

**SUGGESTED FORMULA**

Mesalamine 500mg Suppositories

Version number: 1.0

Volume or quantity: #100 Suppositories

Mesalamine, USP (M1540)

50gm

Witepsol[®] H15, base (W1129)

Q.S 161gm

*It is necessary to calibrate the mold that you are using prior to preparing this compound. This formulation is based off of molds that hold approximately 2gm.

The specific gravity of Witepsol is 0.95 and is factored into the total volume of formulation.

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. Using an appropriate heat source , melt the required quantity of Witepsol
4. Triturate Mesalamine and mix well
5. Slowly sprinkle the powder 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 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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