Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2013
Document Type: USP Monographs
DocId: GUID-916F1413-E104-4107-AB79-A8A0C1F9445B_1_en-US
DOI: https://doi.org/10.31003/USPNF_M17993_01_01
DOI Ref: qe8m2

Clarithromycin for Oral Suspension

DEFINITION

Clarithromycin for Oral Suspension is a dry mixture of Clarithromycin, dispersing agents, diluents, preservatives, and flavorings. It contains NLT 90.0% and NMT 115.0% of the labeled amount of clarithromycin ($C_{38}H_{69}NO_{13}$), the labeled amount being 25 mg or 50 mg/mL when constituted as directed in the labeling.

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 A: 0.067 M monobasic potassium phosphate

Buffer B: 0.067 M dibasic potassium phosphate

Mobile phase: Methanol and *Buffer A* (60:40), adjusted with phosphoric acid to a pH of 3.5. Pass through a suitable filter.

Standard stock solution: Equivalent to 2.1 mg/mL of clarithromycin from USP Clarithromycin RS in methanol

Standard solution: 0.415 mg/mL of clarithromycin from *Standard stock solution* in *Mobile phase*

Sample stock solution: Constitute the Clarithromycin for Oral Suspension as directed in the labeling. Transfer an aliquot of the suspension, equivalent to 1–2 g of clarithromycin, with the aid of 330 mL of *Buffer B*, to a 1000-mL volumetric flask containing 50 mL of *Buffer B*. Shake by mechanical means for 30 min, and dilute with methanol to volume. Sonicate for about 30 min, and allow to cool. Dilute with methanol to volume, add a magnetic stirring bar, and stir for 60 min. Allow to settle, and use the clear supernatant.

Sample solution: Transfer an aliquot of the *Sample stock solution*, nominally equivalent to 20 mg of clarithromycin, to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and pass through a suitable filter.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 210 nm

Columns

Guard (optional): Packing L1

Analytical: 4.6-mm × 15-cm; packing L1

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 1.0–1.7

Relative standard deviation: NMT 2.0%

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 the constituted Clarithromycin for Oral Suspension taken:

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

r_U = peak area response from the *Sample solution*

r_S = peak area response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- **Uniformity of Dosage Units** ⟨905⟩(for powder packaged in single-unit containers)**:** Meets the requirements
- **Deliverable Volume** ⟨698⟩(for powder packaged in multiple-unit containers)**:** Meets the requirements

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample: Use the suspension constituted as directed in the labeling.

  Acceptance criteria: 4.0–5.4

- **Loss on Drying** ⟨731⟩

  Sample: 1 g

  Analysis: Dry under vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

  Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

  USP Clarithromycin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLARITHROMYCIN FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 37(6)

Current DocID: GUID-916F1413-E104-4107-AB79-A8A0C1F9445B_1_en-US

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