MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net



| Suggested Formula | Hydroxyprogesterone Caproate 250 mg/mL Intramuscular Injection (Solution, 100 mL) | FIN | F 000 989v2 |
|---|---|---|---|

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Hydroxyprogesterone Caproate, USP | 25.000 | g | | | | |
| Benzyl Alcohol, NF | 2.0 | mL | | | | |
| Benzyl Benzoate, USP | 46.0 | mL | | | | |
| Cottonseed Oil, NF | q.s. to 100.0 | mL | | | | |

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## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

***Light sensitive*** *(protect from light whenever possible):* *Hydroxyprogesterone Caproate, Benzyl Alcohol, Benzyl Benzoate, Cottonseed Oil*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

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

Special Instruction: This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

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 |
|---|---|---|---|---|---|
| Hydroxyprogesterone Caproate, USP § | 25.000 | g | | | |
| Benzyl Alcohol, NF § | 2.0 | mL | | | |
| Benzyl Benzoate, USP § | 46.0 | mL | | | |
| Cottonseed Oil, NF § | q.s. to 100.0 | mL | | | |

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

| Preparatory Instruction<br>**IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique** | |
|---|---|
| 1. | **Equipment sterilization:**<br>Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature. |
| 2. | **Powder preparation:**<br>A. Triturate the following ingredient:<br>- Hydroxyprogesterone Caproate<br>End result: Fine homogeneous powder. |
| 3. | **Liquid preparation:**<br>A. Combine and mix the following ingredients together:<br>- Benzyl Alcohol<br>- BenzylBenzoate<br>End result: Homogeneous liquid-like solution. |

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| 4. | **Powder to liquid integration:**<br>A. Incrementally add the fine, homogeneous powder (Step 2A) to the following ingredient:<br>- Homogeneous liquid-like solution (Step 3A)<br>Specifications: Continuously mix until all solid particles have completely dissolved.<br>End result: Homogeneous liquid-like solution. |
| 5. | **Filling to volume:**<br>A. Add Cottonseed Oil to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).<br>Specifications: Continuously mix.<br>End result: Homogeneous liquid-like solution. |
| 6. | **Filtering and transferring:**<br>Aseptically filter the solution through a 0.22-µm sterile filter into the recommended dispensing container (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility and endotoxin testing. |
| 7. | **Filter integrity test:**<br>Validate filter integrity by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade. |
| 8. | **Sterility testing:**<br>Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines. |

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## SUGGESTED PRESENTATION

| | | | | |
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| Estimated Beyond-Use Date | 30 days.<br>BUD based on a successful sterility and endotoxin test result. | | Packaging Requirements | Sterile, light-resistant injection vials. |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | 6 | Equilibrate to room temperature before use. |
| | 2 | Keep out of reach of children. | 7 | Protect from light. |
| | 3 | Keep cool but do not refrigerate. | 8 | Discard container after use. |
| | 4 | Equilibrate to room temperature before use. | 9 | Do not use if discolored. |
| | 5 | Discard in the presence of particulate matter. | 10 | **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. | | | |

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## REFERENCES


1. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD: US Pharmacopeial Convention, Inc; 2004: 2461.
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