SUGGESTED FORMULA

Budesonide 1mg Rapid Dissolve Tablet

Version number: 1.0

Volume or quantity: 100 Tablets

Budesonide, USP (HA103)	0.1 g
Mannitol, USP (MA165)	21 g
Lactose, Anhydrous, NF (LA103)	22 g
Flavor	0.68 g
Polyethylene Glycol 3350, NF (PO125)	24.9 g

SUGGESTED COMPOUNDING PROCEDURES

The flavor should be dry powder type and not aqueous or oleaginous. It is necessary to determine the quantity of filler prior to beginning the preparation of this formula based on calibration of the mold. This formula was developed for preparation in ProMold-RDTM Rapid Dissolve Tablet 96 Count Mold (Cat # 551-83043).

*Adjust amount to measure per water determination results reported on certificate of analysis.

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Blend Budesonide, mannitol, lactose and dry flavor together until fine and uniformly mixed.
4. Separately, reduce the particle size of the polyethylene glycol 3350 to approximately 200 mesh.
5. Lightly blend in the polyethylene glycol 3350 into step 3.
6. Place 686 mg of the powder into the cavities of the mold.
7. Place the mold containing the powder in an oven at 80-90°C for approximately 15-20 minutes. Time may vary depending upon the mold, formulation and oven.
8. Remove from the oven and place in a refrigerator for approximately 5 minutes.
9. Remove from the refrigerator and let set at room temperature.
10. Package and label.
11. Suggested Quality assessments:
    a. color, texture, appearance
    c. mixing and filling/potency studies
    d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air-tight container, at controlled room temperature.

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 from 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.

Beyond-Use Date should be based on the current USP <795> Standards – 180 days for solid dosage forms.

Precautions:
Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (powder-containment hoods) when weighing and mixing.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products 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 Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.
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