spectrum® PHARMACY PRODUCTS

800.370.6231
SpectrumRx.com

Morphine Sulfate 4% / Ketamine Hydrochloride 4% / Bupivacaine Hydrochloride 0.25% Spray
Version number: 1.0
Volume: 100 mL

Morphine Sulfate, USP	4 g
Ketamine Hydrochloride, USP	4 g
Bupivacaine Hydrochloride, USP	0.25 g
Methylparaben, NF	0.02 g
Propylparaben, NF	0.02 g
Sodium Hydroxide 10% (w/v)*	as needed for pH
Hydrochloric Acid 10% (w/v)*	as needed for pH
Water for Irrigation, USP	QS 100 mL

*Freshly prepared with water for irrigation.

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. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Heat 95 mL of water to approximately 95°C and add parabens, mix to dissolve
4. Allow mixture to cool and add remaining ingredients
5. Check pH and adjust (if necessary) with sodium hydroxide and/or hydrochloric acid to pH 4-5.5
6. Bring solution to final volume
7. Filter with 0.2 or 0.22 micron filter into sterilized container
8. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Bubble point filter integrity
    b. Particulate
    c. Sterility
    d. Label - auxiliary labels, storage, BUD, compounded medication

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, 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.

If tested for sterility, beyond-Use Date is estimated to be 30 days for topical preparations. If not tested, follow current USP 797 BUD matrix.

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.
05/19rd

Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: SpectrumRx.com | Email: sales@spectrumrx.com