Tobramycin 13.6mg/ml Ophthalmic Solution

Version number: 1.0

Volume: 7mL

Tobramycin 40mg/mL Injection	2mL
Tobramycin 3mg/ml Ophthalmic Solution (commercial)	5mL

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. Aseptically remove the cap from the dropper bottle of tobramycin 3mg/ml (0.3%) ophthalmic solution.
2. Withdraw 2ml of tobramycin sulfate injection (40mg/ml) through a 4 micron filter needle.
3. Replace the filter needle on the syringe with a new needle and transfer the 2mL tobramycin sulfate injection to the opened bottle of tobramycin ophthalmic solution.
4. Replace the dropper tip on the bottle and shake to mix.
5. Package and label.
6. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Particulate
    b. Sterility
    c. Label - auxiliary labels, storage, BUD, compounded medication

Store Refrigerated.

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

Controlled Room Temperature: not more than 30 hours
Cold Temperature: not more than 9 days
Solid Frozen State at -25°C: not more than 45 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 91 days refrigerated.

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.

*Trissel's Stability of Compounded Formulations. 5th edition. pg 479.

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Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: SpectrumRx.com | Email: sales@spectrumrx.com