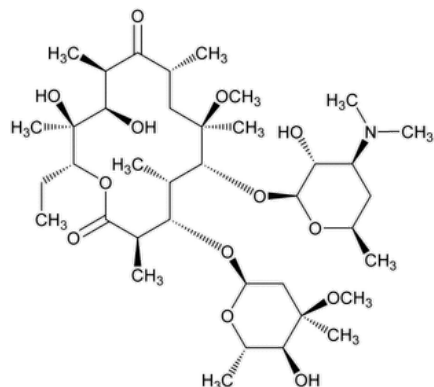


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Clarithromycin



$C_{38}H_{69}NO_{13}$

747.95

Erythromycin, 6-O-methyl-

6-O-Methylerythromycin CAS RN®: 81103-11-9; UNII: H1250JIK0A.

DEFINITION

Clarithromycin contains NLT 96.0% and NMT 102.0% of clarithromycin ($C_{38}H_{69}NO_{13}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- B. The retention time of the major peak of the *Sample solution* corresponds to that of *Standard solution 1*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A, Solution B, Mobile phase, Diluent, Standard solution 1, Standard solution 2, Standard solution 4, Sample solution, and **Chromatographic system:** Proceed as directed in *Organic Impurities*.

System suitability

Samples: *Standard solution 1*, *Standard solution 2*, and *Standard solution 4*

[NOTE—See the relative retention times in [Table 2](#). The typical retention time for clarithromycin is about 11 min.]

Suitability requirements

Peak-to-valley ratio: NLT 3.0, *Standard solution 4*

The *Peak-to-valley ratio* is calculated as follows:

$$\text{Result} = H_p/H_v$$

H_p = height above the baseline of the clarithromycin impurity D peak, *Standard solution 4*

H_v = height above the baseline of the lowest point of the curve separating the clarithromycin impurity D peak from the clarithromycin peak, *Standard solution 4*

Tailing factor: NMT 1.7, *Standard solution 2*

Relative standard deviation: NMT 1.5%, *Standard solution 1*

Analysis

Samples: *Standard solution 1* and *Sample solution*

Calculate the percentage of clarithromycin ($C_{38}H_{69}NO_{13}$) in the portion of Clarithromycin 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 *Standard solution 1*

C_S = concentration of [USP Clarithromycin RS](#) in *Standard solution 1* (mg/mL)

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

Acceptance criteria: 96.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#).

Sample: 0.5 g

Acceptance criteria: NMT 0.2%

• ORGANIC IMPURITIES

Solution A: 4.76 g/L of [monobasic potassium phosphate](#). Adjust with dilute [phosphoric acid](#) (1 in 10) or [potassium hydroxide](#) (45% w/v) to a pH of 4.4. Pass this solution through a C18 filtration kit.

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)

Standard solution 1: 1.5 mg/mL of [USP Clarithromycin RS](#) in [acetonitrile](#) and [water](#) (1:1). Dissolve first in [acetonitrile](#), using 50% of the final volume, and dilute with [water](#) to volume.

Standard solution 2: 75 µg/mL of [USP Clarithromycin RS](#) from *Standard solution 1* in *Diluent*

Standard solution 3: 7.5 µg/mL of [USP Clarithromycin RS](#) from *Standard solution 2* in *Diluent*

Standard solution 4: 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.

Sample solution: 1.5 mg/mL of Clarithromycin in [acetonitrile](#) and [water](#) (1:1). Dissolve first in [acetonitrile](#), using 50% of the final volume, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm × 10-cm; packing [L1](#)

Column temperature: 40°

Flow rate: 1.1 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution 2* and *Standard solution 4*

[NOTE—See the relative retention times in [Table 2](#). The typical retention time for clarithromycin is about 11 min.]



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