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APPLICATION NUMBER: 020902

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

Clinical Pharmacology and Biopharmaceutics Review

NDA:	20-902
Famotidine 10 mg Gelatin-coated tablets (Pepcid AC Gelcaps®)	
Submission Date:	30 September 1997 18 June 1998
Sponsor:	Johnson & Johnson O Merck , Fort Washington, PA
Type of Submission:	New Drug Application
Reviewer:	Michael J. Fossler

JUL 27 1998

Submission

The submission dated 9/30/97 (amended 6/18/98) is a new drug application for Pepcid AC Gelcaps, a proposed alternative to the currently-marketed film-coated tablet. The firm has submitted the results of a single-dose bioequivalence study comparing the gelcap formulation to the film-coated tablet. Comparative dissolution data were also submitted.

Study 085: A Single-Dose, Open-Label, Two-Period Crossover Study to Assess the Bioequivalence of Famotidine 10 mg Gelcaps Compared to Famotidine 10 mg Film-coated Tablets

Study Design

This was a single-dose randomized crossover trial comparing the currently-marketed 10 mg OTC film-coated tablet to a new gelcap formulation. Twenty-four normal volunteers (14 men, 10 women) were given a single 10 mg dose of one of the formulations after an overnight fast. Plasma samples were drawn over 24 hours. Each study was separated by a 5-7 day washout before crossing over to the opposite formulation. All volunteers completed the study.

Assay



Results

The results of the study are shown in Table 2. The gelcap formulation is clearly bioequivalent to the currently-marketed film-coated tablet, as the ratios of test/reference for AUC(0-last), AUC(0-inf.) and Cmax are well within the 80-125% range. The AUC(0-last) values are > 95% of the AUC(0-inf.) values, indicating that sampling was carried out for a sufficient time period. Figure 1 depicts the mean concentrations for both formulations. The two curves are superimposable.

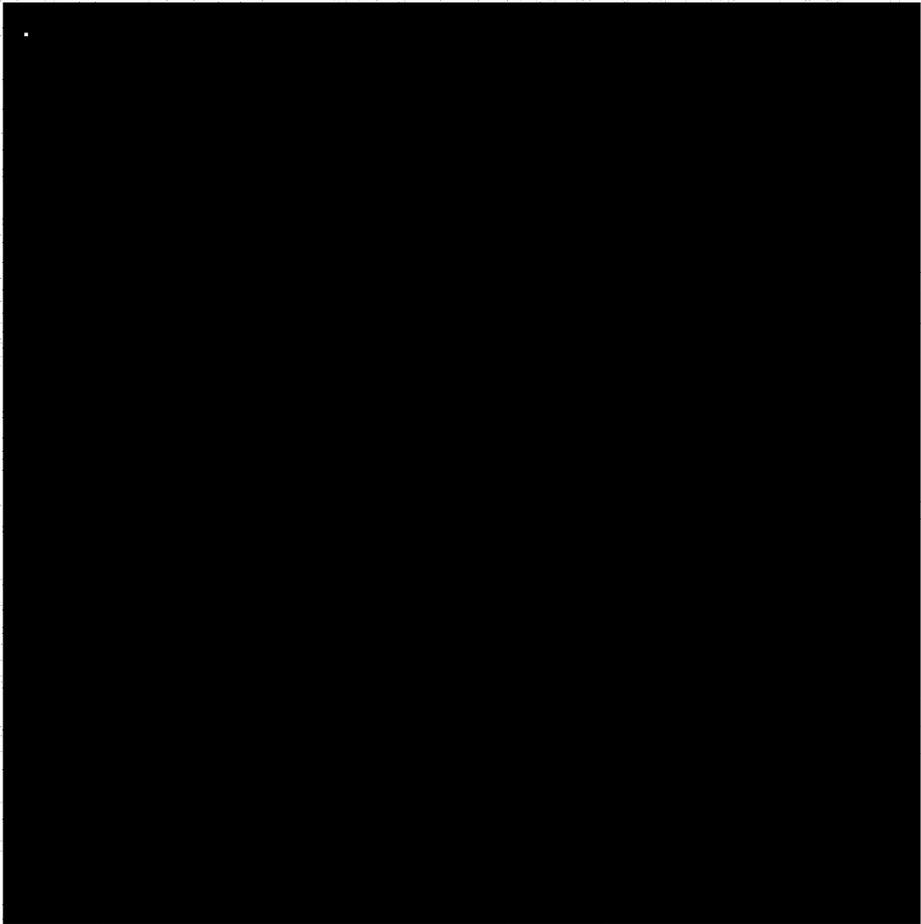


Table 2: Summary of the results for Study 085.

Parameter	Back-Transformed Mean Ratios (90% CI)
AUC(0-last) (ng•hr/ml)	105 (93.9-117)
AUC(0-inf.) (ng•hr/ml)	105 (93.9-117)
C _{max} (ng/ml)	107 (94.5-122)

[†]ratio of the test (gelcap)/reference (film-coated tablet)