

Guidance on Chloroquine Phosphate

This guidance represents the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Chloroquine phosphate

Dosage Form; Route: Tablet; oral

Recommended Studies:

Chloroquine phosphate tablet is a DESI¹-effective drug for which there are no known or suspected bioequivalence problems, and as such is rated “AA” in the FDA/CDER Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

Analyte to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: EQ 150 mg Base and EQ 300 mg Base, pursuant to 21 CFR 320.22 (c) provided that in vitro dissolution profiles of the proposed products are comparable to those of the reference products

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

¹ Drug Efficacy Study Implementation