Notice of Intent to Revise
Official: To Be Determined

Rifabutin Capsules

DEFINITION

Rifabutin Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of rifabutin ($C_{46}H_{62}N_4O_{11}$).

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

  Standard solution: 20 µg/mL of USP Rifabutin RS in methanol, prepared with the aid of sonication. Pass through a filter of 0.5-µm or finer pore size.

  Sample solution: Nominally 20 µg/mL of rifabutin prepared as follows. Suspend a quantity of Capsule contents, equivalent to 200 mg of rifabutin, in 20 mL of methanol. Sonicate for 5 min, and pass through a suitable filter of 0.5-µm or finer pore size. Dilute a portion of the filtrate with methanol to obtain a solution containing 20 µg/mL of rifabutin.

  Acceptance criteria: Meet the requirements

- **B.** 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**

  Solution A: 13.6 g/L of monobasic potassium phosphate

  Mobile phase: Acetonitrile and *Solution A* (50:50). Adjust with 2 N sodium hydroxide TS to a pH of 6.5 ± 0.1. Pass through a suitable filter of 0.5-µm or finer pore size.

  System suitability solution: Dissolve 10 mg of Rifabutin in 2 mL of methanol, add 1 mL of 2 N sodium hydroxide TS, and allow to stand for 4 min. Add 1 mL of 2 N hydrochloric acid TS, and dilute with *Mobile phase* to 50 mL. [Note—Portions of this solution may be stored in the frozen state for future use.]

  Standard solution: 0.5 mg/mL of USP Rifabutin RS prepared as follows. Transfer an amount of USP Rifabutin RS to a suitable volumetric flask. Add acetonitrile to fill 10% of the volume of the flask, and dilute with *Mobile phase* to volume.

  Sample solution: Nominally 0.5 mg/mL of rifabutin prepared as follows. Remove the contents of NLT 20 Capsules, weigh, and determine the average weight of the Capsule contents. Transfer a portion of the powder, equivalent to 25 mg of rifabutin, to a 50-mL volumetric flask, add 5 mL of acetonitrile, and dilute with *Mobile phase* to volume. Pass through a suitable filter of 0.5-µm or finer pore size.

  Chromatographic system

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

  Mode: LC

  Detector: UV 254 nm

  Column: 4.6-mm × 12.5-cm; 5-µm packing L7

  Flow rate: 1 mL/min

  Injection volume: 10 µL

  Run time: NLT 2 times the retention time of the rifabutin peak