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**Apomorphine Hydrochloride 1mg/mL Injection (SDV)**

Version number: 1.0

Volume: 5 mL

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Apomorphine HCL, USP (A1147)	0.005g
Sodium Metabisulfite , NF (SO182)	0.005g
Sodium Hydroxide 10%	pH
Hydrochloric Acid 10%	pH
Sterile Water for Injection	5mL Q.S.

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This compound should be prepared in an ISO Class 5 Biosafety cabinet or compounding aseptic containment isolator by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP chapters <797> and <800> 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 Apomorphine, Sodium Metabisulfite with 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 4.0-5.0
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 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

Or Refer to current 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, 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.

**Beyond-Use Date is estimated to be 360 Days per *Trissel's Stability for Compounded Formulations 5<sup>th</sup> Edition***

#### **Precautions**

Hazardous drugs should be handled according to USP <800>, NIOSH standards and pharmacy SOPs. This preparation should be compounded in a biological safety cabinet or compounding aseptic containment isolator. 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 personal protective equipment.

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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