

SUGGESTED PROCEDURE

Item	Progesterone 300mg Capsule	Formula Date	25 April 2024
API(s)	Progesterone, USP (Micronized)	Procedure No.	P2572
Base	CapsOral®	Revision	R1
Volume/Quantity	100 Capsules	Compound Type	Slow-release capsules #00

Rx	Weight (g)	Percent	Comment
Progesterone, USP (Micronized)	30g	56.6%	
CapsOral®	7.1g	13.4%	CapsOral® packing stats #00 0.626g
Hypromellose, USP (E4M Premium)	15.9g	30%	Hypromellose (E4M) packing stats #00 0.585
Total	53g	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 the principles of Geometric Dilution, mix Progesterone, Hypromellose E4M and CapsOral® together with trituration in a mortar and pestle. Alternately, mix powders together in a planetary-style mixer.
4. Encapsulate in size# 00 capsules.
5. Final preparation should be an encapsulated free-flowing powder.
6. Transfer the final preparation into an appropriate dispensing container.
7. Suggested Quality assessments
 - a. Appearance and fit
 - b. Quantity
 - c. Label - auxiliary labels, storage, BUD, compounded medication

Packaging: Tight, light-resistant 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 compounder and contamination of the preparation by the compounder. 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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