

Guidance on Famotidine

This guidance represents 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: Famotidine

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 40 mg
Subjects: Normal healthy males and females, general population
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 40 mg
Subjects: Normal healthy males and females, general population
Additional comments:

Analytes to measure: Famotidine in plasma

Bioequivalence based on (90% CI): Famotidine

Waiver request of in-vivo testing: 10 mg and 20 mg based on (i) acceptable bioequivalence studies on the 40 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Note: Separate applications should be submitted for the prescription (Rx) and over the counter (OTC) products. You may request a waiver of in-vivo bioequivalence testing for the OTC product, if you conduct the studies on the Rx product, submit acceptable dissolution data on all strengths and the formulations of the products are proportional. Please cross-reference in the OTC application the studies conducted for the Rx product.

Dissolution test method and sampling times:

Please conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.