Draft Guidance on Ulipristal Acetate

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:

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

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 AUC₀₋₅ or AUC₀₋₉ if the drug demonstrates low

Recommended Dec 2012
intrasubject variability in distribution and clearance. Please collect sufficient blood samples in
the bioequivalence studies to adequately characterize the peak concentration ($C_{\text{max}}$) and time to
reach peak concentration ($t_{\text{max}}$).