SUGGESTED FORMULA

Pzi Buffer Solution #1 Injectable
Version number: 1.0
Volume: 200 mL

Zinc Oxide, USP	0.15gm
Hydrochloric Acid 0.1N Liquid	47.5mL
Glycerin Synthetic,USP	11mL
Phenol Liquified 89%,USP	0.75mL
Protamine Sulfate Powder	0.825gm
Sterile Water for Irrigation	200mL Q.S.

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. Weigh and mix Hydrochloric Acid 0.1N in 70% of final volume of Water for irrigation in depyrogenated, calibrated beaker
2. Once dissolved add Zinc Oxide into mixture
3. Once dissolved add remaining ingredients
4. Q.S. to final volume with Sterile Water for Injection.
5. After dissolved allow to sit in refrigerator overnight
6. Filter through 0.22U filter into Sterile vial
6. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Bubble point filter integrity
    b. Particulate
    c. Sterility
    d. Endotoxins
    □ e. Label - auxiliary labels, storage, BUD, compounded medication

Protect from Light

Store Refrigerated

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 _90_days

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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