

SUGGESTED PROCEDURE

Item	Progesterone 40% cream	Formula Date	19 June 2025
API(s)	Progesterone	Procedure No.	P2735
Base	PentraCream™ Anhydrous	Revision	R1
Volume/Quantity	30g	Compound Type	Anhydrous Topical

Rx	Weight (g)	Percent	Comment
Progesterone, USP (Micronized)	12 g	40%	
Ethoxy Diglycol, NF	4.5 g	15%	
PentraCream™ Anhydrous	13.5 g	45%	qs
Total	30 g	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. Consider batch size and density conversions if required.
3. Levigate the Progesterone powder with Ethoxy Diglycol to form a homogeneous paste dispersion.
4. Geometrically incorporate the PentraCream™ Anhydrous base and mix well. If mixing in an Unguator®, disposable blades are recommended to avoid excess heat and/or friction.
5. Final product should be a smooth, uniform white cream.
6. Transfer the final preparation into an appropriate dispensing container.
7. Suggested Quality assessments
 - a. Appearance and feel
 - b. Quantity
 - c. Label - auxiliary labels, storage, BUD, compounded medication, for external use only

Packaging: Tight, light-resistant container, syringe, UnoDose™, Topi-Click™ container.

Estimated Beyond Use Date: 180 days per USP 795*

Labeling: Keep out of reach of children. 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).

*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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