MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Atropine Sulfate 1% Ophthalmic Ointment (Emulsion, 4 g)	FIN	F 001 769v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Atropine Sulfate 40% Stock Solution †	0.10	mL				
Chlorobutanol 1% Stock Solution ††	1.6	mL				
Lanolin (Anhydrous), USP	0.40	g				
Petrolatum (White), USP	2.14	g				
† **Atropine Sulfate 40% Stock Solution**						
Atropine Sulfate, USP	0.100	g				
Sterile Water for Injection, USP	0.15	mL				
Sterile Water for Injection, USP	q.s. to 0.25	mL				
†† **Chlorobutanol 1% Stock Solution**						
Chlorobutanol (Anhydrous), NF	0.10	g				
Mineral Oil (Light), NF	10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Atropine Sulfate, Lanolin, Petrolatum, Mineral Oil*

Air Sensitive *(protect from air whenever possible):* *Atropine Sulfate*

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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
Atropine Sulfate 40% Stock Solution † §	0.10	mL			
Chlorobutanol 1% Stock Solution †† §	1.6	mL			
Lanolin (Anhydrous), USP §	0.40	g			
Petrolatum (White), USP §	2.14	g			
† **Atropine Sulfate 40% Stock Solution**					
Atropine Sulfate, USP §	0.100	g	---	---	
Sterile Water for Injection, USP §	0.15	mL	---	---	
Sterile Water for Injection, USP §	q.s. to 0.25	mL	---	---	
†† **Chlorobutanol 1% Stock Solution**					
Chlorobutanol (Anhydrous), NF §	0.10	g	---	---	
Mineral Oil (Light), NF §	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. † **Atropine Sulfate 40% Stock Solution preparation:**

A. Incrementally add the Atropine Sulfate (0.100 g) in 0.15 mL of Sterile Water for Injection.

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

B. Add additional Sterile Water for injection to the mixture (Step 2A) to fill to the required batch size (0.25 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

3. †† **Chlorobutanol 1% Stock Solution preparation:**

A. Combine and mix the following ingredients together:

-Chlorobutanol (Anhydrous) (0.10 g)
-Mineral Oil (Light) (10.0 mL)

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

4. **Powder-Liquid preparation (Phase A):**

A. Combine and mix the following ingredients together:

-Atropine Sulfate 40% Stock Solution (0.10 mL *plus* processing error adjustments)
-Lanolin (Anhydrous)

Specifications: Continuously mix.

End result: Homogeneous paste-like dispersion.

5. **Powder-Liquid preparation (Phase B):**

A. Combine and mix the following ingredients together:

-Chlorobutanol 1% Stock Solution (1.6 mL *plus* processing error adjustments)
-Petrolatum (White)

Specifications: Continuously mix.

End result: Homogeneous paste-like dispersion.

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6.	**Phase A to Phase B integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 4A) to the homogeneous paste-like dispersion. (Step 5A). Specifications: Continuously mix. End result: Homogeneous cream-like dispersion.
7.	**Transfer into dispensing container:** A. Transfer the final product (Step 6A) 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.
8.	**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.
9.	**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, light-resistant ointment tube.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Cap tightly after use.
	2	Keep out of reach of children.	8		May cause blurred vision. Use care when operating a car or machinery.
	3	Keep in a dry place.	9		Protect from light.
	4	For ophthalmic use only.	10		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Do not use if discolored.	11		Do not allow the dropper tip to come into contact with the body or any type of surface in order to prevent contamination.
	6	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).	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.				
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. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD: 2461.
2. Ophthalmic, Otic, and Nasal Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 1998: 219.
3. Lanolin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition.* American Pharmaceutical Association; 2003: 333.
4. Mineral Oil (Light). In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 398.
5. Petrolatum. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition.* American Pharmaceutical Association; 2003: 419.
6. Atropine (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 151.
7. Atropine. In: Trissel LA. *Trissel's Stability of Compounded Formulations,3rd Edition.* American Pharmaceutical Association; 2005: 34.
8. Atropine (Monograph). *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 200.