

**SUGGESTED FORMULA**

Estradiol 2mg Sublingual Troche

Version number: 1.0

Volume or quantity: 100 Troches

---

Estradiol, USP	0.2 gm
Citric Acid (Anhydrous), USP (CI131)	0.43 gm
Aspartame, NF (A1378)	0.36 gm
Bentonite, NF (BE125)	0.150gm
Acacia, NF (GU115)	0.28 gm
Polyethylene Glycol 1540 MW, NF	q.s.
Flavor	q.s.

---

**SUGGESTED COMPOUNDING PROCEDURES:**

The quantity of PEG 1540 may need to be altered depending upon the size of the molds used. Calibrate Troche Mold and adjust formula as needed. This formula is based on approximately 1 g per troche. It is desirable to calculate for approximately 10% overage of the ingredients to adjust for excess materials required.

**SUGGESTED MIXING INSTRUCTIONS:**

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Mix the estradiol, citric acid, aspartame, bentonite and acacia powders together
4. Heat the PEG 1540 until melted in a beaker to about 55°C
5. Remove from heat, add the fine powder mixture to the heated PEG 1450
6. Add flavoring and mix well
7. Pour into molds and allow to cool
8. Package and Label; Refrigerate
9. Suggested Quality assessments:
  - a. color, texture, appearance
  - b. troche cavity filled / not overfilled
  - c. mixing and filling/potency studies

- d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight light resistance 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 standards of USP General Chapter <795>**

**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.  
5/19 JD

