Contains Nonbinding Recommendations

Draft Guidance on Ranitidine Hydrochloride

Active ingredient: Ranitidine Hydrochloride

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 300 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 300 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

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

Bioequivalence based on (90% CI): Ranitidine

Waiver request of *in-vivo* testing: 150 mg based on (i) acceptable bioequivalence studies on the 300 mg 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 Method 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.