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SUGGESTED FORMULA

Progesterone 100mg, Estradiol 0.75mg, Estriol 0.75mg Slow Release Capsules Size #1

Version number: 1.0

Volume or quantity: 100 capsules

Progesterone, USP Micronized (P1834)	10 g
Estradiol, Hemihydrate, Yam Based Micronized USP (E2914)*	0.075 g
Estriol, Micronized, USP (E1011)	0.075 g
Hypromellose, Sub Type 2910, 4000 mPa.S, USP (H1128)	14.85 g

SUGGESTED COMPOUNDING PROCEDURES

Weigh all ingredients

- 1. Triturate to reduce to fine powders as needed
- 2. Mix powders per pharmacy SOPs − (e.g. geometric dilution, blade, v-blend, RAM™)
- 3. Fill capsules in vented enclosure (hood)
- 4. Cap and "snap" each bottom into its lid.
- 5. Weigh sample capsules to check variability and standard deviation per pharmacy SOPs
- 6. Bottle and label with prescription label and appropriate auxiliary labels.
- 7. Suggested Quality assessments
 - a. % variability & % deviation from theoretical <10% (remake if >10%)
 - b. Capsule size
 - c. Capsule color
 - d. Quantity
 - e. 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, 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.

^{*}Must account for water determination per certificate of analysis.

Beyond-Use Date estimated to be 180 days

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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