

**SUGGESTED FORMULA**

Hydroquinone 8%/ Kojic Acid 1%/ Retinoic Acid 0.1%/ Fluocinolone 0.025%/ Niacinamide 4% Topical Cream

Version number: 1.0

Volume or quantity: 100 gm

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Hydroquinone, USP (HY113)	8gm
Kojic Acid	1gm
Retinoic Acid, USP (R1022)	0.1gm
Fluocinolone, USP	0.025gm
Niacinamide, USP (NI105)	4gm
Butylated Hydroxytoluene, NF (B1196)	0.4gm
Polysorbate 80, NF (PO138)	3mL
Propylene Glycol, USP (PR130)	2.5mL
Sodium Metabisulfite, NF (SO182)	0.3gm
Alcohol 95%, USP (ET108)	XmL
Durabase (B4514)	QS 100gm

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**SUGGESTED COMPOUNDING PROCEDURES**

1. Calculate the required quantity needed for the total amount to be prepared
2. Weigh and/or measure all ingredients
3. Transfer Butylated Hydroxytoluene to mortar and triturate crystals to fine powder
4. Add Hydroquinone, Kojic Acid, Fluocinolone, Niacinamide and Sodium Metabisulfite to mortar and triturate to fine powder
5. Add enough Propylene Glycol to form paste, then add remaining Propylene Glycol
6. Add Polysorbate 80 and mix well
7. Using geometric dilution add Durabase and mix well
8. Process step#7 through ointment mill and/or electronic mortar and pestle to reduce grit
9. Dissolve Retinoic Acid in a small amount of Alcohol 95% and geometrically mix into step#8
10. Package and label
11. Suggested Quality assessments:
  - a. color
  - b. texture
  - c. container
  - d. Label - auxiliary labels, storage, BUD, compounded medication

Store in light resistant 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 should be assigned as directed by the current USP Chapter <795>**

**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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