

SUGGESTED PROCEDURE

Item	Progesterone 2% (20mg/ml) Sublingual Drops	Formula Date	21 Oct 2024
API(s)	Progesterone, USP (Micronized)	Procedure No.	P2653
Base	OraPenn™ SD Anhydrous Sweetened	Revision	R1
Volume/Quantity	30ml	Compound Type	Anhydrous Sublingual Drops

Rx	Weight (g)	Percent	Comment
Progesterone, USP (Micronized)	0.6g	2%	
Flavor, Lemon Drop OS Natural Liquid Flavor Concentrate	0.15ml	0.5%	To taste
OraPenn™ SD	29.25ml	97.5%	qs
Total	30g	100%	

To account for processing error considerations during preparation, it is suggested to measure an additional **10%** of the required quantities of ingredients.

Suggested Method of Preparation

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient. Take into account batch size and density conversions, if required.
3. Using a mortar and pestle, triturate Progesterone into a fine powder.
4. Use a small amount of OraPenn™ to wet powder and levigate to form a smooth viscous paste.
5. Add lemon drop flavor
6. Bring solution to final volume with OraPenn™ SD and mix thoroughly.
7. Final appearance should be a tan-colored liquid with a lemon smell and no visible powder present.
8. Transfer the final preparation into an appropriate dispensing container.
9. Suggested Quality assessments
 - a. Appearance: solution is homogeneous with no particulate.
 - b. Packaging: correct container with dropper or syringe.
 - c. Label: auxiliary labels, storage, BUD, compounded medication, shake well.

Packaging: Tight, light-resistant container, dropper or syringe, store at room temperature

Estimated Beyond Use Date: 90 days per USP 795*

Labeling: Keep out of reach of children. Shake well. Use only as directed. Protect from moisture and light.

Stability: Anhydrous formulation.

Note: Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).

Note: All products, except for API(s) are sourced from SpecializedRx only. Any deviation from ingredients used will invalidate the formula.

*Beyond-Use Date should be based on the current USP General Chapter <795>. Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounding and contamination of the preparation by the compounding. 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 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.

WARNING! Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.

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