Draft Guidance on Ethinyl Estradiol; Norethindrone

Active ingredient: Ethinyl Estradiol; Norethindrone
Form/Route: Tablets/Oral
Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 0.035 mg/1 mg
   Subjects: Healthy nonpregnant females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 0.035 mg/1 mg
   Subjects: Healthy nonpregnant females, general population.
   Additional comments:

Analytes to measure: Ethinyl Estradiol and Norethindrone in plasma

Bioequivalence based on (90% CI): Ethinyl Estradiol and Norethindrone

Waiver request of in-vivo testing: 0.035 mg/0.5 mg based on (i) acceptable bioequivalence studies on the 0.035 mg/1 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

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.

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