spectrum® PHARMACY PRODUCTS

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SUGGESTED FORMULA

Procaine Hydrochloride 2% Injection (MDV)
Version number: 1.0
Volume: 100 mL

_ Procaine Hydrochloride, Crystal, USP	2 g
Sodium Chloride, Powder, USP (SO160)	0.48 g
Chlorobutanol, Anhydrous, NF (CH123)	0.25 g
Sodium Hydroxide 10% (cpd)	pH
Hydrochloric Acid 10% (cpd)	pH
Water for Injection, USP	Q.S. 100 mL

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. Mix Procaine Hydrochloride and Sodium Chloride in 90% of final volume of Water for Injection in depyrogenated, calibrated beaker.
2. Add Chlorobutanol to step 2, and mix on stir plate until homogeneous.
3. Check pH (meter preferred) and adjust pH with Hydrochloric Acid and/or Sodium Hydroxide to 3.0 – 5.5.
4. Q.S. to final volume with Water for Injection.
5. Filter into sterile, depyrogenated vials with 0.2 (0.22) micron filter, stopper with sterilized stoppers, apply seal, crimp and label.
6. Suggested quality assessments:
   Bubble point filter integrity test
   Visual inspection
   Sterility
   Endotoxins

Protect from light
Store at controlled Room temperature

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:

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.

Assign beyond-use date per current USP <797> standards

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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