

Draft Guidance on Famotidine

October 2024

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Active Ingredient: Famotidine

Dosage Form: Tablet

Route: Oral

Strengths: 10 mg, 20 mg, 40 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 40 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Famotidine in plasma

Bioequivalence based on (90% CI): Famotidine

Waiver request of in vivo testing: 10 mg and 20 mg strengths based on (i) acceptable bioequivalence study on the 40 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.