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

**Key Elements:**

- Inpatient
- Fast Enrollment
- Large Cohorts
- High Retention

Clinical Pharmacology of Miami  
 Kenneth Lasseter, M.D.

**Phase:** I

**Indication:** Diabetes

**Individuals Enrolled:** Healthy males and females between 18 and 55 years of age; at least 40% of each gender included

**Start Date:** July 2017

**Study Duration:** 6 weeks from PPFV 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

**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.”

Medical Monitor  
 Top 10 Pharmaceutical Company