Contains Nonbinding Recommendations

Draft Guidance on Calcium Carbonate; Famotidine; Magnesium Hydroxide

Active Ingredient: Calcium carbonate; Famotidine; Magnesium hydroxide

Dosage Form; Route: Tablet; chewable; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 800 mg/10 mg/165 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Tablets should be chewed completely before swallowing

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 800 mg/10 mg/165 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): 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 studies on the mint-flavored chewable tablets, (ii) the formulations are proportionally similar in their active and inactive ingredients, except for the flavoring and coloring agents, and (iii) acceptable in vitro dissolution testing of all flavors for all three components (calcium carbonate, famotidine, and magnesium hydroxide)

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all flavors of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).