Alprostadil 10µm/mL, Papaverine Hydrochloride 30mg/mL and Phentolamine Mesylate 500µm/mL Injection (SDV)
Version number: 1.0
Volume: 1 mL

Alprostadil, USP	10µg
Papverine HCL, USP	30mg
Phentolamine Mesylate, USP	500µg
Sodium Chloride Solution 0.9% injection	0.67mL
Sterile water for Injection	Q.S. 1 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 Alprostadil, Papaverine HCL, Phentolamine Mesylate and Sodium Chloride Solution with 90% of final volume of sterile water for Injection in depyrogenated, calibrated beaker.
2. Mix on stir plate until homogeneous.
3. Q.S. to final volume with Water for Injection.
4. Using a 0.2µm filter, filter into sterile, depyrogenated vials, stopper with sterilized stoppers, apply seal, crimp and label.
5. Suggested Quality Assessments – follow pharmacy SOPs:
   a. Bubble point filter integrity
   b. Particulate
   c. Sterility
   d. Endotoxin
   ☐ e. Label - auxiliary labels, Refrigerate or Freeze, BUD, compounded medication

Protect from light
Store Refrigerated or Frozen

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 for batches of injections that have passed sterility testing is estimated to be 30 Days Refrigerated or 90 Days Frozen from the original date of compound per *International Journal of Pharmacy Compounding*

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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