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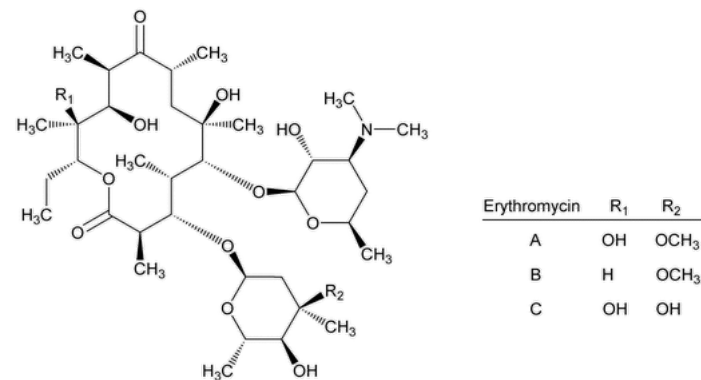
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Do not distribute

Erythromycin

Change to read:

C₃₇H₆₇NO₁₃ 733.94

▲ Erythromycin A

(3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*R*,12*R*,13*S*,14*R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-*L*-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[(3,4,6-trideoxy-3-dimethylamino-β-*D*-xylo-hexopyranosyl)oxy]oxacyclotetradecane-2,10-dione;

C₃₇H₆₇NO₁₂ 717.94

Erythromycin B

(3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*R*,12*R*,13*S*,14*R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-*L*-ribo-hexopyranosyl)oxy]-14-ethyl-7,12-dihydroxy-3,5,7,9,11,13-hexamethyl-6-[(3,4,6-trideoxy-3-dimethylamino-β-*D*-xylo-hexopyranosyl)oxy]oxacyclotetradecane-2,10-dione;

12-Deoxyerythromycin CAS RN®: 527-75-3.

C₃₆H₆₅NO₁₃ 719.91

Erythromycin C

(3*R*,4*S*,5*S*,6*R*,7*R*,9*R*,11*R*,12*R*,13*S*,14*R*)-4-[(2,6-Dideoxy-3-C-methyl-α-*L*-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[(3,4,6-trideoxy-3-dimethylamino-β-*D*-xylo-hexopyranosyl)oxy]oxacyclotetradecane-2,10-dione;

3'-O-Demethylerythromycin CAS RN®: 1675-02-1. ▲ (USP 1-Dec-2024)

Erythromycin

▲ (USP 1-Dec-2024) CAS RN®: 114-07-8; UNII: 63937KV33D.

Change to read:

DEFINITION

Erythromycin consists primarily of erythromycin A (C₃₇H₆₇NO₁₃). The sum of the percentages of erythromycin A, erythromycin B, and erythromycin C is NLT ▲93.0%▲ (USP 1-Dec-2024) and NMT ▲102.0%▲ (USP 1-Dec-2024) calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197S

Standard solution: 50 mg/mL of [USP Erythromycin RS](#), previously dried at a pressure not exceeding 5 mm of mercury at 60° for 3 h, in chloroform

Sample solution: 50 mg/mL of Erythromycin, previously dried at a pressure not exceeding 5 mm of mercury at 60° for 3 h, in chloroform

Spectral range: 4000–2050 cm⁻¹ and 1980–400 cm⁻¹

Acceptance criteria: Meets the requirements

- **B.** The retention times of erythromycin A, erythromycin B, and erythromycin C in the *Sample solution* correspond to those of *Standard solution 1* and *Standard solution 2*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

▲ Prepare the erythromycin solutions immediately before use.

Diluted phosphoric acid: Dilute 7 mL of [phosphoric acid](#) with [water](#) to 100 mL.

Phosphate buffer solution pH 8.0: Dissolve 11.5 g of [dibasic potassium phosphate](#) in 900 mL of [water](#). Adjust to a pH of 8.0 with *Diluted phosphoric acid* and dilute with [water](#) to 1000 mL.

Diluent: *Phosphate buffer solution pH 8.0* and [methanol](#) (60:40)

Phosphate buffer solution pH 7.0: Dissolve 35 g of [dibasic potassium phosphate](#) in 900 mL of [water](#). Adjust to a pH of 7.0 with *Diluted phosphoric acid* and dilute with [water](#) to 1000 mL.

Solution A: *Phosphate buffer solution pH 7.0*, [water](#), and [acetonitrile](#) (5:60:35)

Solution B: *Phosphate buffer solution pH 7.0*, [water](#), and [acetonitrile](#) (5:45:50)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
T_R^a	100	0
$T_R + 2$	0	100
$T_R + 15$	0	100

^a T_R = retention time of erythromycin B, determined by injecting 10 μ L of *Standard solution 2* and eluting with *Solution A*.

Standard solution 1: 4 mg/mL of [USP Erythromycin RS](#) in *Diluent*

Standard solution 2: 0.2 mg/mL of [USP Erythromycin B RS](#) and [USP Erythromycin C RS](#) in *Diluent*

Sample solution: 4 mg/mL of Erythromycin in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 25-cm; 3.5- μ m packing [L1](#)

Temperatures

Column: 65°, preheating the *Mobile phase* may be required, for instance by extending the inlet tubing in the oven to 30 cm

Sampler: 4°

Flow rate: 1.0 mL/min

Injection volume: 100 μ L

System suitability

Sample: *Standard solution 1*

Suitability requirements

Tailing factor: NMT 2.0 for erythromycin A

Relative standard deviation: NMT 1.0% for erythromycin A, 6 replicate injections

Analysis

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

Calculate the percentage of erythromycin A in the portion of Erythromycin taken:

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

r_U = peak response of erythromycin A from the *Sample solution*

r_S = peak response of erythromycin A from *Standard solution 1*

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

C_U = concentration of Erythromycin, calculated on the anhydrous basis, in the *Sample solution* (mg/mL)

P = percentage of erythromycin A in [USP Erythromycin RS](#)

Calculate the percentages of erythromycin B and erythromycin C in the portion of Erythromycin taken:

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

r_U = peak response of the relevant analyte from the *Sample solution*