MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Erythromycin 0.5% Ophthalmic Ointment (Suspension, 4 g)	FIN	F 004 057v4

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 (White), USP	3.81	g				
† Erythromycin 1% Stock Solution						
Erythromycin, USP	TBD					
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*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and sterility testing considerations during preparation, it is suggested to measure an additional **30 to 40%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP 797 and USP 800 when handling hazardous drugs. 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.

Compounder needs to verify as per USP, if every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

All required personal protective equipment (sterile and hazardous if applicable), such as but not limited to, gowns, aprons, sleeves, gloves both inner and outer if applicable, shoe covers, hairnet, head cap, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

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.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 (White), USP §	3.81	g			
† Erythromycin 1% Stock Solution					
Erythromycin, USP §	TBD				
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.

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2. **Ingredient quantification:**

A. Determine the potency of Erythromycin based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Erythromycin, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Erythromycin, in decimal	_____

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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Erythromycin to make an Erythromycin 1% Stock Solution, batch size (10 mL):

Quantity of Erythromycin required for 10 mL	0.100 g
DIVIDED BY	
Potency of Erythromycin, in decimal (Step 2Ai)	_____
EQUALS	
i. Quantity of Erythromycin needed for 10 mL	_____ **g**
MULTIPLIED BY	
Processing error adjustments (30 to 40%)	1.30 to 1.40
EQUALS	
ii. Quantity of Erythromycin needed *plus* processing error adjustments	_____ **g**

4. **Erythromycin 1% Stock Solution Preparation:**

A. Incrementally add the Erythromycin (amount determined in Step 3Aii) to the Alcohol (95%) and continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

5. **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 5A at room temperature under a laminar flow hood, until all the alcohol has evaporated.

End result: Sterile dry powder.

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6. **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.

7. **Powder-liquid preparation:**

A. Triturate the sterile Erythromycin (Step 5C) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 7A) with the sterilized Mineral Oil (Light) (Step 6A).

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

8. **Heat Sterilization:**

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

Specifications:

Heating temperature: 170°C
Heating time: 60 minutes

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

9. **Medium integration:**

A. Incrementally add the homogeneous liquid-like dispersion (Step 7B) to the Sterile Petrolatum (White) (Step 8A).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Sterile ointment dispersion.

10. **Product transfer:**

A. Transfer the final product (Step 9A) into the recommended dispensing containers (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility testing.

Note: Continuously mix the final product during the transfer process in order to maintain homogeneity.

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11.	**Terminal Sterilization:** In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specifications.
12.	**Sterility testing:** Validate the Test sample for sterility, in accordance to current USP 797 regulatory guidelines.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		24 hours controlled room temperature, 3 days refrigerated, or 45 days frozen, as per USP 797.	Packaging Requirements	Sterile, tightly closed, light-resistant ophthalmic ointment tubes.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	For ophthalmic use only.
	2	Keep out of reach of children.	7	Protect from light.
	3	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).	8	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	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	Do not use if product changes color.
	5	Cap tightly after use.	10	Preservative free solution, single use only. Discard any unused portion.
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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