



Suggested Formula	Dehydroepiandrosterone 10 mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	FIN	F 003 522v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Dehydroepiandrosterone (Prasterone) (DHEA) (Micronized)	1.000	g				
Medisca CapsuBlend™-P	TBD					
Sodium Chloride, USP	As required					

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light sensitive** (protect from light whenever possible):

*Dehydroepiandrosterone*

**Hygroscopic** (protect from moisture whenever possible):

*CapsuBlend™-P*

#### Suggested Preparatory Guidelines

Non-Sterile Preparation     Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and 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 Size #1 Capsules)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> : ____	Processing Error	Qty. to measure
Dehydroepiandrosterone (Prasterone) (DHEA) (Micronized) §	1.000	g			
Medisca CapsuBlend™-P §	TBD				
Sodium Chloride, USP	As required				

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

§ Weigh / measure just prior to use.

**Preparatory Instruction**

<b>1.</b>	<p><b><u>Calculate the quantity of CapsuBlend™-P required for 100 x Size #1 Capsules:</u></b></p> <p>A. Determine the average capsule fill weight by filling and weighing <b>five TARED</b> capsules with the CapsuBlend™-P. Divide the total weight by <b>5</b> to obtain <u>average</u> weight. _____ g <b>(A)</b></p> <p>B. Quantity of CapsuBlend™-P required per capsule = (A) – 0.010 g* _____ g <b>(B)</b>        *quantity of Dehydroepiandrosterone (Prasterone) (DHEA) (Micronized) per capsule.</p> <p>C. Total quantity of CapsuBlend™-P required for the batch = (B) x 100 capsules _____ g <b>(C)</b></p> <p>D. Quantity of CapsuBlend™-P to weigh with processing error = (C) x 1.05 ~ 1.09 _____ g <b>(D)</b></p>
<b>2.</b>	<p><b><u>Powder preparation:</u></b></p> <p>A. By geometric addition, combine and triturate the following ingredients together:</p> <p>-Dehydroepiandrosterone (Prasterone) (DHEA) (Micronized)        -CapsuBlend™-P <b>(D)</b></p> <p><u>End result:</u> Homogeneous powder blend.</p>
<b>3.</b>	<p><b><u>Product transfer:</u></b></p> <p>Fill each of the 100 Size #1 Capsules with the homogeneous powder blend (Step 3A). Close each capsule tightly.</p> <p>Clean each capsule by placing the capsules in a container filled with Sodium Chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium Chloride to pass through. Finally, roll the capsules on a cloth-covered surface.</p>



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4.	<p><b><u>Validation technique:</u></b></p> <p>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight (A), in accordance to USP 795 guidelines.</p>
5.	<p><b><u>Product transfer:</u></b></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>

**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	Tightly closed, light-resistant capsule shells and vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Protect from light.
	3	Keep at room temperature (20°C – 23°C).	7	Cap tightly after use.
	4	Consult your health care practitioner if any other 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	Contact your pharmacist in the event of adverse reactions.			

\* 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.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 127.
2.	Sodium Chloride. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2003: 556.
3.	Prasterone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 34<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2005: 1565.
4.	Dehydroepiandrosterone (Monograph). In: O'Neil MJ. <i>The Merck Index 14<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #2871.
5.	USP <795>. <i>United States Pharmacopeia XXXI / National Formulary 26</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2008.

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