



SUGGESTED FORMULA

Progesterone (in Sesame Oil) 100mg Capsule

Version number: 1.0

Volume or quantity: 100 capsules

Progesterone, USP Micronized	11 g
Colloidal Silicon Dioxide, NF	1.1 g
Sesame Oil, NF	46 mL

Progesterone should be in a micronized form. Size 1 oil-filled capsules should be prepared from gelatin derived from pork or beef sources. Formula allows for some loss during preparation. It may be necessary to calibrate formula with the quantity of oil or diluent required prior to beginning the preparation.

SUGGESTED COMPOUNDING PROCEDURES

- 1. Calculate the required quantity of each ingredient for this preparation.
- 2. Accurately weigh and/or measure each ingredient.
- 3. Load a capsule machine with 100 Size 1 empty gelatin capsules, remove the caps and lock capsule bases so that they are elevated higher than the surface of the top machine plate.
- 4. Mix the micronized progesterone and colloidal silicon dioxide together in a mortar. Use caution to prevent inhalation of ingredients.
- 5. Add the Sesame Oil in portions to form a smooth, uniform suspension.
- 6. Transfer to a clean beaker with a magnetic stir bar and spin on stir plate.
- 7. Withdraw suspension in portions using a syringe or micropipette.
- 8. Fill all capsule bases with suspension to brim of capsule base.
- 9. Replace capsule caps and lock in place.
- 10. Remove capsules onto clean, low lint towel and clean if necessary.
- 11. Bottle and label with prescription label and appropriate auxiliary labels.
- 12. 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.

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 primary engineering control (PEC) that meets USP Chapter <800> standards. 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.

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