



SUGGESTED FORMULA

Progesterone 25mg Witepsol Capsules Size #0

Version number: 1.0

Quantity : 100 Capsules

Progesterone, Micronized Powder, USP (P1834)	2.5gm
Colloidal Silicon Dioxide, NF (S1510)	2gm
Witepsol, H-15, Base (W1129)	63.5gm
Capsule Size #0 (clear C1387)	#100

***It is necessary to calibrate molds/capsules prior to compound**

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Add Witepsol to a beaker and start to melt around 33°C to 35°C
4. Once base starts to melt add a spin bar and start to spin
5. While spinning, slowly add the silica gel and allow to dissolve
6. Slowly add the progesterone to Step 5 and mix until homogenous
7. Allow to cool slightly, beaker should be warm to the touch
8. Set capsules in filling machine and keep capsule tops separately in the machine plate.
9. Pour into empty capsules and allow to solidify at room temperature.
10. Set plate with capsule tops on bottoms, connect and snap capsules in place, per SOPs.
11. Suggested quality assessments:
 - a. % variability & % deviation from theoretical <10% - (remake if >10%)
 - b. Capsule size
 - c. Capsule color
 - d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, Refrigerate

Note: 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.

Note: Beyond-Use Dates of preparations are conservative estimates by the formulator using 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 is estimated to be 180 days.

Precautions:

Precautions should be taken when compounding with hormones and other steroids, as they can be absorbed through the skin, mucous membranes and lungs. Wear appropriate personal protective equipment. Use vented safety closures when weighing and mixing compounds to prevent exposure to the compounder. Pregnant women and personnel with hormone related cancers should not compound hormone formulas.

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.

7/18 JD