



Suggested Formula	Progesterone 100 mg Oral Troches (Solid Suspension, 100 x 0.9 mL Troches)	FIN	F 005 854v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Progesterone (Micronized), USP	10.000	g				
Stevia Powder	1.50	g				
Silica Gel (Micronized)	0.50	g				
Chocolate Flavor	2.0	mL				
Marshmallow Flavor	1.0	mL				
Crème de Menthe Flavor	2.0	mL				
Medisca Troche Base	85.20	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): Progesterone

Hygroscopic (protect from moisture whenever possible): Silica Gel, Stevia Powder

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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SUGGESTED PREPARATION (for 100 x 0.9 mL Troches)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : ___	Processing Error	Qty. to measure
Progesterone (Micronized), USP §	10.000	g			
Stevia Powder §	1.50	g			
Silica Gel (Micronized) §	0.50	g			
Chocolate Flavor	2.0	mL			
Marshmallow Flavor	1.0	mL			
Crème de Menthe Flavor	2.0	mL			
Medisca Troche Base	85.20	g			

* Takes into account mold size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction

1. Preparatory step:

A. Prepare a hot water bath.

Specifications: Temperature: 60 to 65°C.



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2.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Using the hot water bath, melt the Troche Base.</p> <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>B. Using the hot water bath, in the given order, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 2A):</p> <ul style="list-style-type: none">-Stevia Powder-Progesterone (Micronized)-Chocolate Flavor-Marshmallow Flavor-Crème de Menthe Flavor-Silica Gel (Micronized) <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p> <p><u>Important:</u> Do not allow the temperature to exceed 65°C.</p>
3.	<p><u>Mold filling:</u></p> <p>A. Fill the 100 mold cavities with the homogeneous liquid-like dispersion (Step 2B). If the mixture starts to solidify while filling, reheat to 60 to 65°C, and continue.</p> <p>B. Allow to cool until the API mixture has completely solidified.</p> <p><u>Note:</u> Continuously mix the final product during the mold filling in order to maintain homogeneity.</p>
4.	<p><u>Validation technique:</u></p> <p>A. Weigh 20 troches separately.</p> <p>B. The final weight of each troche from Step 4A (not including the weight of the troche mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 1.02 g in accordance to USP guidelines.</p>
5.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or a wide-mouth jar.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep in a dry place.
	2	Keep out of reach of children.	7	Protect from light.
	3	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	Cap tightly after use.
	4	Keep at room temperature (20°C – 23°C).	9	May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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REFERENCES

1.	Lozenges/Troches. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 2008: 153.
2.	Progesterone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2125.
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4.	Progesterone (Monograph). <i>United States Pharmacopeia XXXVII / National Formulary 32</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2014: 4428.
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