



Suggested Formula	Progesterone 75 mg Oral Tablets (Solid Suspension, 100 Tablets)	FIN	F 003 766v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Progesterone (Micronized), USP	7.500	g				
Lactose (Monohydrate), NF	TBD					
Methylcellulose (1500 CPS), USP	TBD					
Gelatin, NF	TBD					
Stevia Powder	TBD					
Tutti Frutti Flavor	TBD					
Water-Alcohol 1:3 mixture †	As required					
† Water-Alcohol 1:3 mixture						
Purified Water, USP	10.0	mL				
Alcohol (95%), USP	30.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):

Methylcellulose (1500 CPS), Stevia Powder

Light sensitive (protect from light whenever possible):

Progesterone

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 Tablets)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) : ___	Processing Error	Qty. to measure
Progesterone (Micronized), USP §	7.500	g			
Lactose (Monohydrate), NF	TBD				
Methylcellulose (1500 CPS), USP §	TBD				
Gelatin, NF	TBD				
Stevia Powder §	TBD				
Tutti Frutti Flavor	TBD				
Water-Alcohol 1:3 mixture †	As required				
† Water-Alcohol 1:3 mixture					
Purified Water, USP	10.0	mL	---	---	
Alcohol (95%), USP	30.0	mL	---	---	

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

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><u>Mold calibration:</u></p> <p>Determine the required quantity of each individual excipient for 100 tablets based on the actual size of the tablet mold being used. Refer to the Appendix for details.</p>
2.	<p>† <u>Water – Alcohol 1:3 mixture preparation:</u></p> <p>A. Combine and mix the following ingredients together until homogeneously dispersed:</p> <ul style="list-style-type: none"> -Purified Water – 10.0 mL -Alcohol (95%) – 30.0 mL <p><u>End result:</u> Homogeneous liquid-like solution.</p>



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3.	<p><u>Powder preparation:</u></p> <p>A. Combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none">- Lactose (Monohydrate) (amount calculated in Appendix Step 8)- Methylcellulose (1500 CPS) (amount calculated in Appendix Step 8)- Gelatin (amount calculated in Appendix Step 8)- Stevia Powder (amount calculated in Appendix Step 8)- Tutti Frutti Flavor (amount calculated in Appendix Step 8) <p>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none">- Progesterone (Micronized)- Homogeneous powder blend (Step 3A)
4.	<p><u>Phase integration:</u></p> <p>A. Incrementally add the Water-Alcohol 1:3 mixture (Step 2A) to the homogeneous powder blend (Step 3B) and mix until homogeneously dispersed.</p> <p><u>Specification:</u> Continuously mix.</p> <p><u>End results:</u> Homogeneous paste-like dispersion.</p> <p>IMPORTANT: Add the Water-Alcohol mixture, a few drops at a time and mix well until the mixture attains a paste-like consistency. Do not add too much.</p>
5.	<p><u>Mold filling:</u></p> <p>A. Fill each of the 100 tablet mold with the API-excipient mixture (Step 4A), and press into the molds until firmly packed and uniform.</p> <p>B. Allow the tablets to air dry then gently remove them from the mold.</p>
6.	<p><u>Validation technique:</u></p> <p>A. Weigh 20 tablets separately.</p> <p>B. The final weight of each tablet from Step 6A (not including the weight of the tablet mold) should be between 90 and 110% of the theoretically calculated weight (Appendix, Step 6B), in accordance to USP guidelines.</p>
7.	<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	Tight, light-resistant vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Protect from light.
	2	Keep out of reach of children.	7	Keep in a dry place.
	3	Keep at room temperature (20°C – 23°C).	8	Cap tightly after use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.		
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.			



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REFERENCES

1.	Tablets. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 145.
2.	Crinone. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2008</i> . 607.
3.	Lactose, monohydrate. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 5th Edition</i> . American Pharmaceutical Association; 2006: 389.
4.	Gelatin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 5th Edition</i> . American Pharmaceutical Association; 2006: 295.
5.	Methylcellulose. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 5th Edition</i> . American Pharmaceutical Association; 2006: 462.
6.	Progesterone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2125.
7.	Progesterone (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #7773.
8.	Progesterone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 4th Edition</i> . American Pharmaceutical Association; 2009: 473.
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Appendix	Tablet mold calibration		
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SUGGESTED CALCULATION

Preparatory Instruction

1. **API weighing:**

A. Weigh and / or measure the following ingredients:

Ingredient	Quantity
Progesterone (Micronized), USP	0.750 g
Lactose (Monohydrate), NF	1.67 g
Methylcellulose (1500 CPS), USP	0.045 g
Gelatin, NF	0.49 g
Stevia Powder	0.002 g
Tutti Frutti Flavor	0.02 g
Water-Alcohol 1:3 mixture †	As required
† Water-Alcohol 1:3 mixture	
Purified Water, USP	1.0 mL
Alcohol (95%), USP	3.0 mL

Notes: - Weigh the exact amount, do not consider processing error for calibration step.
- Data within this calibration table are based on a 0.2 mL mold size.

2. **† Water – Alcohol 1:3 mixture preparation:**

A. Combine and mix the following ingredients together until homogeneously dispersed:

- Purified Water – 1.0 mL
- Alcohol (95%) – 3.0 mL

End result: Homogeneous liquid-like solution.



Appendix	Tablet mold calibration		
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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and mix the following ingredients together to form a homogeneous powder blend:</p> <ul style="list-style-type: none">- Lactose (Monohydrate)- Methylcellulose (1500 CPS)- Gelatin- Stevia Powder- Tutti Frutti Flavor <p>B. By geometric addition, combine and mix the following ingredients together to form a homogeneous Powder blend:</p> <ul style="list-style-type: none">- Progesterone (Micronized)- Homogeneous powder blend (Step 3A)										
4.	<p><u>Phase integration:</u></p> <p>A. Incrementally add the Water-Alcohol 1:3 mixture (Step 2A) to the homogeneous powder blend (Step 3B) and mix until homogeneously dispersed.</p> <p><u>Specification:</u> Continuously mix.</p> <p><u>End results:</u> Homogeneous paste-like dispersion.</p> <p>IMPORTANT: Add the Water-Alcohol mixture, a few drops at a time and mix well until the mixture attains a paste-like consistency. Do not add too much.</p>										
5.	<p><u>Mold filling:</u></p> <p>A. Fill 5 tablet molds with the mixture (Step 4A), and press into the molds until firmly packed and uniform.</p> <p>B. Allow the tablets to air dry and remove them from the mold.</p>										
6.	<p><u>Calculate the average tablet weight:</u></p> <p>A. Weigh the five tablets and record the total weight here (not including the weight of the empty tablet mold): _____ g</p> <p>B. Calculate the average tablet weight:</p> <table border="1" style="margin-left: 40px;"><tr><td>Combined weight of the tablets (from Step 6a):</td><td>_____ g</td></tr><tr><td>DIVIDED BY</td><td></td></tr><tr><td>Number of Tablets</td><td>5</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td>Average (theoretical) tablet weight</td><td>_____ g</td></tr></table>	Combined weight of the tablets (from Step 6a):	_____ g	DIVIDED BY		Number of Tablets	5	EQUALS		Average (theoretical) tablet weight	_____ g
Combined weight of the tablets (from Step 6a):	_____ g										
DIVIDED BY											
Number of Tablets	5										
EQUALS											
Average (theoretical) tablet weight	_____ g										



Appendix	Tablet mold calibration		
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7. Ingredient calculation:

A. Calculate the quantity of excipient blend required for 100 tablets:

Average tablet weight (from Step 6B)	_____ g	
MINUS		
Quantity (in g) of Progesterone (Micronized) per tablet	0.075 g	
EQUALS		
i. Quantity of excipient blend required per tablet	_____ g	
MULTIPLY BY		
Number of tablets required	100	
EQUALS		
ii. Total quantity of excipient blend required for 100 tablets	_____ g	

8. Calculate the required quantities of each individual excipient for 100 Tablets:

Ingredient	Proportion		Quantity of Excipient blend required (Step 7Aii)		Quantity of each individual Excipient required		Processing error	Quantity of each individual Excipient required <i>plus</i> processing error
Lactose	0.75203	Multiply	_____ g	Equals	_____	Multiply	1.05 - 1.09	_____ g
Methylcellulose	0.02033				_____			_____ g
Gelatin	0.22019				_____			_____ g
Stevia Powder	0.00068				_____			_____ g
Tutti Frutti	0.00678				_____			_____ g

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