

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: 04065	
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 Fed, 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 fed conditions.		
Number of patients: enrolled: 38 completed: 35		
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		

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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 non-fasted conditions. The results are summarized below:</p>																		
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">PK parameters</th> <th style="text-align: center;">T/R Ratio</th> <th style="text-align: center;">Lower 90% C.I.</th> <th style="text-align: center;">Upper 90% C.I.</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CMAX (ng/mL)</td> <td style="text-align: center;">93.3%</td> <td style="text-align: center;">86.5%</td> <td style="text-align: center;">100.7%</td> </tr> <tr> <td style="text-align: center;">AUCT (ng·h/mL)</td> <td style="text-align: center;">98.8%</td> <td style="text-align: center;">92.5%</td> <td style="text-align: center;">105.5%</td> </tr> <tr> <td style="text-align: center;">AUCI (ng·h/mL)</td> <td style="text-align: center;">98.9%</td> <td style="text-align: center;">92.4%</td> <td style="text-align: center;">105.9%</td> </tr> </tbody> </table>			PK parameters	T/R Ratio	Lower 90% C.I.	Upper 90% C.I.	CMAX (ng/mL)	93.3%	86.5%	100.7%	AUCT (ng·h/mL)	98.8%	92.5%	105.5%	AUCI (ng·h/mL)	98.9%	92.4%	105.9%
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