spectrum® PHARMACY PRODUCTS

800.370.6231
SpectrumRx.com

SUGGESTED FORMULA

Chloroquine Phosphate 161 mg Oral Capsule
Version number: 1.1
Volume or quantity: 100 capsules

Chloroquine Phosphate, USP (C1960)	16.1gm
Lactose, Monohydrate Powder, NF (LA108)	q.s.

This drug may be available as an FDA-approved, commercially manufactured drug product. Compounding of this preparation may be deemed by the FDA as essentially a copy of a commercial product, unless currently on the FDA-drug shortage list or approved to be compounded by state and federal regulators. Compounders are encouraged to document appropriate authority permitting the compounding of this preparation.

This preparation requires thorough mixing of components. Chloroquine Phosphate 161mg is equivalent to Chloroquine 100mg.

It is necessary to determine the quantity of active drug and calibrate empty capsules prior to beginning the preparation of this formula. Reference guides to this process can be found on SpectrumRx.com>Resources>Technical Documents>Formulating Capsules Guide

SUGGESTED COMPOUNDING PROCEDURES

Check Calculations and Weigh all ingredients

1. Geometrically triturate powders together until uniformly mixed avoiding heat of friction
2. Mix powders per pharmacy SOPs – (e.g. geometric dilution, blade, v-blend, RAM™)
3. Fill capsules in vented enclosure (hood)
4. Cap and “snap” each bottom into its lid.
5. Weigh sample capsules to check variability and standard deviation per pharmacy SOPs
6. Bottle and label with prescription label and appropriate auxiliary labels.
7. Suggested Quality assessments
    a. % variability & % deviation from theoretical <10% - (remake if >10%)
    b. Capsule size
    c. Capsule color
    d. Quantity
    e. 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 based on the current issue of the 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.

3/20 JD/RD

Phone: 800.370.6231 | Fax: 732.608.5420 | Internet: SpectrumRx.com | Email: sales@spectrumrx.com