Contains Nonbinding Recommendations

Draft Guidance on Raltegravir Potassium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Dosage Form; Route: Chewable tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 100 mg base (recommended dose: 100 mg)
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments: The chewable tablets should be swallowed whole with about 8 ounces (240 mL) of water.

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 100 mg base (recommended dose: 100 mg)
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments: See comment above

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

Bioequivalence based on (90% CI): Raltegravir

Waiver request of in vivo testing: EQ 25 mg base based on (i) acceptable bioequivalence studies on the 100 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations across both strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website 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).

For additional information on the evaluation of scored tablets, please refer to the CMC guidance for industry “Tablet Scoring: Nomenclature, Labeling and Data” at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf