

Guidance on Acetaminophen; Butalbital; Caffeine; Codeine Phosphate

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Active Ingredient: Acetaminophen; Butalbital; Caffeine; Codeine Phosphate

Dosage Form; Route: Capsules; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 325 mg; 50 mg; 40 mg; 30 mg
Subjects: Healthy males and non-pregnant, non-lactating females, general population
Additional comments: Female subjects should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 325 mg; 50 mg; 40 mg; 30 mg
Subjects: Healthy males and non-pregnant, non-lactating females, general population
Additional comments: See comments above.

Analytes to measure (in appropriate biological fluid): Butalbital and codeine in plasma

Bioequivalence based on (90% CI): Butalbital and codeine

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 web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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).