

Formulation Record

Name: Tri-estrogen Capsules

Strength: 1.25 mg/cap

Dosage Form: Capsule

Route of Administration: Oral

Date of Last Review or Revision: Today

Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Estriol	80%	white to cream powder	insoluble in water, soluble in alcohol and vegetable oils	endogenous estrogen
Estrone	10%	white to cream powder	insoluble in water, 4 mg/ml in alcohol	endogenous estrogen
Estradiol	10%	white to cream powder	insoluble in water, 35.7 mg/ml in alcohol	endogenous estrogen
Lactose, hydrous	qs	white powder	1 g/5 ml water, slightly soluble in alcohol	bulk diluent

Additional Information:

- A #2 capsule will hold between 300 – 360 mg of hydrous lactose.
- Colored capsules may be used for aesthetic appeal or to differentiate dosages.

Example Calculations:

- The low dose of tri-estrogen requires that a triturate be made. Make a triturate using hydrous lactose such that 150 mg contains 1.25 mg of tri-estrogen (i.e., 148.75 mg of hydrous lactose and 1.25 mg of tri-estrogen). An additional 200 mg of hydrous lactose will be used to bulk fill the #2 capsule to 350 mg.
- Calculate the formula for 2 extra capsules to account for losses during compounding.

Equipment Required:

- prescription balance

Method of Preparation:

1. Accurately weigh the stock triturate and the hydrous lactose used for bulk filling.
2. Triturate the powders using geometric dilution.
3. Hand punch the required number of capsules. Verify the weight variation.

Description of Finished Product:

White to off-white powder mixture.

Quality Control Procedures:

Record the following information for 4 randomly selected capsules. Use an empty #2 capsule on the right pan as a tare.

Number	Weight of Contents in Capsule
1	
2	
3	
4	

Average "Weight of Contents in Capsule"	
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Percent Difference in Average and Weight 1	
Percent Difference in Average and Weight 2	
Percent Difference in Average and Weight 3	
Percent Difference in Average and Weight 4	

- Each capsule should be within 5% of the average.

Packaging Container:

Package in plastic prescription vials

Storage Requirements:

Store at room temperature.

Beyond-Use Date Assignment:

USP Guidelines:

Nonaqueous liquids and solid formulations:

If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product's expiration date, or 6 months, whichever is earlier.

If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months.

Assign 6 months.

Label Information:

Possible drug-food interaction with grapefruit juice.

Source of Recipe:**Literature Information:**

Allen's Compounded Formulations: The U.S. Pharmacist Collection, 1995-1998, p. 76-77, © 1999.