

**SUGGESTED FORMULA**

Diazepam 5mg Suppositories

Version number: 1.0

Volume or quantity: #24 Suppositories

Diazepam, USP (D2985)	0.120 gm
Propylene Glycol, USP (PR130)	0.24 mL
Colloidal Silicon Dioxide, NF (S1510)	0.64 gm
Witepsol® H15, base (W1129)	43.22 g

*Prior to beginning, it is necessary that any mold used be calibrated with the formula to determine the quantity of base required. This formula is based on an estimated calibration of 1.83 gm of Witepsol per blank suppository.

SUGGESTED COMPOUNDING PROCEDURE

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Warm and gently melt Witepsol base to fluid state
4. Combine diazepam and the propylene glycol to a homogenous mixture
5. Add the colloidal silicon dioxide to the warmed Witepsol base mixing well
6. Remove base from heat source and geometrically add to the diazepam mixture
7. Pour into the molds and permit to harden; remove when firm
8. Package and label
9. 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**Store at room temperature**

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> BUD Guidelines.

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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