MEDISCA® NETWORK INC.
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Suggested Formula	Atropine Sulfate 1% Ophthalmic Ointment (Emulsion, 4 g)	FIN	F 001 769

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				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

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

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 **30 to 40%** 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
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.

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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.

6. **Phase A to Phase B integration:**

A. Incrementally add the homogeneous paste-like dispersion (Step 4A) to the following ingredient:

- 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 into the recommended dispensing container (see Packaging requirements).

Note: After sterilization, a sample is to be used as the Test sample for sterility and endotoxin testing.

8. **Sterilization:**

Following the manufacturer's specifications, dry heat sterilize the mixture, then return to ambient temperature.

Specifications:

Heating temperature: 150°C
Heating time: 60 minutes

IMPORTANT: The temperature of the heated chamber must reach 150°C before the exposure duration is timed.

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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		14 days BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, heat stable, 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 room temperature (20°C - 23°C).			
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

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