Buprenorphine Hydrochloride 0.324mg/mL Sterile Injection
Version number: 1.0
Volume: 100 mL

Buprenophine Hydrochloride	32.4mg
Dextrose, Anhydrous	5gm
Hydrochloric Acid Diluted Solution (10%)	XmL
Water for Injection, USP (Preservative-Free)	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.

***This is a high risk preparation**

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. In a suitable container, dissolve the powders in about 90mL of Sterile water for injection
4. Adjust the pH if necessary to pH 3.5 to 5.5 with the Hydrochloric Acid Solution and record value
5. Add sufficient Sterile Water for injection to volume and mix well
6. Filter through an appropriate Sterile 0.2-µm filter into suitable sterile container for injection
7. Package and Label
8. Quality assessments
    a. Sterility
    b. Particle size
    c. Suspension settling
    d. Label - auxiliary labels, storage, BUD, compounded medication

Keep away from eyes and mucous membranes
For Hospital or Office use
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
BUD should be assigned based on the 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.

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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