MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Erythromycin 200 mg/mL Intramuscular Injection (Solution, 100 mL)	FIN	F 003 152v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Erythromycin, USP	20.000	g				
Polyethylene Glycol 400, NF	40.0	mL				
Ethyl Acetate, NF	20.0	mL				
Alcohol (95%), USP	20.0	mL				
Alcohol (95%), USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Hygroscopic *(protect from moisture whenever possible):* *Erythromycin, Polyethylene Glycol 400*

Moisture Sensitive *(protect from humidity whenever possible):* *Ethyl Acetate*

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
Erythromycin, USP §	20.000	g			
Polyethylene Glycol 400, NF §	40.0	mL			
Ethyl Acetate, NF §	20.0	mL			
Alcohol (95%), USP §	20.0	mL			
Alcohol (95%), USP §	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 **IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique**
1.	**Equipment sterilization:** Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.
2.	**Powder-liquid preparation:** A. Triturate the Erythromycin to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 2A) with the Ethyl Acetate. End result: Homogeneous liquid-like dispersion.
3.	**Powder-liquid to medium incorporation:** A. Incrementally add the homogeneous liquid-like dispersion (Step 2B) to the Polyethylene Glycol 400. Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogenous liquid-like dispersion. B. Incrementally add the homogenous liquid-like dispersion (Step 3A) to the following ingredient: -Alcohol (95%) (20.0 mL *plus* processing error adjustments) Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogenous liquid-like dispersion.

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4.	**Filling to volume:** A. Add additional Alcohol (95%) to the mixture (Step 3B) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques, until all solid particles have completely dissolved. End result: Homogenous liquid-like solution.
5.	**Filtering and transferring:** 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.
6.	**Filter integrity test:** 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.
7.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements	Sterile, tightly closed, light-resistant unit dose injection vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Equilibrate to room temperature before use.	
	2	Keep out of reach of children.	8	Discard container after use.	
	3	Keep in a dry place.	9	For veterinary use only.	
	4	Keep refrigerated. Do not freeze.	10	Protect from light.	
	5	**Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.**	11	Discard in the presence of particulate matter.	
	6	Do not use if discolored.			
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: To be dispensed and administered only under the close supervision of the prescribing veterinarian.**				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

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