

Draft Guidance on Diphenhydramine Hydrochloride and Naproxen Sodium

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Active Ingredient: Diphenhydramine hydrochloride; naproxen sodium

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in vivo
Strength: 25 mg/220 mg (recommended dose – 2 x 25 mg/220 mg tablets)
Subjects: Normal healthy males and nonpregnant females, general population

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 25 mg/220 mg (recommended dose – 2 x 25 mg/220 mg tablets)
Subjects: Normal healthy males and nonpregnant females, general population

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

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

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. The 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 abbreviated new drug application (ANDA).