

Draft Guidance on Ethinyl Estradiol; Norethindrone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Ethinyl Estradiol; Norethindrone

Form/Route: Chewable Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 0.025 mg/0.8 mg
Subjects: Healthy non-pregnant females who are not taking hormonal contraceptives. Additional Comments: The drug product should be administered as specified in the labeling, i.e., chewing without water.

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 0.025 mg/0.8 mg
Subjects: Healthy non-pregnant females who are not taking hormonal contraceptives.
Additional Comments: The drug product should be given in the manner specified in the labeling, i.e., chewing without water.

Please refer to the Amantadine Hydrochloride Tablet Guidance for additional information regarding fed studies.

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.