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Draft – Not for Implementation

Draft Guidance on Calcium Carbonate; Famotidine; Magnesium Hydroxide

November 2022

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Active Ingredients: Calcium carbonate; Famotidine; Magnesium hydroxide

Dosage Form; Route: Tablet, chewable; oral

Recommended Studies: Two in vivo bioequivalence studies 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: Males and non-pregnant, non-lactating females, general population
   Additional comment: Tablets should be chewed, then swallowed without water.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 800 mg; 10 mg; 165 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comment: See comment above.

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 studies 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 and reference products. Specifications will be determined upon review of the Abbreviated New Drug Application (ANDA).

Revision History: Recommended June 2015; Revised November 2022

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