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### SUGGESTED FORMULA

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#### TRIS EDTA OTIC SOLUTION

Version number: 1.0

Volume: 100 ML

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Tromethamine, USP	0.605 g
Edetate Disodium, Dihydrate, USP	0.02g
Sodium Lauryl Sulfate, NF	0.19g
Sodium Hydroxide 20% Aqueous Solution	pH
Water, Sterile for Irrigation (PF)	QS 100 mL

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#### Notes:

Prepare the sodium hydroxide 20% solution by dissolving 2 g of sodium hydroxide, NF in sufficient sterile water for irrigation to make 10 mL. Although an otic preparation is generally not required to be prepared under sterile conditions, sterile water for irrigation is used to assist in avoiding heavy metal ions that might be present in purified water.

#### SUGGESTED COMPOUNDING PROCEDURES

1. Accurately measure each ingredient
2. Dissolve the tromethamine (TRIS) in 90 mL of sterile water for irrigation
3. Use low heat and minimal stirring to avoid foaming and dissolve the edetate disodium and sodium lauryl sulfate into the solution
4. Add sterile water for irrigation to approximately 98 mL
5. Add sufficient sodium hydroxide 20% solution to bring solution to pH of 8
6. Bring solution to final volume and mix well
7. As an added precaution, solution may be sterilized by autoclaving or sterile filtration (0.22 micron filter)
8. Package and label
  - a. Clarity
  - b. Color
  - c. Label (s)- auxiliary labels (otic use), storage, BUD

Protect from light.

Store at room temperature away from excessive heat

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 30 days per** Allen, Lloyd V Jr. EDTA-TRIS Otic Solution V-2 (Veterinary). International Journal of Pharmaceutical Compounding. 5(2);2001:128.

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.

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