

SUGGESTED PROCEDURE

Item	Methimazole 5mg Klear Gummy (Flavored)	Formula Date	13 May 2024
API(s)	Methimazole, USP	Procedure No.	P2647
Base	Klear Gummy™ Anhydrous	Revision	R2
Volume/Quantity	100 gummies	Compound Type	Anhydrous Gummy

Rx	Weight (g)	Percent	Comment
Methimazole, USP	0.5g	0.41%	
Klear Gummy™	120.89g	99.1%	qs Approximate relative density 1.22g/cm ³
SpecializedRx Natural Liquid Flavor Concentrate (WS)	0.61ml	0.5%	To taste
Total	122g	100%	Average Klear Gummy™ calibration weight per cavity with SmartScripps™ troche mold is 1.22g

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. In an appropriate size beaker, melt Klear Gummy™ base in a hot water bath at 90°C, stirring frequently. Keep melted base on the hot water bath. Do not heat above 100°C as this can cause the base to lose gel strength.
4. Using a mortar and pestle, triturate Methimazole to a fine powder.
5. Sift the powder from Step 4 into the Step 3 melted base and stir until evenly dispersed.
6. Add flavor to step 5 and mix well.
7. Pour Step 6 into mold.
8. Allow Step 6 to congeal at room temperature.
9. Final preparation should be a transparent molded gummy.
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

Average weight for troche when using Klear Gummy™ base with SmartScripps™ mold is 1.22g

Packaging: Tight, light-resistant container. Store in refrigerator.

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.

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

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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