MEDISCA® NETWORK INC.
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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Progesterone 100 mg Oral Rapid Dissolve Tablets (Solid Suspension, 100 tablets)	FIN	F 004 167v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Progesterone (micronized), USP	10.000	g				
Raspberry Flavor (powder)	2.00	g				
Silica Gel (micronized)	2.50	g				
Polyethylene Glycol 3350, NF (PEG 3350)	6.00	g				
Stevia Powder	0.30	g				
Acesulfame Potassium, NF	0.40	g				
Effervescent Tablet Blend †	TBD					
† **Effervescent Tablet Blend (100 g)**						
Citric Acid (anhydrous), USP	2.00	g				
Sodium Bicarbonate, USP	2.40	g				
Mannitol, NF	9.00	g				
Polyethylene Glycol 3350, NF (PEG 3350)	12.54	g				
Sucrose or Dextrose (anhydrous)	74.06	g				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light Sensitive *(protect from light whenever possible):* *Progesterone, Acesulfame Potassium*

Moisture Sensitive*:* *Citric Acid, Sodium Bicarbonate*

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 §	10.000	g			
Raspberry Flavor (powder)	2.00	g			
Silica Gel (micronized) §	2.50	g			
Polyethylene Glycol 3350, NF (PEG 3350)	6.00	g			
Stevia Powder §	0.30	g			
Acesulfame Potassium, NF §	0.40	g			
Effervescent Tablet Blend † §	TBD				
† **Effervescent Tablet Blend (100 g)**					
Citric Acid (anhydrous), USP §	2.00	g	--	--	
Sodium Bicarbonate, USP §	2.40	g	--	--	
Mannitol, NF	9.00	g	--	--	
Polyethylene Glycol 3350 (PEG 3350)	12.54	g	--	--	
Sucrose or Dextrose (anhydrous)	74.06	g	--	--	

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	**† <u>Effervescent Tablet Blend preparation</u> <u>(100 g)</u>:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Citric Acid (anhydrous) -Sodium Bicarbonate -Mannitol -Sucrose or Dextrose (anhydrous) B. Combine and mix the following ingredients together to form a fine, homogeneous powder blend: -Fine, homogeneous powder blend (Step 1A) -Polyethylene Glycol 3350 C. Pass the mixture (Step 1B) through a 40 or 50 mesh sieve. D. Pack the powder mixture into an amber glass bottle and protect from humidity and heat.

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2. **Blank Mold filling:**

A. Pack 5 tablet molds with the Effervescent Tablet Blend, until firmly packed and uniform. The powder should be pressed into the mold at least 3 times to ensure it is completely filled.

B. Using a dry heat oven, bake only the filled RDT bottom plate between 100 and 110°C for 30 minutes.

C. Remove the mold from the oven and allow the tablets to cool in the mold for 15 minutes. If the tablets remain in the mold longer than 15 minutes, it may be difficult to remove them.

D. Invert the mold and tap it using a spatula handle to remove the tablets. Allow the tablets to dry for an additional 15 to 30 minutes.

3. **Calculate the quantity of Effervescent Tablet Blend required for 100 tablets:**

i. Weigh the 5 tablets and divide by 5 in order the determine the average tablet weight _____ g **(A)**

ii. Quantity of Effervescent Tablet Blend required per tablet = (A) – 0.212g* _____ g **(B)**
*****Quantity of Progesterone, Raspberry, Silica Gel, PEG 3350, Stevia and Acesulfame K per tablet

iii. Total quantity of Effervescent Tablet Blend required for the batch = (B) x 100 tablets _____ g **(C)**

iv. Quantity of Excipient Blend to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g **(D)**

4. **Powder preparation:**

A. Combine and mix the following ingredients together to form a fine, homogeneous powder blend:

-Progesterone (micronized)
-Raspberry Flavor (powder)
-Silica Gel (micronized),
-Polyethylene Glycol 3350 (3350)
-Stevia Powder
-Acesulfame Potassium
-Effervescent Tablet Blend (amount determined above **(D)**)

5. **Mold filling:**

A. Pack the 100 tablet molds with the mixture, until firmly packed and uniform. The powder should be pressed into the mold at least 3 times to ensure it is completely filled.

B. Using a dry heat oven, bake only the filled RDT bottom plate between 100 and 110°C for 30 minutes.

C. Remove the mold from the oven and allow the tablets to cool in the mold for 15 minutes. If the tablets remain in the mold longer than 15 minutes, it may be difficult to remove them.

D. Invert the mold and tap it using a spatula handle to remove the tablets. Allow the tablets to dry for an additional 15 to 30 minutes.

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6.	**Validation technique:** A. Weigh the content of 20 tablets separately. B. The final weight of each tablet from Step 6A (not including tablet mold) should fall between 90 and 110% of the theoretically calculated weight (**A**), in accordance to USP 795 guidelines.
7.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP	Packaging Requirements	Tight, light-resistant blister packs or vials.
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	Cap tightly after use.
	3	Protect from light.	8	May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Keep at room temperature (20°C - 23°C).	9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredient to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

1. Tablets. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 145.
2. Progesterone (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #7773.
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4. Progesterone (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 3399.
5. USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.