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Azithromycin Tablets

DEFINITION

Azithromycin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$).

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.

• **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197A](#)

Standard solution: 25 mg/mL of [USP Azithromycin RS](#) in [acetonitrile](#). Pass the solution through a suitable filter, and remove the solvent by natural evaporation.

Sample solution: Equivalent to 25 mg/mL of azithromycin from Tablets in [acetonitrile](#). Pass the solution through a suitable filter, and remove the solvent by natural evaporation.

Acceptance criteria: Meet the requirements

ASSAY

PROCEDURE

Buffer: Dissolve 4.6 g of [monobasic potassium phosphate anhydrous](#) in 900 mL of [water](#). Adjust with [1 N sodium hydroxide](#) to a pH of 7.5, and dilute with [water](#) to 1 L.

Mobile phase: [Acetonitrile](#) and *Buffer* (65:35)

Standard solution: 1 mg/mL of [USP Azithromycin RS](#) in *Mobile phase*. Sonicate and shake as needed to dissolve.

Sample solution: Nominally 1 mg/mL of azithromycin in *Mobile phase* from NLT 20 Tablets, finely powdered. Sonicate and shake as needed to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 50°

Flow rate: 2 mL/min

Injection volume: 100 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$) in the portion of Tablets taken:

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

r_U = peak response of azithromycin from the *Sample solution*

r_S = peak response of azithromycin from the *Standard solution*

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

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

P = potency of [USP Azithromycin RS](#) (μg/mg)

F = conversion factor, 0.001 mg/μg

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS• **[DISSOLUTION \(711\)](#)****Medium:** pH 6.0 phosphate buffer; 900 mL**Apparatus 2:** 75 rpm**Time:** 30 min**Solution A:** 4.4 mg/mL of [dibasic potassium phosphate](#) and 0.5 mg/mL of sodium 1-octanesulfonate; adjusted with [phosphoric acid](#) to a pH of 8.20 ± 0.05 **Mobile phase:** [Acetonitrile](#), [methanol](#), and *Solution A* (9:3:8)**Diluent:** 17.5 mg/mL of [dibasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 8.00 ± 0.05 . Prepare a mixture of this solution and [acetonitrile](#) (80:20).**Standard stock solution:** Dissolve [USP Azithromycin RS](#) in *Medium* to obtain a solution with a known concentration of about $(L/1000)$ mg/mL, where L is the label claim in mg/Tablet.**Standard solution:** Dilute the *Standard stock solution* with *Diluent* to obtain a solution with a known concentration of about $(L/2000)$ mg/mL, where L is the label claim in mg/Tablet.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size. Dilute a portion of the filtrate with *Diluent* to obtain a solution with a theoretical concentration of about $(L/2000)$ mg/mL, where L is the label claim in mg/Tablet, assuming complete dissolution.**Chromatographic system**(See [Chromatography \(621\)](#), *System Suitability*.)**Mode:** LC**Detector:** UV 210 nm**Column:** 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)**Column temperature:** 50°**Flow rate:** 1.5 mL/min**Injection volume:** 50 μ L**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$) dissolved:

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

 r_U = peak response of azithromycin from the *Sample solution* r_S = peak response of azithromycin from the *Standard solution* C_S = concentration of [USP Azithromycin RS](#) in the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 900 mL D = dilution factor for the *Sample solution*, if necessary**Tolerances:** NLT 80% (Q) of the labeled amount of azithromycin ($C_{38}H_{72}N_2O_{12}$) is dissolved.• **[UNIFORMITY OF DOSAGE UNITS \(905\)](#):** Meet the requirements**IMPURITIES**• **ORGANIC IMPURITIES**Protect all solutions containing azithromycin from light. Refrigerate the *Standard solution* and the *Sample solution* after preparation and during analysis, using a refrigerated autosampler set at 4°. The solutions must be analyzed within 24 h of preparation.**Solution A:** [Water](#) and [ammonium hydroxide](#) (2000:1.2). The pH of this solution is about 10.5.**Solution B:** [Acetonitrile](#), [methanol](#), and [ammonium hydroxide](#) (1800:200:1.2)**Mobile phase:** See [Table 1](#).**Table 1**