

Draft Guidance on Raltegravir Potassium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Raltegravir potassium

Dosage Form; Route: Tablet; oral

Recommended Studies: Four studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: Eq 400 mg base
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: Eq 400 mg base
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

3. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: Eq 600 mg base
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

4. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: Eq 600 mg base
Subjects: Males and non-pregnant, non-lactating females, general population.
Additional Comments: None

Analyte to measure (in appropriate biological fluid): Raltegravir in plasma.

Bioequivalence based on (90% CI): Raltegravir

Waiver request of in-vivo testing: Not applicable

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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).