

**SUGGESTED FORMULA**

Estradiol 2 mg Triturate Tablet

Version number: 1.0

Volume or quantity: 100 Tablets

Estradiol, Micronized, USP (E2918)	0.2 g
Polyethylene Glycol 3350, USP (PO125)	0.6 g
Lactose, Anhydrous, NF (LA103)	6.15 g
Alcohol (50%)	QS

SUGGESTED COMPOUNDING PROCEDURES

It is necessary to calibrate the mold and determine the quantity of lactose or other diluent required as a filler prior to beginning the preparation of this formula. This formula is calculated for a mold that produces 65 mg lactose triturate tablets. The alcohol (ethanol) should be a 50% concentration, diluted and prepared with purified water.

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredients.
3. Place Estradiol in mortar and mix in lactose and polyethylene glycol 3350.
4. Add the 50% ethanol in small portions and mix until a dough consistency is obtained.
5. Place the mixture on tablet triturate mold on a clean flat surface and use a steel spatula to firmly fill each cavity. Clean and smooth the surfaces on both sides of the mold making sure cavities are filled.
6. Match the pins on the top portion of the mold and press mold gently to leave the tablets on the pegs.
7. Allow to air dry.
8. Package and label.
9. Suggested Quality assessments:
 - a. color, texture, appearance
 - b. mixing and filling/potency studies
 - c. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, at Controlled 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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