

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: Primidone Tablets 50mg	Report Date: August 2004	
Name of Active Ingredient: primidone	Final Report Number: 04090	
Title of Study: A Randomized, Two-Way Crossover, Single-Dose, Open-Label Study to Evaluate the Relative Bioequivalence of a Test Tablet Formulation of Primidone (50 mg), Compared to an Equivalent Dose of a Commercially Available Reference Drug Product (Mysoline®, Wyeth-Ayerst Pharmaceuticals) in 22 Fasted, Healthy, Adult Subjects		
Investigators: Thomas Siler, M.D., Principal Investigator Mahendra Bhuyan, M.B.B.S, M.D., Sub-Investigators		
Study Center(s): Gateway Medical Research, Inc. (Clinical) 400 Fountain Lakes Blvd. St. Charles, MO 63301 SFBC Analytical Laboratories, Inc. (Bioanalytical) 401A Industrial Drive North Wales, PA 19454		
Study dates: Period I: May 28–31, 2004 Period II: June 11-14, 2004	Phase of development: Phase 1	
Objectives: The objective of this randomized, single-dose, two-way evaluation was to compare the bioequivalence of a test primidone formulation (Mutual Pharmaceutical Co.) to an equivalent oral dose of the commercially available primidone (Mysoline®, Wyeth-Ayerst Pharmaceuticals) in a test population of 22 adult subjects under fasting conditions.		
Number of patients: enrolled: 22 completed: 21		
Test product (A): Mutual Pharmaceutical's Primidone Tablets Dose: 50mg Mode of administration: Oral Batch number: BB 737 0126 Reference product (B): Mysoline® Tablets Dose: 50mg Mode of administration: Oral Batch number: 3023635		

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Name of Finished Product: Primidone Tablets, 50mg	Report Date: August 2004		
Name of Active Ingredient: primidone	Final Report Number: 04090		
Criteria for evaluation: Bioequivalence			
SUMMARY – CONCLUSIONS			
<p>Bioequivalence: Mutual Pharmaceutical’s Primidone Tablets, 50mg were bioequivalent to Wyeth-Ayerst Pharmaceuticals Mysoline® Tablets, 50mg. Analysis results of the major PK parameters are summarized in the following table:</p>			
PK parameters	T/R ratio	Lower 90% C.I.	Upper 90% C.I.
CMAX (ng/mL)	97.8	91.3	104.6
AUCT (ng·h/mL)	101.3	98.2	104.5
AUCI (ng·h/mL)	101.9	98.8	105.2