

**SUGGESTED FORMULA****Mesalamine 100mg/mL Enema Suspension**

Version number: 1.0

Volume: 100mL

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Mesalamine, USP (5-Aminosalicylic acid)(M1540)	10g
Sodium Phosphate dibasic (anhydrous)	0.4g
Sodium Phosphate monobasic (anhydrous)	0.0045g
Sodium Chloride, USP (SO155)	9g
Sodium Ascorbate, USP (S1349)	0.5g
Tragacanth, NF (TR105)	4g
Methylparaben, NF (ME163)	2g
Propylparaben, NF (PR133)	0.5g
Propylene Glycol, USP (PR130)	25mL
Purified Water, USP (W1014)	q.s. 100mL

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**SUGGESTED COMPOUNDING PROCEDURES**

1. Accurately weigh and/or measure each ingredient.
2. Dissolve parabens in the propylene glycol
3. Add the tragacanth to the propylene glycol solution and thoroughly disperse
4. Add approximately  $\frac{3}{4}$  of the remaining volume of water, followed by the remaining ingredients and continue to stir or use a blender.
5. Bring to final volume and mix until uniform.
6. Package and label
5. Suggested Quality Assessments – follow pharmacy SOPs:
  - a. Weight to Volume calculation
  - b. Color
  - c. Pourability
  - d. Settling
  - e. Resuspendability

Store at Room Temperature or 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. It is recommended that you follow USP <795> recommendations for potency testing.

**Beyond-Use Date is estimated to be 90 Days at either temperature** - Montgomery HA, Smith FM, Scott BE. Stability of 5-aminosalicylic acid suspension. Am J Hosp Pharm. 43(1);1986:118.

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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