**Draft Guidance on Ethinyl Estradiol and Norethindrone Acetate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Ethinyl estradiol; Norethindrone acetate

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

**Recommended Studies:** Two studies

1. **Type of study:** Fasting
   **Design:** Single-dose, two-way crossover in-vivo
   **Strength:** 0.02 mg; 1 mg
   **Subjects:** Healthy non-pregnant, non-lactating females.
   **Additional Comments:** None

2. **Type of study:** Fed
   **Design:** Single-dose, two-way crossover *in-vivo*
   **Strength:** 0.02 mg; 1 mg
   **Subjects:** Healthy non-pregnant, non-lactating females.
   **Additional comments:** None

**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:** N/A

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products.

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