Contains Nonbinding Recommendations

Draft Guidance on Ethinyl Estradiol and Levonorgestrel

Active ingredient: Ethinyl Estradiol and Levonorgestrel

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover *in-vivo*
Strength: 0.03 mg/0.15 mg
Subjects: Normal healthy males and females, general population.
Additional Comments:

Analytes to measure (in appropriate biological fluid): Ethinyl estradiol and levonorgestrel in plasma. Only ethinyl estradiol for the single component tablet in Seasonique.

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

Waiver request of in-vivo testing:

Bioequivalence studies conducted on Seasonique® (ethinyl estradiol and levonorgestrel) Tablets, 0.03 mg/0.15 mg, may be referenced to support a request for a waiver of evidence of *in vivo* bioequivalence for Seasonale® (ethinyl estradiol and levonorgestrel) Tablets, 0.03 mg/0.15 mg. Please submit separate applications for each RLD.

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.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.