

## **Draft Guidance on Acetaminophen; Codeine Phosphate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Acetaminophen; Codeine phosphate

**Dosage Form; Route:** Tablet; oral

### **Recommended Studies:**

Acetaminophen; Codeine Phosphate Tablet is TE-coded “AA” in the FDA/CDER’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”), which indicates that there are no known or suspected bioequivalence problems for Acetaminophen; Codeine Phosphate Tablets. Pursuant to Section 21 CFR § 320.22 (c), the waiver of in vivo BE study requirements for Acetaminophen; Codeine Phosphate Tablets may be granted.

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**Analytes to measure (in appropriate biological fluid):** Not Applicable

**Bioequivalence based on (90% CI):** Not Applicable

**Waiver request of in vivo testing:** 300 mg; 7.5 mg, 300 mg; 15 mg, 300 mg; 30 mg, and 300 mg; 60 mg pursuant to 21 CFR § 320.22 (c) provided that the in-vitro dissolution profiles of the proposed product is comparable to those of the reference product.

**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).