

SUGGESTED PROCEDURE

Item	Ketamine 50mg Troche (Flavored)	Formula Date	08 May 2024
API(s)	Ketamine Hydrochloride, USP	Procedure No.	P2572
Base	Techna 10 SF	Revision	R3
Volume/Quantity	30 Troches	Compound Type	Anhydrous Troche

Rx	Weight (g)	Percent	Comment
Ketamine HCl, USP	1.5g	4.18%	100% displacement factor
Techna 10 SF	34.17g	95.31%	Approx. Relative density 1.2g/cm ³
Natural Liquid Flavor Concentrate (WS)	0.18ml	0.5%	To taste
Total	35.85g	100%	Average Techna 10 SF calibration weight per cavity with SmartScripps troche mold is 1.195g

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. Formula may need to be adjusted depending on the size of the mold being used. Most powders are added or deleted at a displacement factor of around 70%. Highly micronized powders or liquids have a displacement factor of 100%. It is recommended that placebos are compounded to determine the average amount of total base required.
2. Accurately weigh and/or measure each ingredient. Consider batch size and density conversions, if required.
3. In an appropriate size beaker, melt Techna 10 base in a hot water bath to 50-55°C, stirring frequently. Keep melted base on the hot water bath. Do not overheat.
4. Slowly add Ketamine HCl powder to melted base to prevent clumping and ensure mixture is uniform before adding additional powder.
5. Add flavor to step 4 and mix well.
6. Allow mixture to cool to between 45-50°C before pouring.
7. Pour mixture into SmartScripps Troche Molds, quickly filling each cavity.
8. Allow to cool at room temperature. Cooling in refrigerator or freezer may result in contraction and surface deformations. Set times may vary but should be between 10-15 minutes.
9. Final preparation should be a molded troche.
10. Transfer the final preparation into an appropriate dispensing container.
11. Suggested Quality assessments
 - a. Appearance and feel
 - b. Quantity
 - c. Label - auxiliary labels, storage, BUD, compounded medication.

Packaging: Tight, light-resistant container, SmartScripps

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. Protect from heat. Store in refrigerator.

Stability: Anhydrous formulation.

Note: Potency Range Recommendation: ≥90% and ≤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 duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounding 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.

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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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