Active ingredient: Ranitidine Hydrochloride
Form/Route: Tablets/Oral
Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 150 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 150 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:
   Please note that Ranitidine Tablets, 75 mg, and 150 mg, are the subject of two separate reference products. Two separate applications must be submitted. It may not be necessary to conduct fasting and fed bioequivalence studies on the 75-mg strength provided that the fasting and fed bioequivalence studies on the 150-mg strength are acceptable.

Analytes to measure: Ranitidine in plasma

Bioequivalence based on (90% CI): Ranitidine

Waiver request of in-vivo testing: 75 mg regular and 150 mg cool mint tablets are eligible for a waiver of in-vivo bioequivalence testing based on (i) acceptable bioequivalence studies on the 150 mg regular strength, (ii) acceptable in vitro dissolution testing for all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times:

Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.

Recommended Nov 2009