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*Draft - Not for Implementation*

**Draft Guidance on Acetaminophen; Ibuprofen**

**August 2022**

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This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic acetaminophen; ibuprofen.

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**Active Ingredients:** Acetaminophen; Ibuprofen

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

**Recommended Studies:** Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 250 mg; 125 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: None
2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 250 mg; 125 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: None

**Analytes to measure:** Acetaminophen and ibuprofen in plasma

**Bioequivalence based on (90% CI):** Acetaminophen and ibuprofen

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the ANDA.

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