

Draft Guidance on Acetaminophen; Butalbital; Caffeine; Codeine Phosphate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the 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: 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 nonpregnant females, general population.
Additional comments: None

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 nonpregnant females, general population.
Additional comments: None

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 N/A

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/>. 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).