



## SUGGESTED FORMULA

Melatonin 10 mg/mL Sublingual Solution

Version number: 1.0

Volume or quantity: 100 mL

Melatonin Powder (M2095)	1 gm
Stevia Leaves Extract, Sweet Powder (S1964)	0.25 gm
Alcohol, 190 Proof, USP (ET108)	15 mL
Flavor, Water soluble	2 mL
Glycerin, USP (G1016)	QS 100mL

## **SUGGESTED COMPOUNDING PROCEDURES**

- 1. Calculate the required amount for each ingredient
- 2. Weigh and/or measure all ingredients
- 3. Mix melatonin and stevia thoroughly using a mortar and pestle
- 4. Transfer powder blend to appropriately sized graduated cylinder or calibrated beaker
- 5. Add ½ total volume of Alcohol to mortar, rinse and transfer to the graduated cylinder or beaker
- 6. Add remaining volume of Alcohol and stir until dissolution is complete
- 7. Add flavor and stir
- 8. Add sufficient glycerin to bring to final volume and thoroughly mix
- 9. Package in amber glass bottle with dropper or syringe/adapter to measure prescribed dose
- 10. Quality assessments
  - a. color
  - c. particulate
  - d. Label auxiliary labels, storage, BUD, compounded medication

Store in light resistant air-tight container, at Controlled 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 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 estimated to be <u>90 days</u>** Per: Haywood A, Burrell a, van Breda K, et al. "*Stability of melatonin in an extemporaneously compounded sublingual solution and hard gelatin capsule.*" Int J Pharm Compound. 2009;13:170-4.

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. 5/16 rd

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