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Draft Guidance on Famotidine

October 2024

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Active Ingredient: Famotidine

Dosage Form: Tablet, orally disintegrating

Route: Oral

Strengths: 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: The orally disintegrating tablet should be placed on the tongue, allowed to disintegrate, and swallowed without water.

Analyte to measure: Famotidine in plasma

Bioequivalence based on (90% CI): Famotidine

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

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 both 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.*