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**Vancomycin Hydrochloride 14mg/mL Sterile Ophthalmic Solution – Preserved**

Version number: 1.0

Volume: 35.5mL

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Vancomycin HCl, USP	0.5g
Sodium Chloride 0.9%, USP For Injection	35mL
Benzalkonium Chloride 1%	0.135mL

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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.

**SUGGESTED COMPOUNDING PROCEDURES**

1. Reconstitute one vial of Vancomycin HCl 500mg for injection with 10-mL sodium chloride 0.9% for injection and mix well.
2. Add Benzalkonium Chloride to step 1 and mix well.
3. Transfer the solution from step 2 into a 60mL sterile syringe and bring volume to 35.5mL with sodium chloride 0.9% for injection.
4. Pass step 3 through 0.22 micron sterilizing filter into sterile ophthalmic droppers.
5. Aseptically apply dropper tips and caps.
6. Label
6. Suggested Quality Assessments – follow pharmacy SOPs:
  - a. Bubble point filter integrity
  - b. Particulate
  - c. Sterility
  - d. Label - auxiliary labels, storage, BUD, compounded medication

Store Refrigerated or Frozen.

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  
Refer to 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, 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 is estimated to be 60 days if refrigerated and 6 months if frozen\***

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.

\*McLellan Christine, Ngo Van, Pasedis Sophia, Dohlman Claes H. Testing the Long-Term Stability of Vancomycin Ophthalmic Solution. International Journal of Pharmaceutical Compounding. 12(5);2008:456.

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