Active Ingredient: Everolimus

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 5 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

Analytes to measure (in appropriate biological fluid): Everolimus in whole blood

Bioequivalence based on (90% CI): Everolimus

Waiver request of in vivo testing: 2.5 mg, 7.5 mg, and 10 mg based on (i) acceptable bioequivalence studies on the 5 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).