

**SUGGESTED FORMULA**

Baclofen 4mg / Diazepam 5mg Suppository

Version number: 1.0

Volume or quantity: #100 Suppositories

Baclofen, USP (B1049)	0.4gm
Diazepam, USP (D2985)	0.5gm
Silica Gel, NF (S1510)	2.5gm
Witepsol [®] H-15, Base (W1129)	Q.S. 200gm

SUGGESTED COMPOUNDING PROCEDURES

*This formulas is based on molds that are approximately 2gm, it is important to calibrate molds with base and accuracy of this formula before dispensing.

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
4. Triturate the Baclofen and Diazepam to fine powder then slowly add to step 3 mixing well.
5. Slowly sprinkle the Silica Gel into the melt while stirring until a homogenous 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.

10/19 JD

Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: SpectrumRx.com | Email: sales@spectrumrx.com
© 2015 Spectrum Pharmacy Products. All rights reserved.

spectrum
PHARMACY PRODUCTS