



SUGGESTED FORMULA

Estradiol 0.9mg/gm and Estriol 0.02mg/gm in HRT Cream (0.02%)

Version number: 1.0

Volume or quantity: 100 gm

Estradiol, Micronized, USP (E1435)	0.090gm
Estriol, Micronized, USP (E1011)	0.002gm
Glycerin, USP (G1016)	0.5mL or as needed
HRT Cream (B4518)	q.s. 100gm

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Levigate the Estradiol and Estriol powder with the glycerin to form a paste
4. Geometrically incorporate the HRT Cream Base (or other suitable oil-in-water vehicle) into Step#3 and mix until uniform
5. An Electric Mortar and Pestle and/or ointment mill may be used to mix and reduce particle size
6. Transfer to appropriate container- click jar, syringe, tube or jar
7. Suggested Quality assessments:
 - a. color
 - b. texture
 - c. container
 - d. Label - auxiliary labels, storage, BUD, compounded medication

Labeling: For vaginal use
Keep out of the reach of children
Keep away from eyes and mucous membrane

Store in air-tight container at room temperature

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates from reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date.

It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date should be assigned based on the current USP <795> Standards

Precautions:

Precautions should be taken when compounding hormones. These may be absorbed through skin, mucous membranes and lungs. Wear appropriate personal protective equipment – and inform personnel of the risk. Mix and prepare in vented enclosure (hood). Pregnant women and personnel with hormone related cancers should not compound hormone preparations.

Hazardous drugs should be handled according to USP <800>, NIOSH standards and pharmacy SOPs. This preparation should be compounded in a biological safety cabinet or compounding aseptic containment isolator. Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate personal protective equipment.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.

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