

Formulation Record

Name of Formulation: Enalapril Suspension
Strength: 1 mg/ml
Dosage Form: Suspension
Route of Administration: Oral

Date of Last Review or Revision: 01/23/07
Person Completing Last Review or Revision: Robert Shrewsbury

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Enalapril Maleate Tablets USP, 5 mg	24 tablets	Round, white, scored tablets	0.025 g/ml in water, 0.08 g/ml in alcohol, 0.20 g/ml in methanol	ACE inhibitor
Simple Syrup NF	qs 120 ml	Viscous, slightly yellow liquid	Miscible with water	Vehicle
Flavor	qs	Most are colorless, but some have color	Concentrates are water miscible	Flavor

To Determine The Amount of Flavoring:

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:

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

Percentage of flavor added to simple syrup: _____ %

Step 2. Formulate the suspension using the percentage of flavor determined in Step 1. For example, if making 60 ml of suspension, and the flavor percentage found in Step 1 was 2%, then add 12 tablets, 1.2 ml of flavor, and then qs to 60 ml with Simple Syrup.

Step 3. Place 15 ml of the suspension in the sample container provided. Add additional flavor concentrate (if needed) to the **flavored suspension** to achieve the same taste as in Step 1. Record the volume of flavor concentrate added. Calculate the percentage of flavoring agent:

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

Percentage of flavor added to flavored suspension: _____ %

Equipment Required:

- mortar and pestle
- rubber spatula
- 100 ml graduated cylinder

Method of Preparation:

1. Precalibrate the final container.
2. Grind tablets to a fine powder in a mortar with a pestle.
3. Levigate powder with a small amount of base solution to form a paste. Add flavoring.
4. Add a portion of the base solution to the mortar and thoroughly mix. Transfer mixture into final container.
5. Continue to add portions of the base solution to the mortar to rinse mortar until final container is brought to volume. If needed, use a rubber spatula to loosen powder from the bottom and sides of mortar.
6. Shake well before dispensing.

Description of Finished Product:

Slightly yellow, viscous suspension; may be slight different color depending on flavoring agent used.

Quality Control Procedures:

Visual inspection
Total product weight

Packaging Container:

Package in a amber, plastic prescription bottle.

Storage Requirements:

Can be stored at room temperature or refrigerated.

Beyond-Use Date Assignment:

Source of Recipe provides references for stability measurements. Assign 90 days.

Label Information:

Shake well before use

Source of Recipe:

Extemporaneous Formulations, Rita K. Jew, Robert J. Mullen, Winson Soo-Hoo; American Society of Health-System Pharmacists, Bethesda, MD 2003, p. 23

Literature Information:

see Source of Recipe references