SUGGESTED FORMULA

Budesonide 1 mg Tablet Triturate

Version number: 1.0

Volume or quantity: 100 Tablets

Budesonide, Micronized, EP (B1595)	0.1 gm
Polyethylene Glycol 3350, USP (PO125)	1.0 gm
Flavor, Powder	0.5 gm
Lactose, Anhydrous, NF (LA103)	8.4 gm
Alcohol, 190 Proof, USP (ET108)	3 mL
Water, Purified, USP	3 mL

Calibration of the mold using inactive ingredients is recommended prior to preparing this formula. This formulation is based on a mold that holds 100 mg of lactose tablet triturates.

The quantity of alcohol and water is provided to prepare a proper ratio (50/50) – do not use the entire amount to prepare this compound. Use only enough alcohol/water mixture to wet powders to a wet sand consistency (see procedures).

SUGGESTED COMPOUNDING PROCEDURES

1. Gather all the chemicals and supplies.
2. Check label and printed formula versus Rx, calculations, quantity, supplies to be dispensed and document on worksheet.
3. Secure mold to clean, dry, non-porous surface or ointment slab.
4. Weigh budesonide, flavor and lactose, triturate to fine powder and mix thoroughly by geometric dilution, in mortar, with EMP or v-blender until uniform.
5. Transfer step 4 to weigh boat or suitable container.
6. Blend in the polyethylene glycol 3350 geometrically to dry powders and mix well.
7. Mix alcohol and water in syringe.
8. Add alcohol-water mixture drop by drop and mix into powder with spatula, slowly until mixture has a wet sand or dough consistency.
9. Transfer to mold and press mixture into mold cavities with spatula until all cavities are filled.
10. Slide mold across smooth surface to detach and flip mold over.
11. Fill any gaps or crevices with additional moist mixture until all cavities are filled.
12. Detach mold from surface and place on mold pegs and gently push until tablets are raised up on mold pegs.
13. Allow tablets to dry for 2-3 hours.
14. Detach tablets from pegs and inspect for defects, chips, pockets and cracks. Discard any defective tablets.

15. Place cotton in bottom of dispensing container and transfer intact tablets to dispensing container. Packet desiccant may be added to absorb moisture.
16. Package and label.
17. 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 assigned based on the current USP <795> Standards

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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