

*Contains Nonbinding Recommendations*  
**Draft Guidance on Phelzine Sulfate**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

**Form/Route:** Tablet/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 15 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments:
  - During the bioequivalence study, subjects should not receive the following foods: high protein food that has undergone protein breakdown by aging, fermentation, pickling, smoking, or bacterial contamination; cheeses; liver; yeast extract; brewer's yeast; dry sausage (including Genoa salami, hard salami, pepperoni, and Lebanon bologna); pods of broad beans (fava beans); yogurt; caffeine; and chocolate.
  - Subjects on regimens of the following drugs should be excluded from the bioequivalence study: sympathomimetic drugs and related compounds; narcotics which are CNS depressants; meperidine; guanethidine; bupropion hydrochloride; and serotonergic agents.
  - Study subjects should not consume alcoholic beverages during the study or within 7 days of study initiation.
  - Study subjects should not take dextromethorphan during the study or within 7 days of study initiation.

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: 15 mg  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: Please see comments above.
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**Analytes to measure (in appropriate biological fluid):** Phelzine in plasma

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

**Waiver request of in-vivo testing:** Not Applicable

**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/>. 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.