

**SUGGESTED FORMULA**

Diltiazem HCl 10mg / Lidocaine 100mg / Hydrocortisone 100mg Suppository

Version number: 1.0

Volume or quantity: #30 Suppositories

Diltiazem HCl, USP (D1163)	0.3 gm
Lidocaine, USP (LI102)	3 gm
Hydrocortisone Micronized, USP (CO137)	3 gm
Silica Gel, NF (S1510)	0.75 gm
Witepsol H15, Base (W1129)	53.65 gm

***It is important to calibrate the suppositories molds you are using and adjust formulation accordingly.
This formulation is based on a mold that holds approximately 2gm**

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. Melt Witepsol over a water bath or on hot plate stirrer until melted.
4. Triturate the Diltiazem HCl, Lidocaine and Hydrocortisone to fine powder and slowly add to step 3 and mix well.
5. Slowly sprinkle the Silica Gel into the melt with stirring until a mixture is obtained.
6. Cool slightly, then pour into the mold in a continuous motion, if appropriate for the mold being used.
7. Cool, trim if necessary, package and label.
8. Suggested Quality assessments
 - a. % variability & % deviation from theoretical <10% - (remake if >10%)
 - b. Surface appearance and feel
 - c. Melting test
 - d. Quantity
 - e. Label - auxiliary labels, storage, BUD, compounded medication

Package in air tight, Light resistant containers

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 from 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 based on the current USP <795> Standards

Precautions:

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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