

SUGGESTED PROCEDURE

Item	Ketamine 25mg Capsule Size #1	Formula Date	23 April 2024
API(s)	Ketamine Hydrochloride, USP	Procedure No.	P2636
Base	DisperseRx UFP Nasal Base	Revision	R2
Volume/Quantity	100 Capsules	Compound Type	Anhydrous capsule

Rx	Weight (g)	Percent	Comment
Ketamine HCl, USP	2.5g	6.89%	
DisperseRx UFP	33.8g	93.11%	
Total	36.3g	100%	Packing statistic: 363mg DisperseRx in a size #1 capsule

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. Consider batch size and density conversions, if required.
3. Using the principles of Geometric Dilution, mix Ketamine HCl and DisperseRx 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
 - b. Quantity
 - c. Label - auxiliary labels, storage, BUD, compounded medication.

Note: For optimal functionality, SpecializedRx recommends approximately $\geq 75\%$ DisperseRx to be used as filler ($\leq 20\text{-}25\%$ API). Aqueous dilution will vary based on target API concentration in the finished dose.

Note: This preparation is designed for the powder contents of the capsule to be mixed with an appropriate amount of Normal Saline or water for irrigation at time of use and administered via a nasal nebulizer/irrigation device.

Note: A clear solution will be obtained once the preparation has been dispersed and mixed in Normal Saline or Water for Irrigation.

Note: Preparation should be labeled as non-sterile.

Note: According to USP guidelines, "in the absence of a USP-NF compounded Preparation Monograph of CNSP-Specific Stability information," the maximum Beyond Use Date (BUD) for a compounded nonsterile preparation (CNSP) that is a nonaqueous dosage form (excluding nonaqueous oral liquid) with a water activity (Aw) of <0.6 is 180 days.

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: $\geq 90\%$ and $\leq 110\%$ of the theoretically calculated active(s).

*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 compounding and contamination of the preparation by the compounding. 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

SpecializedRx
3787 95th Ave NE, Ste 100
Circle Pines, MN. 55014 USA
888.512.1209
www.specializedrx.com

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.

Disclaimer: SpecializedRx makes no warranties or claims to the safety, accuracy, or efficacy of the above information, expressed or implied given the variations in use, materials, and formulations. SpecializedRx 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 SpecializedRx and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein. This is a copyrighted formula that may not otherwise be distributed, copied or disclosed without SRx's written permission. This formula is subject to SRx intellectual property rights.