This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Orally Disintegrating Tablet/Oral

**Recommended studies:** 2 studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-way crossover in-vivo  
   **Strength:** 25 mg/250 mg  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional Comments:** The whole tablet should be placed on the tongue and allowed to disintegrate for 30 seconds. After 30 seconds, all subjects should consume 240 mL of water.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-way crossover in-vivo  
   **Strength:** 25 mg/250 mg  
   **Subjects:** Healthy males and nonpregnant females, general population  
   **Additional Comments:** See comments above

**Analytes to measure (in appropriate biological fluid):** Carbidopa and Levodopa in plasma

**Bioequivalence based on (90% CI):** Carbidopa and Levodopa

**Waiver request of in-vivo testing:** 10 mg/100 mg and 25 mg/100 mg based on (i) acceptable bioequivalence studies on the 25 mg/250 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:**

Please note that a Dissolution Methods Database is available to the public at the OGD website at [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). 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.

*Recommended Feb 2010*