

*Contains Nonbinding Recommendations*

**Draft Guidance on Ulipristal Acetate**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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:** Ulipristal Acetate

**Form/Route:** Tablets/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: 30 mg  
Subjects: Healthy nonpregnant females, general population.  
Additional Comments:

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: 30 mg  
Subjects: Healthy nonpregnant females, general population.  
Additional Comments:

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**Analytes to measure (in appropriate biological fluid):** Ulipristal acetate in plasma

**Bioequivalence based on (90% CI):** Ulipristal acetate

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

**Dissolution test method and sampling times:** Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.

**Information Regarding Long Half-Life Drugs**

Ulipristal Acetate has a long terminal elimination half-life. Please ensure adequate washout periods between treatments in the crossover studies. Please also consider using a parallel study design due to Ulipristal Acetate's long half-life. For a long half-life drug product, an AUC truncated to 72 hours may be used in place of AUC<sub>0-t</sub> or AUC<sub>0-inf</sub> if the drug demonstrates low

intrasubject variability in distribution and clearance. Please collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration ( $C_{\max}$ ) and time to reach peak concentration ( $t_{\max}$ ).