Active ingredient: Ethinyl Estradiol; Norethindrone

Form/Route: Chewable Tablets/Oral

Recommended study: 2 studies

1. Type of study: Fasting Design: Single-dose, two-way crossover in-vivo
   Strength: 0.035 mg/0.4 mg
   Subjects: Healthy nonpregnant female subjects who are not taking hormonal contraceptives.
   Additional Comments:

2. Type of study: Fed Design: Single-dose, two-way crossover in-vivo
   Strength: 0.035 mg/0.4 mg
   Subjects: Healthy nonpregnant female subjects who are not taking hormonal contraceptives.
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Ethinyl estradiol and norethindrone in plasma

Bioequivalence based on (90% CI): Ethinyl estradiol and norethindrone

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.