MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Ciprofloxacin 0.3%, Triamcinolone Acetonide 0.1% Otic Liquid (Suspension, 100 mL)	FIN	F 008 756

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ciprofloxacin Hydrochloride, USP	TBD					
Triamcinolone Acetonide (Micronized), USP	0.100	g				
Propylene Glycol, USP	50.0	mL				
Glycerin, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Ciprofloxacin Hydrochloride, Propylene Glycol, Triamcinolone Acetonide*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol, Glycerin*

Heat Sensitive *(protect from heat whenever possible):* *Triamcinolone Acetonide*

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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 **5 to 9%** 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.

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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ciprofloxacin Hydrochloride, USP §	TBD				
Triamcinolone Acetonide (Micronized), USP §	0.100	g			
Propylene Glycol, USP §	50.0	mL			
Glycerin, 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.

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2. **Ingredient quantification:**

A. Determine the potency of Ciprofloxacin Hydrochloride based on the certificate of analysis:

	100%
MINUS	
Water Content result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Ciprofloxacin Hydrochloride, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Potency of Ciprofloxacin Hydrochloride, in decimal	_____
DIVIDED BY (Salt to Base conversion)	1.164
EQUALS	
i. Potency of Ciprofloxacin Hydrochloride (base equivalent), in decimal	_____

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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Ciprofloxacin Hydrochloride to make a **Ciprofloxacin (Base)** 0.3% Otic Liquid, batch size (100 mL):

Quantity of **Ciprofloxacin (Base)** required for 100 mL	0.300 g
DIVIDED BY	
Potency of Ciprofloxacin Hydrochloride (base equivalent), in decimal (Step 2Ai)	_____
EQUALS	
i. Quantity of Ciprofloxacin Hydrochloride needed for 100 mL	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
ii. Quantity of Ciprofloxacin Hydrochloride needed *plus* processing error adjustments	_____ **g**

4. **Powder-Liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Ciprofloxacin Hydrochloride (amount determined in Step 3Aii)
-Triamcinolone Acetonide (Micronized)

B. Levigate the fine, homogeneous powder blend (Step 4A) with the Propylene Glycol.

End result: Homogeneous liquid-like dispersion.

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5.	**Filling to volume and transfer into dispensing container:** A. Add Glycerin to the homogeneous liquid-like dispersion (Step 4B) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specification: Continuously mix using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. B. Transfer the final product (Step 5A) 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 into the recommended dispensing containers in order to maintain homogeneity.
6.	**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 specification.
7.	**Sterility testing:** Validate the Test sample for sterility, in accordance to current USP 797 regulatory guidelines.

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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 otic dropper bottle.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C)
	2	Keep out of reach of children.	8		Protect from light.
	3	For otic use only.	9		Keep in a dry place.
	4	Cap tightly after use.	10		**Shake well before use.**
	5	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	11		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	6	May impair mental and/or physical ability. Use care when operating a car or machinery.	12		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: DRUG-DRUG INTERACTION EXISTS BETWEEN CIPROFLOXACIN HYDROCHLORIDE AND TRIAMCINOLONE ACETONIDE. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.**				
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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