Contains Nonbinding Recommendations

Draft Guidance on Ranitidine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Effervescent Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 25 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: The following passage is reproduced from the Dosage and Administration section of the labeling:
   Tablets should not be chewed, swallowed whole, or dissolved on the tongue. Dissolve 1 tablet in no less than 5 mL (1 teaspoonful) of water in an appropriate measuring cup. Wait until the tablet is completely dissolved before administering the solution.

   Subsequently, after swallowing the solution, any residue should be re-suspended in 240 mL of water and swallowed by the subjects.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 25 mg
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please see comments above.

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

Bioequivalence based on (90% CI): Ranitidine

Waiver request of in-vivo testing: N/A

Dissolution test method and sampling times:
Please note that **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.