

SUGGESTED PROCEDURE

Item	Progesterone 50mg Suppository	Formula Date	14 Oct 2024
API(s)	Progesterone, USP	Procedure No.	P2678
Base	Supposi-Plex™ V65	Revision	R1
Volume/Quantity	100 (2.0ml RocketMolds™)	Compound Type	Anhydrous Suppository

Rx	Weight (g)	Percent	Comment
Progesterone, USP (Micronized)	5g	2.6%	
Supposi-Plex™ V65	187g	97.4%	qs (specific gravity of Supposi-Plex™ V65 at 40°C is 0.96)
Total	192g	100%	Using $P = (N \times S) - DF$ where P is the amount of suppository base required, N is the number of prepared suppositories, S is the size of the mold used, D is the amount of drug used and F is the displacement value of the drug.

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. Add Supposi-Plex V65™ base to beaker and gently melt on a hot plate (33°-35°C)
4. Incorporate Progesterone powder and mix well.
5. Allow mixture to cool slightly before pouring.
6. Pour the mixture into RocketMolds™ up to fill line and allow to cool at room temperature.
7. Final preparation should be a smooth white to off-white suppository.
8. Suggested Quality assessments
 - a. % variability and % deviation from theoretical <10% - (remake if >10%)
 - b. Surface appearance and feel
 - c. Melting test
 - d. Quantity
 - e. Label - auxiliary labels, storage, BUD, compounded medication.

Packaging: RocketMolds™, refrigerated

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. Not to be taken by mouth

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. Compounding 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.

SpecializedRx
3787 95th Ave NE, Ste 100
Circle Pines, MN. 55014 USA
888.512.1209
www.specializedrx.com

Disclaimer: SpecializedRx makes no warranties or claims to the safety, accuracy, or efficacy of the above information, expressed or implied given the variations in use, materials, and formulations. SpecializedRx accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold SpecializedRx and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein. This is a copyrighted© formula that may not otherwise be distributed, copied or disclosed without SRx's written permission. This formula is subject to SRx intellectual property rights.