

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: 04065																	
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 data-bbox="310 709 597 749">PK parameters</th> <th data-bbox="597 709 812 749">T/R Ratio</th> <th data-bbox="812 709 1073 749">Lower 90% C.I.</th> <th data-bbox="1073 709 1334 749">Upper 90% C.I.</th> </tr> </thead> <tbody> <tr> <td data-bbox="310 749 597 789">CMAX (ng/mL)</td> <td data-bbox="597 749 812 789">93.3%</td> <td data-bbox="812 749 1073 789">86.5%</td> <td data-bbox="1073 749 1334 789">100.7%</td> </tr> <tr> <td data-bbox="310 789 597 829">AUCT (ng·h/mL)</td> <td data-bbox="597 789 812 829">98.8%</td> <td data-bbox="812 789 1073 829">92.5%</td> <td data-bbox="1073 789 1334 829">105.5%</td> </tr> <tr> <td data-bbox="310 829 597 869">AUCI (ng·h/mL)</td> <td data-bbox="597 829 812 869">98.9%</td> <td data-bbox="812 829 1073 869">92.4%</td> <td data-bbox="1073 829 1334 869">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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