

## Formulation Record

Name: Progesterone Suppositories  
Strength: 200 mg/suppository  
Dosage Form: Suppository  
Route of Administration: Vaginal

Date of Last Review or Revision: 08/31/06

Person Completing Last Review or Revision: Robert Shrewsbury

### Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Progesterone	200 mg/supp	White, crystalline powder	Insoluble in water; soluble in alcohol	hormone replacement
Silica gel	35.0 mg/supp	White, amorphous powder, very low density (aerosolizes easily)	Insoluble in water; soluble in hot alkaline hydroxides	suspending agent
Witepsol H-15 base	s.a.	off-white beadlets with waxy feel and odor	water miscible semisolid	suppository base

### Example Calculations:

Weight of suppository with only Witepsol Base = 1.83 gm

Weight of progesterone in each suppository = 0.20 gm

Density Factor of progesterone in Witepsol Base = 0.85

For making 10 suppositories (calculations based on 12 for anticipated loss of material):

Weight of progesterone needed =  $0.20 \text{ g} \times 12 = 2.40 \text{ g}$

Weight of Witepsol needed if plain suppository =  $1.83 \text{ g} \times 12 = 21.96 \text{ g}$

Weight of Witepsol displaced: (weight of progesterone)/(density factor) =  $2.40 \text{ g}/0.85 = 2.82 \text{ g}$

Weight of Witepsol base to weigh =  $21.96 \text{ g} - 2.82 \text{ g} = 19.14 \text{ g}$

Weight of silica gel to weigh =  $35.00 \text{ mg} \times 12 = 420.00 \text{ mg}$  (Note: volume of silica gel is ignored)

The shaded lines will need to be calculated based on the suppository weight in the individual molds. You will find that information on the mold you use in lab.

### Equipment Required:

- Class A prescription balance
- mortar and pestle
- plastic suppository shells
- 40 mesh sieve
- hard rubber spatula
- 100 ml beaker
- low temperature hot plate with small stir bar
- stirring rod

### Method of Preparation:

1. Using the prescription balance, weigh Witepsol, progesterone, and silica gel.
2. Sieve the silica gel and progesterone through a 40 mesh sieve (**USE ONLY HARD RUBBER SPATULA**) into a mortar and triturate with a pestle.
3. Transfer the Witepsol to a 100 ml beaker.
4. Heat (not to exceed 60°C) and melt the Witepsol.
5. Turn the heat to the lowest temperature setting possible and begin a rapid stirring with the stir bar.
6. Add the sieved powder blend. **Do not add all at once**; add in portions to avoid clumping. Add the powder along the edge of the beaker, not in the middle. It may be helpful to transfer all of the mortar's contents to a large weigh boat before beginning this process.

7. Turn off the heat. Allow the dispersion to cool approximately to the congealing temperature (about 40°C), stir with a glass stirring rod one final time, and then pour into the suppository mold.
8. Fill each suppository shell to the capacity mark using a backfill light.
9. Once the suppositories have congealed in the mold, heat seal the shells.
10. Break the shell strip into individual shells and dispense in an appropriate container.

**Description of Finished Product:**

Creamy white to white semisolid with no visible particles

**Quality Control Procedures:**

- Observations of excessive softening or hardening
- Observations of drug "clumps"

**Packaging Container:**

12-hole suppository box

**Storage Requirements:**

Witepsol suppository should not melt at reasonable room temperatures. Patient should be consulted as to where they might store their medication in their home. If the storage area has an elevated temperature, then refrigeration might be required.

**Beyond-Use Date Assignment:**

USP Guidelines:

For all other formulations that are not solids or liquids: The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

Assign a beyond-use date of either intended duration of therapy or 30 days, whichever is earlier.

**Label Information:**

Pharmacist's Note: Consideration should be given to adding a preservative if long-term therapy. The "unknown" is the susceptibility of Witepsol Base to microbial growth.

**Source of Recipe:**

Pharmaceutics Laboratory Web page: <http://pharmlabs.unc.edu>

**Literature Information:**

Applied Pharmaceutics and Contemporary Compounding, Chapter 10.