Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Calcium Carbonate; Famotidine; Magnesium Hydroxide

October 2024

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Active Ingredients: Calcium carbonate; Famotidine; Magnesium hydroxide

Dosage Form: Tablet, chewable

Route: Oral

Strength: 800 mg; 10 mg; 165 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: 800 mg; 10 mg; 165 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comment: Tablets should be chewed, then swallowed without water.

Analyte to measure: Famotidine in plasma

Bioequivalence based on (90% CI): Famotidine

Waiver request of in vivo testing: Berry flavored and tropical fruit-flavored chewable tablets based on (i) acceptable bioequivalence study on the mint-flavored chewable tablets, (ii) acceptable in vitro dissolution testing of all flavors for all three components (calcium carbonate, famotidine, and magnesium hydroxide), and (iii) proportional similarity of formulations in their active and inactive ingredients, except for the flavoring and coloring agents

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 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.*