Contains Nonbinding Recommendations

Draft Guidance on Elvitegravir

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Elvitegravir

Dosage Form; Route: Tablet; oral

Recommended Studies: Two in vivo studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 150 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional comments: Females should not be pregnant or breastfeeding

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 150 mg
   Subjects: Healthy males and non-pregnant females, general population
   Additional comments: See comments above

Analytes to measure (in appropriate biological fluid): Elvitegravir in plasma

Bioequivalence based on (90% CI): Elvitegravir

Waiver request of in vivo testing: 85 mg, based on (i) acceptable bioequivalence studies on the 150 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).