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SUGGESTED PROCEDURE

Item	Baclofen 10mg Suppository	Formula Date	12 June 2024
API(s)	Baclofen, USP	Procedure No.	P2679
Base	Supposi-Plex V65	Revision	R1
Volume/Quantity	100 (2.4ml RocketMolds)	Compound Type	Anhydrous Suppository

Rx	Weight (g)	Percent	Comment
Baclofen, USP	1g	0.43%	
Supposi-Plex V33	229.4g	99.57%	qs (specific gravity of Supposi-Plex V65 is 0.96
Total	230.4g	100%	Using P= (N x S) – DF where P is the amount of suppository base required, N is the number of prepared suppositories, S is the size of the mold used, D is the amount of drug used and F is the displacement value of the drug.

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. Take into account batch size and density conversions, if required.
3. Add Supposi-Plex V65 base to beaker and gently melt on a hot plate (32°-35°C)
4. Incorporate Baclofen powder and mix well.
5. Allow mixture to cool slightly before pouring.
6. Pour the mixture into RocketMolds and allow to cool at room temperature.
7. Final preparation should be a smooth white to off-white suppository.
8. Suggested Quality assessments
    a. % variability and % deviation from theoretical <10% - (remake if >10%)
    b. Surface appearance and feel
    c. Melting test
    d. Quantity
    e. Label - auxiliary labels, storage, BUD, compounded medication.

Packaging: RocketMolds, refrigerated
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. Not to be taken by mouth
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 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.