spectrum® PHARMACY PRODUCTS

800.370.6231
SpectrumRx.com

SUGGESTED FORMULA

Lidocaine Hydrochloride 2% Viscous Oral Topical Gel, Preserved
Version number: 1.0
Quantity: 100gm

Lidocaine HCL, USP (LI103)	2gm
Amaranth	XmL
Methylparaben, NF (ME163)	0.2gm
Propylparaben, NF (PR133)	0.02gm
Carboxymethylcellulose Sodium	1gm
Sodium Hydroxide 10% Aqueous Solution	XmL
Hydrochloric Acid, Diluted 10% Solution	XmL
Purified Water, USP	Q.S. 100mL

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required amount of each ingredient
2. Accurately weigh and measure each ingredient
3. Heat about 90mL of purified water to about 90°C and disperse the parabens and the Sodium Carboxymethylcellulose and mix until completely dissolved
4. Remove from heat, cool add the lidocaine HCL and Amaranth and mix until uniform
5. Adjust the pH to 6.0—7.0 using the Sodium Hydroxide 10% solution and/or Hydrochloric acid 10% solution and record value
6. Add sufficient purified water to final volume and mix well
7. Suggested quality assessments:
    a. Uniform gel with no lumps
    b. pH
    c. Label (s)- auxiliary labels (external use), storage, BUD

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 should be assigned base on the current USP <795> 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.

9/18 JD

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