Contains Nonbinding Recommendations

Guidance on Phenytoin

This guidance represents 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: Phenytoin

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 125 mg/ 5 mg (dose 300 mg)
   Subjects: Normal healthy males and females, general population.
   Additional Comments: Washout period of at least 14 days. The single dose studies for fasting and fed can be conducted as single dose, two- treatment, four periods, replicated design. The strength(s) designated in the Orange Book as the RLD should be used in the studies.

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 125 mg/ 5 mg (dose 300 mg)
   Subjects: Normal healthy males and females, general population.
   Additional comments: Please see comments above.

Analytes to measure: Phenytoin in plasma

Bioequivalence based on (90% CI): Phenytoin

Waiver request of in-vivo testing: Not applicable.

Dissolution test method and sampling times:

Please conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the USP method.

A dosage unit for a suspension is the labeled strength (5 ml). A total of 12 units from 12 different bottles should be used.