

Formulation Record

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

Date of Last Review or Revision: _____ Today
Person Completing Last Review or Revision: RPS _____

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	insoluble in water; soluble in hot alkaline hydroxides	suspending agent
PEG Base	s.a.	Water miscible semisolid		suppository base

Example Calculations:

Weight of suppository with only PEG Base = 2.1 gm

Weight of progesterone in each suppository = 0.2 gm

Density Factor of progesterone in PEG Base = 0.92

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

Weight of progesterone needed = $0.2 \text{ g} \times 12 = 2.4 \text{ g}$

Weight of PEG needed if plain suppository = $2.1 \text{ g} \times 12 = 25.2 \text{ g}$

Weight of PEG displaced: $(\text{weight of progesterone})/(\text{density factor}) = 2.4 \text{ g}/0.92 = 2.6 \text{ g}$

Weight of PEG base to weigh = $25.2 \text{ g} - 2.6 \text{ g} = 22.6 \text{ g}$

Weight of Silica Gel to weigh = $35 \text{ mg} \times 12 = 420 \text{ mg}$ (Note: displacement by silica gel is ignored)

PEG base is 40% PEG 300 and 60% PEG 3350. Density of PEG 300 = 1.13.

Weight of PEG base to weigh = 22.6 g

Weight of PEG 300: $22.6 \text{ g} \times 0.4 = 9.0 \text{ g}$ or 8.0 ml

Weight of PEG 3350: $22.6 \text{ g} \times 0.6 = 13.6 \text{ g}$

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
- Metal suppository mold
- 40 mesh sieve
- hard rubber spatula
- 100 ml beaker
- low temperature hot plate with stir bars

Method of Preparation:

1. Using the prescription balance, weigh PEG 3350.
2. Transfer the PEG 3350 to a 100 ml beaker.
3. Heat (not to exceed 60°C) and melt the PEG 3350.
4. Add the PEG 300 and reduce the temperature.
5. Using the prescription balance, weigh progesterone and silica gel.
6. Sieve progesterone through a 40 mesh sieve onto a glassine paper using a hard rubber spatula, and transfer into the melted base while constantly stirring. Do not add all at once; add in portions to avoid clumping.
7. Sieve silica gel through a 40 mesh sieve onto a glassine paper using a hard rubber spatula, and transfer into the melted base while constantly stirring. Do not add all at once, add in portions to avoid clumping.
8. When ingredients are dispersed in the base, remove from heat. Allow to cool approximately to the congealing temperature (about 40°C) and then pour into suppository molds.
9. Overfill each suppository cavity.
10. Once the suppositories have congealed in the mold, remove them from the mold and wrap in individual papers.
11. 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

Packaging Container:

If suppository are individually wrapped, put in a suppository box (either 6 hole or 12 hole as needed).

Storage Requirements:

PEG 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:

Solid formulation:

If the course of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months. Progesterone is USP, PEG Base is NF. However, this requirement does not apply since this is a semisolid preparation.

For all other formulations:

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:

Consideration should be given to adding a preservative if long-term therapy. The "unknown" is the susceptibility of PEG Base to microbial growth.

Source of Recipe:

Pharmaceutics Laboratory Web page: www.unc.edu/courses/phar051/

Literature Information:

Applied Pharmaceutics and Contemporary Compounding, Chapter 10.

Compounding Record

[This information is completed at the time of compounding]

Name: _____

Strength: _____

Dosage Form: _____

Route of Administration: _____

Quantity Prepared: _____

Date of Preparation: _____

Person Preparing Formulation: _____

Person Checking Formulation: _____

Formula:

Ingredient	Manufacturer and Lot Number	Purity Grade	Description	Quantity Required	Actual Quantity Used

Calculations:

[Calculations performed at the time of compounding]

Mold Number _____

Calibrate weight of PEG Base in mold _____

Equipment Required and its Operation:

[Equipment performance notes or alternate equipment used]

Method of Preparation:

[Description of any deviation from the Formulation Record method of preparation]

Description of Finished Product:

Quality Control Procedures:

[Details of quality assurance test results and data]

Packaging Container:

Storage Requirements:

Beyond-Use Date Assignment:

[What beyond-use date was assigned, and reasons for difference from Formulation Record if applicable]