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|-------------------|--|-----|-----------|
| Suggested Formula | Progesterone 20% Topical Lotion (Emulsion, 100 mL) | FIN | F 006 418 |
|-------------------|--|-----|-----------|

SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|--------------------------------|---------------|------|-------|----------|------------|-------------|
| Progesterone (Micronized), USP | 20.000 | g | | | | |
| Ethoxy Diglycol | 10.0 | mL | | | | |
| Medisca VersaPro™ Lotion Base | 60.0 | mL | | | | |
| Medisca VersaPro™ Lotion Base | q.s. to 100.0 | mL | | | | |

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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 mL)

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing | Qty. | Unit | Multiplication factor ^(*) : _____ | Processing Error | Qty. to measure |
|----------------------------------|---------------|------|--|------------------|-----------------|
| Progesterone (Micronized), USP § | 20.000 | g | | | |
| Ethoxy Diglycol § | 10.0 | mL | | | |
| Medisca VersaPro™ Lotion Base | 60.0 | mL | | | |
| Medisca VersaPro™ Lotion Base | q.s. to 100.0 | mL | | | |

§ Weigh / measure just prior to use.

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

| Preparatory Instruction | |
|-------------------------|--|
| 1. | <p><u>Powder-liquid preparation:</u></p> <p>A. Levigate the Progesterone (Micronized) with the Ethoxy Diglycol.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p> |
| 2. | <p><u>Powder-liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 1A) to the VersaPro™ Lotion Base (60.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous lotion-like dispersion.</p> |
| 3. | <p><u>Filling to volume:</u></p> <p>A. Add additional VersaPro™ Lotion Base to the mixture (Step 2A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous lotion-like dispersion.</p> |
| 4. | <p><u>Product transfer:</u></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process in order to maintain homogeneity.</p> |



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SUGGESTED PRESENTATION

| Estimated Beyond-Use Date | | Packaging Requirements | | |
|---------------------------|--|--|--|---|
| | 30 days, as per USP. | | - Tightly closed, light-resistant dispensing bottle. - To be administered with a metered-dose measuring device. | |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | 7 | Cap tightly after use. |
| | 2 | Keep out of reach of children. | 8 | Keep at room temperature (20°C – 23°C). |
| | 3 | Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use. | 9 | Keep in a dry place. |
| | 4 | Protect from light. | 10 | Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants. |
| | 5 | May impair mental and/or physical ability. Use care when operating a car or machinery. | 11 | For external use only. |
| | 6 | Shake well before 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. IMPORTANT: The quantity of API administered is directly dependent on the quantity of product applied. | | | |



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REFERENCES

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| 1. | Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 265. |
| 2. | Crinone. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 821. |
| 3. | Diethylene Glycol Monoethyl Ether. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 256. |
| 4. | Progesterone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 2125. |
| 5. | Progesterone. In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #7889. |
| 6. | Progesterone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 409. |
| 7. | Progesterone (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 5018. |
| 8. | Progesterone. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2526. |
| 9. | USP <795>. <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559. |

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