

## SUGGESTED PROCEDURE

Item	Mirtazapine 15mg/ml Suspension	Formula Date	4 June 2024
API(s)	Mirtazapine, 15mg tablets	Procedure No.	P2609
Base	SuspendRx Anhydrous , Sweetened	Revision	R3
Volume/Quantity	10ml	Compound Type	Anhydrous Suspension

Rx	Weight (g)	Percent	Comment
Mirtazapine, 15mg tablets	10 tablets	1.5%	
SRx Flavor, Liquid Oil Soluble	0.05ml (1 drop)	0.5%	To taste
SuspendRx Anhydrous Sweetened	10ml	98%	qs
<b>Total</b>	10ml	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 a mortar and pestle, triturate Mirtazapine tablets to a fine powder
4. Use a minimal amount of SuspendRx to wet powder and levigate to form a viscous, but smooth and uniform paste.
5. Continue adding SuspendRx, geometrically, mixing well after each addition.
6. Transfer to a graduated cylinder.
7. Rinse mortar with SuspendRx, adding rinse to graduated cylinder.
8. QS to final volume with SuspendRx and mix well.
9. Transfer the final preparation into an appropriate dispensing container.
10. Suggested Quality assessments
  - a. Appearance
  - b. Pourability
  - c. Settling
  - d. Quantity
  - e. Resuspendability
  - f. Label - auxiliary labels, storage, BUD, compounded medication.

**Packaging:** Tight, light-resistant container.

**Estimated Beyond Use Date:** 90 days per USP 795\*

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

**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 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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