

## Draft Guidance on Nifedipine

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:** Nifedipine

**Form/Route:** Extended Release Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way, crossover *in-vivo*  
Strength: 90 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional Comments:

- 
2. Type of study: Fed  
Design: Single-dose, two-way, crossover *in-vivo*  
Strength: 90 mg  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments:
- 

**Analytes to measure:** Nifedipine in plasma

**Bioequivalence based on (90% CI):** Nifedipine

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

In addition to the method above, for modified release products, dissolution profiles on 12 dosage units each of test and reference products generated using USP Apparatus I at 100 rpm and/or Apparatus II at 50 rpm in at least three dissolution media (pH 1.2, and pH 4.5 and 6.8 buffer) should be submitted in the application. Agitation speeds may have to be increased if appropriate. It is acceptable to add a small amount of surfactant, if necessary. Please include early sampling times of 1, 2, and 4 hours and continue every 2 hours until at least 80% of the drug is released, to provide assurance against premature release of drug (dose dumping) from the formulation.