

Draft Guidance on Ethinyl Estradiol; Norethindrone Acetate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Tablet, chewable; oral

Recommended Studies: Three studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 0.01 mg/1 mg Ethinyl Estradiol and Norethindrone Acetate
Subjects: Healthy non-pregnant females, general population.
Additional Comments: 1. Subjects should not be taking hormonal contraceptives. 2. The drug product should be administered as specified in the labeling, i.e., chewed and swallowed with water.

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 0.01 mg/ 1 mg Ethinyl Estradiol and Norethindrone Acetate
Subjects: Healthy non-pregnant females, general population. Additional Comments: Please see comments above.

3. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 0.01mg Ethinyl Estradiol
Subjects: Healthy non-pregnant females, general population.
Additional Comments: 1. Subjects should not be taking hormonal contraceptives. 2. The drug product should be administered as specified in the labeling, i.e., swallowed whole with water.

Analytes to measure (in appropriate biological fluid): Ethinyl Estradiol and Norethindrone in plasma

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

Waiver request of in-vivo testing: Not Applicable

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/>. 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 abbreviated new drug application (ANDA).