Clarithromycin Tablets

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

IDENTIFICATION
- 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 then pass through a suitable filter.
Standard stock solution: 625 µg/mL of clarithromycin from USP Clarithromycin RS dissolved in methanol. [NOTE—Shake and sonicate to facilitate dissolution.]
Standard solution: 125 µg/mL of clarithromycin from the *Standard stock solution* diluted with *Mobile phase* 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 clarithromycin from the *Standard stock solution* and 125 µg/mL of clarithromycin related compound A from the *System suitability stock solution* in *Mobile phase*
Sample stock solution: Equivalent to 4 mg/mL of clarithromycin in methanol. [NOTE—Shake for 30 min by mechanical means.]
Sample solution: 120 µg/mL of clarithromycin in *Mobile phase* from the *Sample stock solution*. Pass through a suitable filter.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 210 nm
Column: 4.6-mm × 15-cm; packing L1
[NOTE—A guard column containing packing L1 may be added.]
Column temperature: 50°
Flow rate: 1 mL/min
Injection size: 20–50 µL
System suitability
Samples: *Standard solution* and *System suitability 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*
Column efficiency: NLT 750 theoretical plates from the clarithromycin peak, *Standard 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 label claim of $C_{38}H_{69}NO_{13}$ in the portion of Tablets taken:

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

r_U = peak area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of the *Standard solution* (µg/mL)
C_U = nominal concentration of the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- **DISSOLUTION** ⟨**711**⟩

●**0.1 M Sodium acetate 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 (the proportion is almost 1:1).▲*USP33*● (RB 1-Oct-2010)
Medium: *0.1 M Sodium acetate buffer*, 900 mL
Apparatus 2: 50 rpm
Time: 30 min
Mobile phase, Standard solution, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.
Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Mobile phase* to yield a nominal concentration of about 125 µg/mL of clarithromycin.
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of clarithromycin dissolved:

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

r_U = peak area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of the *Standard solution* (µg/mL)
L = label claim (mg/Tablet)
V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of $C_{38}H_{69}NO_{13}$ is dissolved.

- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

SPECIFIC TESTS
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a portion of powdered Tablets in a vacuum at a pressure not exceeding 5 mm of mercury at 110° for 3 h: it loses NMT 6.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Clarithromycin RS
USP Clarithromycin Related Compound A RS