MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Atropine Sulfate 0.5 mg/mL Injection (Solution, 100 mL)	FIN	F 000 906

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Atropine Sulfate (Monohydrate), USP	0.050	g				
Chlorobutanol, NF	0.50	g				
Sodium Chloride, USP	0.77	g				
Sterile Water For Injection, USP	80.0	mL				
Sterile Water For Injection, USP	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Atropine Sulfate*

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 **5 to 9%** 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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Atropine Sulfate (Monohydrate), USP §	0.050	g			
Chlorobutanol, NF §	0.50	g			
Sodium Chloride, USP §	0.77	g			
Sterile Water For Injection, USP §	80.0	mL			
Sterile Water For Injection, 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.
2.	**Powder preparation:** A. Combine and triturate the following ingredients together to form a fine homogeneous powder blend: - Atropine Sulfate (Monohydrate) - Chlorobutanol - Sodium Chloride

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3.	**Powder to liquid integration:** A. Incrementally add the fine homogeneous powder blend (Step 2A) to the Sterile Water For Injection (80.0 mL plus processing error adjustments) Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
4.	**Filling to volume:** A. Add additional Sterile Water For Injection to the mixture (Step 3A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix End result: Homogeneous liquid-like solution
5.	**Filtering and transferring:** Aseptically filter the solution through a 0.22-µm sterile filter 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 and endotoxin testing.
6.	**Filter integrity test:** 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.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days BUD based on a successful sterility and endotoxin test result.		Packaging Requirements	Sterile, light-resistant unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep at room temperature (20°C - 23°C).
	2	Keep out of reach of children.	7	Protect from light.
	3	For veterinary use only.	8	Discard container after use.
	4	Discard in the presence of particulate matter.	9	**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.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **Keep at room temperature to prevent precipitation of the preservative.**			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

1. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVII / National Formulary 22.* Rockville, MD: US Pharmacopeial Convention, Inc.
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3. Sodium Chloride. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003:556.
4. Chlorobutabol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003:141.
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6. Atropine Sulfate (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 151.
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