

Guidance on Amlodipine Besylate

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Active ingredient: Amlodipine Besylate

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 10 mg
Subjects: Normal healthy males and females, general population.
Additional Comments:
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2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 10 mg
Subjects: Normal healthy males and females, general population.
Additional comments:
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Analytes to measure: Amlodipine in plasma

Bioequivalence based on (90% CI): Amlodipine

Waiver request of in-vivo testing: 2.5 mg, and 5 mg based on (i) acceptable bioequivalence studies on the 10 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.