



SUGGESTED FORMULA

Progesterone 50 mg Rapid Dissolving Tablet

Version number: 1.0

Volume or quantity: 100 Tablets

Progesterone, Micronized, USP	5 g
Mannitol, USP	21 g
Lactose, Anhydrous, NF	21 g
Flavor	qs*
Polyethylene Glycol 3350, NF	21 g

SUGGESTED COMPOUNDING PROCEDURES

* The flavor should be dry powder type and not aqueous or oleaginous. It is necessary to determine the quantity of lactose or other diluent required as a filler prior to beginning the preparation of this formula based on calibration of the mold.

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredients.
3. Blend progesterone, mannitol, lactose and dry flavor together until fine and uniformly mixed.
4. Separately, reduce the particle size of the polyethylene glycol 3350 to approximately 200 mesh.
5. Lightly blend in the polyethylene glycol 3350 into step 3.
6. Place 100 mg of the powder into the cavities of the mold.
7. Place the mold containing the powder in an oven at 80-90°C for approximately 15-20 minutes. Time may vary depending upon the mold, formulation and oven.
8. Remove from the oven and place in a refrigerator for approximately 5 minutes.
9. Remove from the refrigerator and let set at room temperature.
10. Package and label.
11. Suggested Quality assessments:
 - a. color, texture, appearance
 - c. mixing and filling/potency studies
 - d. 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 6 months

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.

05/16 rd