Phenylephrine (Preservative Free/Sulfite Free) 1.5% Injection (SDV)
Version number: 1.0
Volume: 200 mL

Phenylephrine Hydrochloride, USP	3 g
Sodium Chloride, USP	0.7 g
Citric Acid, USP	0.1828 g
Sodium Citrate, USP Anhydrous	0.8 g
Sodium Hydroxide 10%	pH
Hydrochloric Acid 10%	pH
Water for Injection	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. Weigh and mix Phenylephrine HCl, Sodium Chloride, Citric Acid and Sodium Citrate in 90% of final volume of Water for Injection in depyrogenated, calibrated beaker.
2. Mix on stir plate until homogeneous.
3. Check pH (meter preferred) and adjust pH to 3 –6.5.
4. Q.S. to final volume with Water for Injection.
5. Filter into sterile, depyrogenated vials, stopper with sterilized stoppers, apply seal, crimp and label.
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

Note: This formula is usually available as a commercial product. Do not compound unless it has been verified that the product is currently on the FDA Drug Shortage List.

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:

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, per Trissels Stability of Compounded Formulations, 4th edition.

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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