Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-E582F57B-35E4-4B38-B696-B3E18D8FFB6D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M5553_01_01
DOI Ref: e9878



# Rifabutin Compounded Oral Suspension

**DEFINITION**

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

Prepare Rifabutin Compounded Oral Suspension 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

| | |
|---|---|
| Rifabutin capsules[a] equivalent to | 3 g of rifabutin |
| Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus,[b] a sufficient quantity to make | 150 mL |

[a] Mycobutin 150-mg capsules, Pfizer Inc., New York, NY.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Empty the required number of *Rifabutin capsules* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a rifabutin liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

**ASSAY**

• **Procedure**

**Solution A:** 100 mM monobasic potassium phosphate buffer, adjusted with 2 N sodium hydroxide to a pH of 6.5

**Mobile phase:** Acetonitrile and *Solution A* (50:50). Filter and degas.

**Standard stock solution:** 2.0 mg/mL of USP Rifabutin RS in *Mobile phase*

**Standard solution:** Transfer 10 mL of *Standard stock solution* to a 100-mL volumetric flask. Immediately rinse the volumetric apparatus with 10 mL of acetonitrile and 10 mL of *Mobile phase*. Dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of 0.2 mg/mL of rifabutin. Pass through a filter of 0.45-µm pore size.

**Sample solution:** Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of Oral Suspension into a 100-mL volumetric flask. Immediately rinse the pipette with 10 mL of acetonitrile and 10 mL of *Mobile phase*. Dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of 0.2 mg/mL of rifabutin. Pass through a filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L7

**Flow rate:** 1.0 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

[Note—The retention time for the rifabutin is about 14.0 min.]

**Suitability requirements**

**Column efficiency:** NLT 4500 theoretical plates

**Tailing factor:** NMT 3.0

**Relative standard deviation:** NMT 2.0% for replicate injections

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rifabutin ($C_{46}H_{62}N_4O_{11}$) in the portion of Oral Suspension taken:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

$C_S$ = concentration of USP Rifabutin RS in the *Standard solution* (mg/mL)

$C_U$ = nominal concentration of rifabutin 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 tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 84 days after the date on which it was compounded, when stored in a refrigerator or at controlled room temperature

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

• **USP Reference Standards** ⟨11⟩

USP Rifabutin RS

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

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

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 41(1)

**Current DocID: GUID-E582F57B-35E4-4B38-B696-B3E18D8FFB6D_1_en-US**

**DOI: https://doi.org/10.31003/USPNF_M5553_01_01**

**DOI ref: e9878**