MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
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Suggested Formula	Erythromycin 0.5% Ophthalmic Ointment (Suspension, 4 g)	FIN	F 004 057v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Erythromycin 1% Stock Solution †	2.00	mL				
Mineral Oil (Light), NF	0.2	mL				
Petrolatum, USP	3.81	g				
† Erythromycin 1% Stock Solution						
Erythromycin, USP	0.100	g				
Alcohol (95%), USP	10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Mineral Oil, Petrolatum*

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

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 **20 to 25%** 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 4 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Erythromycin 1% Stock Solution †	2.00	mL			
Mineral Oil (Light), NF §	0.2	mL			
Petrolatum, USP §	3.81	g			
† Erythromycin 1% Stock Solution					
Erythromycin, USP §	0.100	g			
Alcohol (95%), USP	10.0	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.	**Erythromycin 1% Stock Solution Preparation:** A. Incrementally add the Erythromycin to the Alcohol (95%) and continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
3.	**Erythromycin Sterilization:** A. Aseptically filter the Erythromycin 1% Stock Solution (**2.00 mL** *plus* processing error adjustments) through a. 0.22-µm sterile filter and transfer the product into a sterile beaker. B. 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. C. Evaporate the sterile solution (**2.00 mL** *plus* processing error adjustments) from Step 3A at room temperature under a laminar flow hood, until all the alcohol has evaporated. End result: Sterile dry powder.

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4. **Mineral Oil Sterilization:**

A. Aseptically filter the Mineral Oil (Light) through a 0.22-µm sterile Teflon filter.

End result: Sterile homogeneous liquid-like solution.

B. 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.

5. **Powder-liquid preparation:**

A. Triturate the sterile Erythromycin (Step 3C) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 5A) with the sterilized Mineral Oil (Light) (Step 4A)

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

6. **Heat Sterilization:**

A. Following the manufacturer's specifications, dry-heat sterilize the Petrolatum.

Specifications:

Heating temperature: 170°C
Heating time: 60 minutes

IMPORTANT: The heated chamber must reach the indicated temperature before the exposure duration is timed.

7. **Medium integration:**

A. Incrementally add the homogeneous liquid-like dispersion (Step 5B) to the Sterile Petrolatum (Step 6A).

Specifications: Continuously mix.

End result: Sterile ointment dispersion.

8. **Transferring into containers:**

Transfer the Sterile ointment dispersion (Step 7A) 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 testing.

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9.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tightly closed, light-resistant ophthalmic ointment tubes.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Cap tightly after use.
	2	Keep out of reach of children.		7	For ophthalmic use only.
	3	Keep at room temperature (20°C – 23°C).		8	Protect from light.
	4	Do not allow the applicator tip to come into contact with the body or any type of surface in order to prevent contamination.		9	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Keep in a dry place.		10	Do not use if product changes color.
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

1.	Ophthalmic, Otic and Nasal Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition*. American Pharmaceutical Association; 2008: 277.
2.	Mineral Oil, Light. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 5th Edition*. American Pharmaceutical Association; 2006: 474.
3.	Petrolatum. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 5th Edition*. American Pharmaceutical Association; 2006: 509.
4.	Erythromycin (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #3681.
5.	Erythromycin (Monograph). *United States Pharmacopeia XXXII / National Formulary 27*. Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 2282.
6.	Erythromycin. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 3rd Edition.* American Pharmaceutical Association; 2005: 162.
7.	USP <797>. *United States Pharmacopeia XXXII / National Formulary 27*. Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 318.