

SUGGESTED PROCEDURE

Item	Naltrexone 2mg capsule	Formula Date	28 June 2024
API(s)	Naltrexone Hydrochloride	Procedure No.	P2673
Base	ProCap™ 100 HD	Revision	R1
Volume/Quantity	100 Capsules (Size #1)	Compound Type	Capsules #1

Rx	Weight (g)	Percent	Comment
Naltrexone HCL, USP (Micronized)	0.2g	0.6%	
ProCap™ 100 HD	33.3g	99.4%	ProCap™ 100 HD packing stats for capsule size #1 0.335g
Total	33.5g	100%	

To account for processing error considerations during preparation, it is suggested to measure an additional **10%** of the required quantities of ingredients.

Suggested Method of Preparation

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient. Account for batch size and density conversions, if required.
3. Using the principles of Geometric Dilution, mix Naltrexone and ProCap™ 100 HD together with trituration in a mortar and pestle. Alternately, mix powders together in a planetary-style mixer.
4. Encapsulate in size #1 capsules.
5. Final preparation should be an encapsulated free-flowing powder.
6. Transfer the final preparation into an appropriate dispensing container.
7. Suggested Quality assessments
 - a. Appearance and feel
 - b. Quantity
 - c. Label: auxiliary labels, storage, BUD, compounded medication

Packaging: Tight, light-resistant container

Estimated Beyond Use Date: 180 days per USP 795*

Labeling: Keep out of reach of children. Use only as directed. Protect from moisture and light.

Stability: Anhydrous formulation.

Note: Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).

Note: All products, except for API(s) are sourced from SpecializedRx only. Any deviation from ingredients used will invalidate the formula.

***Beyond-Use Date should be based on the current USP General Chapter <795>.** Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. 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.

WARNING! Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.

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