



SUGGESTED FORMULA

Fluconazole 200mg in Polybase™ Suppositories

Version number: 1.0

Volume or quantity: #100 Suppository

Fluconazole, USP (F1355)	20gm
Polybase™ [Paddock Perrigo]	q.s.

SUGGESTED COMPOUNDING PROCEDURES

*It is important to calibrate the suppositories molds you are using and adjust formulation accordingly

Weigh all ingredients

1. Calculate the required quantity of each ingredient for the total amount to be prepared
2. Accurately weigh and/or measure each ingredient
3. If not previously done, calibrate the mold to be used to determine the quantity of polyethylene glycol (Polybase™) for each suppository (approximately 1gm size), since Fluconazole will displace some of the base
4. Pulverize the required number of Fluconazole tablets or bulk powder
5. Melt the Polyethylene Glycol (Polybase™) to about 55°C
6. Sprinkle the powder from Step4 on the melted base, stirring to mix well
7. Cool slightly, then pour into molds
8. Cool, trim if necessary, package and label
9. Suggested Quality assessments
 - a. % variability & % 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

Package in air tight, light resistant containers and room temperature 25°C

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 (hoods) when weighing and mixing

Hazardous drugs should be handled according to USP <800>, NIOSH standards and pharmacy SOPs. This preparation should be compounded in a biological safety cabinet or compounding aseptic containment isolator. 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 personal protective equipment.

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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