

Draft Guidance on Ethinyl Estradiol; Etonogestrel

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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; Etonogestrel

Form/Route: Ring/Vaginal

Recommended studies: 1 study

Type of study: Bioequivalence (BE) Study with Pharmacokinetic (PK) Endpoints

Design: Single-dose, two-treatment, two-period crossover in vivo

Strength: 0.015 mg/24 hr; 0.12 mg/24 hr

Subjects: Nonpregnant, nonsmoking healthy females aged 18 to 45 years of age and without any contraindication for contraceptive steroids.

Additional comments:

1. If the test product is not Q1/Q2 to the Reference Listed Drug (RLD) an additional clinical study or studies to identify any increased risk posed by the differing inactive ingredients or formulation differences between the test product and the RLD may be necessary.
2. Depending upon the specific clinical study or studies recommended, e.g., vaginal safety study, a test drug product that is not Q1/Q2 to the RLD may need to be submitted in a NDA to the Office of New Drugs.

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

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

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.