SUGGESTED FORMULA

Ketotifen Hydrogen Fumarate 0.2mg/mL Syrup, Preserved
Version number: 1.0
Volume: 100 mL

Ketotifen Hydrogen Fumarate, EP (K3012)	0.02 g
Methylparaben, NF (ME163)	0.033 g
Propylparaben, NF (PR133)	0.017 g
Citric Acid, Anhydrous, USP (CI131)	0.21 g
Sodium Phosphate, Dibasic, Dried, USP (SO138)	0.32 g
Alcohol, 190 Proof, USP (ET108)	2 ml
Sucrose, Crystal, NF (SU103)	30 g
Sorbitol, Powder, NF (SO219)	35 g
Water, Purified, USP (W1014)	QS 100 mL

SUGGESTED COMPOUNDING PROCEDURES

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Weigh and/or measure each ingredient accurately.
3. Heat 30 mL of purified water to 90° to 95°C and cool to 30°C and add the methylparaben and propylparaben mixing well.
4. Add the citric acid, sodium phosphate dibasic, sucrose and sorbitol to the aqueous mixture stirring until solution is clear; cool to room temperature.
5. In a separate container dissolve the ketotifen hydrogen fumarate in the alcohol until solution is clear.
6. Add the alcohol mixture slowly to the syrup while stirring at room temperature; avoid entrapment of air in the mixture and mix well.
7. Bring to volume with purified water mixing well.
8. Package and label.
9. Suggested Quality Assessments – follow pharmacy SOPs:
    a. Weight to Volume calculation
    b. Color
    c. Clarity
    d. Label - auxiliary labels, storage, BUD, compounded medication

Store in air tight amber plastic containers refrigerated.

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 the 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 *as directed by the current USP <795>*

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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