Atropine Sulfate 1% Sterile Ophthalmic Solution, Preserved
Version number: 1.0
Volume: 100mL

Atropine Sulfate, Monohydrate	1gm
Boric Acid	2gm
Hypromellose	0.600gm
Benzalkonium Chloride	10mg*
Sodium Hydroxide 10% Aqueous Solution	qs
Hydrochloric Acid, Diluted (10% or 0.1N)	qs
Water, Sterile for injection (Preservative-free)	qs. 100mL

*The final concentration of Benzalkonium Chloride should be 0.01%

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs. **This is a high risk preparation**

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Disperse the Hypromellose in about 90mL of sterile water for injection previously heated to about 80°C
4. Remove from heat and cool to room temperature
5. Add the Atropine Sulfate, Boric Acid and Benzalkonium Chloride and mix well
6. Adjust the pH to 3.5 to 6.0 using Hydrochloric acid 10% solution and/or Sodium Hydroxide 10% Solution
7. Add sufficient sterile water for injection to final volume and mix well
8. Sterile filter (with filter appropriate for use with Benzalkonium Chloride) into appropriate sterile ophthalmic containers
9. Package and label. Freeze immediately upon completion.
10. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Bubble point filter integrity

b. Particulate
c. Sterility
d. Endotoxins
d. Label - auxiliary labels, storage, BUD, compounded medication

*Keep away from light and moisture

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours
Cold Temperature: not more than 3 days
Or Refer to current USP chapter <797>.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date.
It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date should be assigned based on the current issue of USP <797> Standards

Precautions:
Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.
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