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Rifampin Compounded Oral Suspension

DEFINITION
Rifampin Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of rifampin ($C_{43}H_{58}N_4O_{12}$).

Prepare Rifampin Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Rifampin	1.20 g
Citric Acid or Sodium Citrate	To adjust pH
Syrup, a sufficient quantity to make	120 mL

Empty the required number of capsules into a suitable mortar, or use *Rifampin* powder. If necessary, gently crush the capsule contents with a pestle to produce a fine powder. Add 2 mL of *Syrup* to the mortar, and triturate until a smooth paste is formed. Add 10 mL of *Syrup*, and triturate to form a suspension. Continue to add *Syrup* until 80 mL has been added. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add *Syrup* in portions to rinse the mortar, and add the rinses to the bottle. If necessary, add *Citric Acid* or *Sodium Citrate* to adjust to a pH of 5.0. Add a suitable flavor if desired. Add sufficient *Syrup* to bring the preparation to final volume. Shake vigorously.

ASSAY

• **Procedure**

Solution A: 1.0 M monobasic potassium phosphate containing 6.3 mL/L of phosphoric acid

Solution B: Acetonitrile, 1.0 M dibasic potassium phosphate, 1.0 M monobasic potassium phosphate, 1.0 M citric acid, and water (25:7.7:2.3:1:64)

Mobile phase: Acetonitrile, *Solution A*, 1.0 M citric acid, 0.5 M sodium perchlorate, and water (36:10:2:2:50). Pass through a suitable filter of 0.7-µm or finer pore size, and degas.

Diluent: Acetonitrile and water (50:50)

System suitability solution: 0.1 mg/mL of USP Rifampin RS and 0.1 mg/mL of USP Rifampin Quinone RS in acetonitrile. Transfer 1.0 mL of the solution into a 10-mL volumetric flask, and dilute with *Solution B* to volume.

Standard solution: 0.5 mg/mL of USP Rifampin RS in *Diluent*. If necessary, sonicate for 30 s to dissolve. Transfer 5.0 mL of the solution to a 50-mL, low-actinic volumetric flask, and dilute with *Diluent* to volume. Use the solution within 1 h.

Sample solution: Transfer 5.0 mL of Oral Suspension, freshly mixed and free of air bubbles, to a 100-mL, low-actinic volumetric flask, and dissolve in and dilute with *Diluent* to volume. Transfer 5.0 mL of the resulting solution to a 50-mL, low-actinic volumetric flask, and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 10-cm; 5-µm packing L7

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for rifampin quinone and rifampin are about 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between rifampin quinone and rifampin, *System suitability solution*

Relative standard deviation: NMT 1.0% for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rifampin ($C_{43}H_{58}N_4O_{12}$) in the portion of Oral Suspension 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 USP Rifampin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.5–5.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a tight, light-resistant container. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 30 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to state that it is to be well shaken and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Rifampin RS

USP Rifampin Quinone RS

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

Topic/Question	Contact	Expert Committee
RIFAMPIN COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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