Buffer*, 900 mL

Apparatus 2: 50 rpm

Time: 30 min

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

Standard stock solution: 625 $\mu\text{g/mL}$ of clarithromycin from [USP Clarithromycin RS](#) dissolved in *Buffer*. Shake, and sonicate to facilitate dissolution.

Standard solution: 125 $\mu\text{g/mL}$ of clarithromycin from the *Standard stock solution* in *Mobile phase*. Pass through a suitable filter.

Sample solution: Dilute with *Mobile phase* to yield a solution containing nominally 125 $\mu\text{g/mL}$ of clarithromycin.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clarithromycin ($\text{C}_{38}\text{H}_{69}\text{NO}_{13}$) dissolved:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_s = concentration of the *Standard solution* ($\mu\text{g/mL}$)

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

Tolerances: NLT 80% (Q) of the labeled amount of clarithromycin ($\text{C}_{38}\text{H}_{69}\text{NO}_{13}$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 4.76 g/L of [monobasic potassium phosphate](#) adjusted with dilute [phosphoric acid](#) (1 in 10) or 4.5% (w/v) of [potassium hydroxide](#) to a pH of 4.4

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
32	40	60
34	40	60
36	75	25
42	75	25

Diluent: [Acetonitrile](#) and water (1:1)

System suitability solution: 1.5 mg/mL of [USP Clarithromycin Identity RS](#) in [acetonitrile](#) and water (1:1). Dissolve first in acetonitrile, using

50% of the final volume, and dilute with water to volume.