



### SUGGESTED FORMULA

Naltrexone Hydrochloride 1 mg Capsule Size #4

Version number: 1.0

Volume or quantity: 100 capsules

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|---|--------|
| Naltrexone Hydrochloride, Dihydrate, USP* (N1374) | 0.1g   |
| Microcrystalline Cellulose, NF (C1679)            | 10.9 g |

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### SUGGESTED COMPOUNDING PROCEDURES

\*Check certificate of analysis and adjust for water determination. For example, if water determination is 8.4% and assay (on anhydrous basis) is 99.9%, subtract 8.4% from 99.9% ( $100.0\% - 8.4\% = 91.6\%$  active); Divide amount to weigh by activity:  $0.1\text{g} \div 0.916$  (91.6%) = 0.109 g of Naltrexone Hydrochloride, Dihydrate to be weighed for the compound.

Weigh all ingredients

1. Triturate to reduce to fine powders as needed
2. Mix powders per pharmacy SOPs – (e.g. geometric dilution, blade, v-blend, RAM™)
3. Fill capsules in vented enclosure (hood)
4. Cap and “snap” each bottom into its lid.
5. Weigh sample capsules to check variability and standard deviation per pharmacy SOPs
6. Bottle and label with prescription label and appropriate auxiliary labels.
7. 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, 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 180 days

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.

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