Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Desogestrel; Ethinyl Estradiol

October 2024

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Active Ingredients: Desogestrel; Ethinyl estradiol

Dosage Form: Tablet

Route: Oral-28

Strengths: 0.15 mg, N/A; 0.02 mg, 0.01 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 0.15 mg; 0.02 mg desogestrel; ethinyl estradiol
   Subjects: Healthy non-pregnant, non-lactating females
   Additional comments: None

2. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 0.01 mg ethinyl estradiol
   Subjects: Healthy non-pregnant, non-lactating females
   Additional comments: None

Analytes to measure: Active metabolite of desogestrel, 3-ketodesogestrel, and ethinyl estradiol in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for area under the curve (AUC) and maximum concentration (C_{max}).

Bioequivalence based on (90% CI): 3-ketodesogestrel and ethinyl estradiol

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended August 2008; Revised July 2009, October 2024

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*