



SUGGESTED FORMULA

Diazepam 1mg/mL Methylcellulose Rectal Gel, Preserved

Version number: 1.0

Volume: 100mL

Diazepam, USP (D2985)	0.100gm
Methylcellulose [EM4] 1500 mPa (cps)	2.5gm
Methylparaben, NF (ME163)	0.100gm
Glycerin, USP (G1015)	5gm
Purified Water, USP	Q.S. 100 mL

***The viscosity of the gel can be altered by changing the quantity of Methylcellulose in this formula. The formula is intended for several dosage units or dilution prior to administration. Use as a vaginal insert may be appropriate in certain diagnoses.**

SUGGESTED COMPOUNDING PROCEDURES

Weigh and/or measure all ingredients

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. Pulverize Diazepam to a fine powder
4. Mix the Diazepam ,Methylcellulose and Methylparaben powders thoroughly
5. Add the glycerin to the powders and mix to form a smooth paste
6. Add about 10mL of Purified water to the paste and mix well, follow with another 10mL of Purified Water and mix well
7. Slowly incorporate additional Purified Water to volume and mix well.
8. Package and Label
9. Suggested quality assessments:
 - a. Solubility
 - b. Color
 - c. Container
 - d. Label (s) - auxiliary labels, storage, BUD

*Do not drink alcoholic beverages with the medicine

*For Vaginal Use

Store in air-tight container.

*Rectal use only

*May cause drowsiness

Store Refrigerated

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.

Beyond Use Dating should be assigned according to the current USP <795> Standards

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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