

Draft Guidance on Diltiazem Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Diltiazem hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 120 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: None

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 120 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: None

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

Bioequivalence based on (90% CI): Diltiazem

Waiver request of in vivo testing: 30 mg, 60 mg, and 90 mg based on (i) acceptable bioequivalence studies on the 120 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, 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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Diltiazem tablets, 60 mg, 90 mg, and 120 mg are scored. For additional information on the evaluation of scored tablets, refer to the FDA Guidance *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.