

FORMULATION RECORD

Name: Rifampin Suspension
Strength: 10 mg/ml
Dosage Form: Suspension
Route of Administration: Oral

Date of Last Review or Revision: 09/24/03
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Rifampin 300 mg capsules	4 capsules	red to brown-red powder blend	slightly soluble in water (1 g/762 ml); soluble in methanol	Antibiotic
Simple Syrup	qs	viscous, slightly yellow liquid	NA	Vehicle
Flavor	qs	most are colorless, but some have color	Concentrates are water miscible	flavor

Calculations:

Step 1. Determine the volume of flavor concentrate needed to adequately flavor Simple Syrup. Place 15 ml of Simple Syrup in the sample container provided. Add flavor concentrate to the Simple Syrup to achieve desired flavoring. Record the volume of flavor concentrate added. Calculate the percentage of flavoring agent:

$$\text{Percentage} = \frac{\text{volume of flavor concentrate added}}{\text{volume of Simple Syrup} + \text{volume of flavor concentrate added}}$$

Step 2. Formulate the suspension using the percentage of flavor determined in Step 1. Place 15 ml of the flavored suspension in the sample container provided. Add flavor concentrate to the flavored suspension to achieve desired flavoring. Record the volume of flavor concentrate added. Calculate the percentage of flavoring agent:

$$\text{Percentage} = \frac{\text{volume of flavor concentrate added}}{\text{volume of flavored suspension} + \text{volume of flavor concentrate added}}$$

Equipment Required:

- Rubber spatula
- Weighing paper
- 4 oz. amber prescription bottle
- 150 ml beaker
- 50 ml graduated cylinder

Method of Preparation:

- Empty contents of four 300 mg capsules onto a piece of weighing paper
- If necessary, gently crush powder with rubber spatula to produce a fine powder.
- Place powder in a 4 oz. amber plastic prescription bottle.
- Prepare 120 ml of flavored syrup in a calibrated 150 ml beaker.

- Rinse weighing paper and spatula with 20 ml of flavored syrup and add rinse to prescription bottle. Shake vigorously.
- Add 100 ml of flavored syrup to prescription bottle. Shake vigorously.

Description of Finished Product:

Red to reddish-brown suspension with medium viscosity. There may be some color alterations with the colored flavor concentrates.

Quality Control Procedures:

Observations of mold growth
Rapid resuspension (redispersion) on shaking
Product weight
Analysis of rifampin concentration

Packaging Container:

4 oz. amber plastic prescription bottle

Storage Requirements:

Stability studies indicate that the suspension is stable when stored at room temperature (25°C) or in a refrigerator (2 – 8°C) for 4 weeks.

Beyond-Use Date Assignment:

Cannot use the information from PDR – we have changed the formulation adding a flavoring agent....

Compounded prescriptions come under the jurisdiction of USP/NF Section <795>.

Aqueous solutions:

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Label Information:

Shake well

Source of Recipe:

Physician's Desk Reference 57th ed., copyright 2003, pp. 759-762

Literature Information:

The Merck Index, 12th ed., copyright 1996, p. 1414