

SYNOPSIS

Name of Sponsor/Company: Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	Page 1 of 2	Mutual Pharmaceutical Company, Inc <i>This report is the property of Mutual Pharmaceutical Company, Inc, and may not be used without the permission of Mutual Pharmaceutical Co., Inc.</i>
Name of Finished Product: Zolpidem Tartrate Tablets, 10mg	Report Date: June 2004	
Name of Active Ingredient: Zolpidem Tartrate	Final Report Number: 04064	
Title of Study: A Randomized, Two-Way Crossover, Single-Dose, Open-Label Study to Evaluate the Relative Bioequivalence of a Test Tablet Formulation of Zolpidem Tartrate (10mg), Compared to an Equivalent Dose of a Commercially Available Reference Listed Drug Product (Ambien®, Sanofi-Synthelabo Inc.) in 38 Fasted, Healthy Adult Subjects		
Investigators: Irwin Plisco, M.D., Principal Investigator		
Study Center(s): Gateway Medical Research Inc. (Clinical) Frontage Laboratories, Inc. (Bioanalytical) 400 Fountain Lakes Blvd 100 Grove Road St. Charles, MO 63301 Thorfare, NJ 08086		
Study dates: 5/8/04 – 5/15/04	Phase of development: Phase 1	
Objectives: The objective of this randomized, single-dose, two-way crossover evaluation is to compare the bioequivalence of a test zolpidem tartrate formulation (Mutual Pharmaceutical Co., Inc.) to an equivalent oral dose of the commercially available zolpidem tartrate (Ambien®, Sanofi-Synthelabo Inc.) in a test population of 38 adult subjects under fasted conditions.		
Number of patients: enrolled: 38 completed: 31		
Test product (A): Mutual Pharmaceutical's Zolpidem Tartrate Tablets Dose: 10mg Mode of administration: Oral Batch number: BB 725 0124 Reference product (B): Ambien® Tablets Dose: 10mg Mode of administration: Oral Batch number: TG03C		

Name of Sponsor/Company: Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	Page 2 of 2	Mutual Pharmaceutical Company, Inc <i>This report is the property of Mutual Pharmaceutical Company, Inc, and may not be used without the permission of Mutual Pharmaceutical Co., Inc.</i>																
Name of Finished Product: Zolpidem Tartrate Tablets, 10mg	Report Date: June 2004																	
Name of Active Ingredient: Zolpidem Tartrate	Final Report Number: 04064																	
Criteria for evaluation: Bioequivalence																		
SUMMARY CONCLUSIONS																		
<p>Bioequivalence: The study successfully demonstrated the bioequivalence of the Test and the Reference products with respect to CMAX, AUCT, and AUCI under fed conditions. The results are summarized below:</p>																		
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th data-bbox="310 709 597 745">PK parameters</th> <th data-bbox="597 709 812 745">T/R Ratio</th> <th data-bbox="812 709 1073 745">Lower 90% C.I.</th> <th data-bbox="1073 709 1334 745">Upper 90% C.I.</th> </tr> </thead> <tbody> <tr> <td data-bbox="310 745 597 781">CMAX (ng/mL)</td> <td data-bbox="597 745 812 781">97.2%</td> <td data-bbox="812 745 1073 781">88.8%</td> <td data-bbox="1073 745 1334 781">106.4%</td> </tr> <tr> <td data-bbox="310 781 597 816">AUCT (ng·h/mL)</td> <td data-bbox="597 781 812 816">98.3%</td> <td data-bbox="812 781 1073 816">90.1%</td> <td data-bbox="1073 781 1334 816">107.3%</td> </tr> <tr> <td data-bbox="310 816 597 852">AUCI (ng·h/mL)</td> <td data-bbox="597 816 812 852">98.2%</td> <td data-bbox="812 816 1073 852">89.7%</td> <td data-bbox="1073 816 1334 852">107.5%</td> </tr> </tbody> </table>			PK parameters	T/R Ratio	Lower 90% C.I.	Upper 90% C.I.	CMAX (ng/mL)	97.2%	88.8%	106.4%	AUCT (ng·h/mL)	98.3%	90.1%	107.3%	AUCI (ng·h/mL)	98.2%	89.7%	107.5%
PK parameters	T/R Ratio	Lower 90% C.I.	Upper 90% C.I.															
CMAX (ng/mL)	97.2%	88.8%	106.4%															
AUCT (ng·h/mL)	98.3%	90.1%	107.3%															
AUCI (ng·h/mL)	98.2%	89.7%	107.5%															