

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Amlodipine Besylate
October 2024

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Active Ingredient: Amlodipine besylate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 2.5 mg Base, EQ 5 mg Base, EQ 10 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 10 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of amlodipine. Alternatively, a parallel study design may be considered.

Analyte to measure: Amlodipine in plasma

Bioequivalence based on (90% CI): Amlodipine

Waiver request of in vivo testing: EQ 2.5 mg Base, and EQ 5 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 10 mg Base 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 in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.