Draft Guidance on Diphenhydramine Citrate and Ibuprofen

Active ingredient: Diphenhydramine Citrate and Ibuprofen
Form/Route: Tablets/Oral
Recommended studies: 1 study

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 200 mg/38 mg
   Subjects: Healthy males and nonpregnant females, general population.
Additional comments:

Analytes to measure (in appropriate biological fluid): Diphenhydramine and ibuprofen in plasma

Bioequivalence based on (90% CI): Diphenhydramine and Ibuprofen

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.

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