

Draft Guidance on Ranitidine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

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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.