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Suggested Formula

Itraconazole 1% Ophthalmic Ointment
Version number: 1.0
Volume: 10 g

Itraconazole Micronized, USP (I2662)	0.1 g
Dimethyl Sulfoxide, USP (D1258)	2.75 mL
Ophthalmic Ointment, Self Emulsifying (PF)	7.15 g

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.

SUGGESTED COMPOUNDING PROCEDURES

1. Dissolve Itraconazole in warm DMSO (do not heat higher than 40°C) while stirring. Use 1.75 mL if making 10g of final formula.
2. Filter step 1 through 0.2 or 0.22 micron DMSO safe filter into another Luer-lock syringe using a sterile connector. Filter another 1 mL of DMSO to rinse out all of the Itraconazole and the filtrate into the previous solution.
3. In a second luer-lock syringe, of appropriate size, aseptically remove the plunger and transfer the Ophthalmic Ointment, Self Emulsifying (PF) into the syringe.
4. Replace the plunger, invert the syringe and remove air (may warm the ointment to soften).
5. Connect the 2 syringes with a sterile luer-lock to luer-lock connector and push contents back and forth from one syringe to the other to mix thoroughly.
6. Transfer to aseptically to the appropriate sterile dispensing container, or dispense in sterile syringe, with sterile cap.
    a. Appearance
    b. Clarity / visual particulate
    c. Sterility
    d. Label - auxiliary labels, storage, BUD, compounded medication

Store at controlled room temperature.

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high- risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours
Cold Temperature: not more than 3 days
Refer to USP chapter <797>.

If sterility testing has been performed and preparation passes, beyond-use date is estimated to be 30 days based on non-aqueous, topical formulations – USP Chapter <795>.

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.

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.

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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