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.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

In June 2015, FDA issued a draft product-specific guidance for industry on generic enzalutamide. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

**Active Ingredient:** Enzalutamide

**Dosage Form; Route:** Capsule; oral

**Recommended Studies:** Two studies

1. **Type of study:** Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 40 mg
   Subjects: Healthy males
   Additional comments: Exclude subjects with a history of or risk factors for seizure. Subjects with female partners of reproductive potential should use effective contraception during the study and for three months after the last dose. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of enzalutamide. Alternatively, a parallel study design may be considered.
2. Type of study: Fed  
   Design: Single-dose, two-treatment, two-period crossover in vivo  
   Strength: 40 mg  
   Subjects: Healthy males  
   Additional comments: See comments above.

**Analyte to measure:** Enzalutamide in plasma

**Bioequivalence based on (90% CI):** Enzalutamide

**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/](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 evaluation of the abbreviated new drug application.

**Revision History:** Recommended June 2015; Revised February 2022

**Unique Agency Identifier:** PSG_203415