

**SUGGESTED FORMULA****Amitriptyline Hydrochloride 1mg/mL**

Version number: 1.0

Volume: 100 mL

Amitriptyline Hydrochloride, USP (A1322)	1gm
Glycerin, USP (G1016)	*To form paste*
Edetate Disodium, Dihydrate, USP (ED150)	0.01gm
Simple Syrup, NF	100mL Q.S.

**SUGGESTED COMPOUNDING PROCEDURES**

1. Weigh Amitriptyline and Edetate Disodium and place in glass mortar and pestle
2. Dry triturate to break down any clumps in the chemical
3. Add enough of Glycerin into mortar and pestle to form a "paste"
4. Triturate until all Amitriptyline is broken down and incorporated into liquid
5. Add Simple Syrup until pourable mixture and pour into calibrated final container
6. Perform liquid "washes" in mortar and pestle to integrate remaining chemical
7. Pour each "wash" into final container taking precaution not to go over the final volume
8. Q.S. medication and shake well.
8. Suggested Quality Assessments—follow pharmacy SOPs:
  - a. Weight to Volume calculation
  - b. Color
  - c. Pourability
  - d. Settling
  - e. Resuspendability

Store in air tight amber plastic containers

Store 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 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 37 Days per Trissel's Stability of Compounded Formulation 5<sup>th</sup> Edition**

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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Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: [SpectrumRx.com](http://SpectrumRx.com) | Email: [sales@spectrumrx.com](mailto:sales@spectrumrx.com)  
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