Contains Nonbinding Recommendations

Draft Guidance on Desogestrel; Ethinyl Estradiol

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 0.15 mg; 0.025 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 0.15 mg; 0.025 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional Comments:

Analytes to measure (in appropriate biological fluid): Ethinyl Estradiol and the active metabolite of Desogestrel, Etonogestrel (ENG) (3-ketodesogestrel) in plasma.

Bioequivalence based on (90% CI): Both Ethinyl Estradiol and Etonogestrel (ENG) (3-keto-desogestrel)

Waiver request of *in-vivo* testing: 0.125 mg/0.025 mg and 0.1 mg/0.025 mg based on (i) acceptable bioequivalence studies on the 0.15 mg/0.025 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 **Dissolution Method Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. 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.