

Draft Guidance on Primaquine Phosphate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

- Active Ingredient:** Primaquine phosphate
- Dosage Form; Route:** Tablet; oral
- Recommended Studies:** Two options: BCS waiver or in vivo studies

I. BCS Waiver Option:

It may be possible to request a waiver of in vivo testing of this product, provided that the appropriate documentation regarding high solubility, high permeability, and rapid dissolution, as detailed in the guidance for industry *Waiver of In Vivo Bioavailability and Bioequivalence for Immediate-Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System*, is submitted in the application. You may use the information contained in the approved labeling of the reference product. Peer-reviewed articles may not contain the necessary details of the testing for FDA to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon review of the data submitted in the application.

II. In Vivo Studies:

1. Type of study: Fasting
Design: Single-dose, two-way crossover
Strength: EQ 15 mg base
Subjects: Normal healthy males and nonpregnant females, general population
Additional comments: The prospective study participants should be screened for glucose-6-phosphate dehydrogenase enzyme (G6PD) deficiency prior to enrollment. Subjects found to be G6PD-deficient should not be included in the study. All safety precautions should be followed as per Reference Listed Drug labeling recommendations.

2. Type of study: Fed
Design: Single-dose, two-way crossover
Strength: EQ 15 mg base
Subjects: Normal healthy males and nonpregnant females, general population
Additional comments: same as above

Analyte to measure (in appropriate biological fluid): Primaquine in plasma

Bioequivalence based on (90% CI): Primaquine

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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).