

**SUGGESTED FORMULA**

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Melatonin 6 mg Capsule Size #4

Version number: 1.0

Volume or quantity: 100 capsules

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Melatonin Powder (M2095)	0.6g
Microcrystalline Cellulose, NF (C1679)	10.4 g
Size #4 Capsules	#100

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It is necessary to determine the quantity of lactose or other diluent required as a filler prior to beginning the preparation of this formula.

**SUGGESTED COMPOUNDING PROCEDURES**

1. Calculate the required quantity for each ingredient needed for this compound
2. Weigh and/or measure each ingredient
3. Triturate to reduce to fine powders as needed
4. Mix powders per pharmacy SOPs – (e.g. geometric dilution, blade, v-blend, RAM™)
5. Fill capsules in vented enclosure (hood)
6. Cap and “snap” each bottom into its lid.
7. Weigh sample capsules to check variability and standard deviation per pharmacy SOPs
8. Bottle and label with prescription label and appropriate auxiliary labels.
9. Suggested Quality assessments
  - a. % variability & % deviation from theoretical <10% - (remake if >10%)
  - b. Capsule size
  - c. Capsule color
  - d. Quantity
  - e. Label - auxiliary labels, storage, BUD, compounded medication

Store in 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 should be based on the current USP <795> Standards

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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