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Bioequivalence Healthy Volunteers Case Study

Bioequivalence study comparing XXXXX XX mg tablet commerical formulation (test) and XXXXX XX mg tablet development formulation (reference) in healthy male and female subjects under fasted conditions

Clinical Pharmacology of Miami

Phase: I
Indication: Diabetes
Individuals Enrolled: Healthy males and females between 18 and 55 years of age; at least 40% of each gender included
Study Duration: 6 weeks from FPFV to LPLV
Enrollment Period: 4 weeks
# of Subjects: 152 Screened, 76 Enrolled, 12 Alternates, 1 Dropped
Screen Failure Rate: 42%
Inpatient Period: 4 periods with 2 overnight stays per period; 1,216 Total Bed Nights

Key Elements:

- Inpatient
- Fast Enrollment
- Large Cohorts
- High Retention

OBJECTIVES

Primary

To determine the bioequivalence of a single dose of the commercial XXX mg tablet XXX compared to the development of XXX mg tablet of XXX under fasting conditions in healthy male and female subjects.

Secondary

To evaluate the single-dose pharmacokinetics of XXX and its main metabolite XXX following administration of a single XXX mg tablet or XXX mg tablet in healthy male and female subjects under fasting conditions.
To evaluate safety and tolerability of a single dose XXX mg tablet XXX compared to a single XXX mg tablet administered under fasted conditions in healthy male and female subjects.

Method of Administration: Oral
Lab Assessments: Screening, PK

Pharmacokinetics

By subject / Treatment Period 1	14
By subject / Treatment Period 2	14
By subject / Treatment Period 3	14
By subject / Treatment Period 4	14
Total by subject	56
Total Number of Samples Collected:	4,256

"You have all been a pleasure to work with. I have appreciated your professionalism and diligence. There is more work to be done for us at XXXX, and the anxiety will continue a bit longer for some, but due to CPMI's significant contribution a lot of the weight has been removed."

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