

**SYNOPSIS**

<b>Name of Sponsor/Company:</b> Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	<b>Page 1 of 2</b>	<b><i>Mutual Pharmaceutical Company, Inc</i></b> <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>
<b>Name of Finished Product:</b> Quinine Sulfate Capsules, 324mg	<b>Report Date:</b> August 2004	
<b>Name of Active Ingredient:</b> Quinine sulfate	<b>Final Report Number:</b> R04-0376	
<b>Title of Study:</b> A Dose Proportionality Study of Quinine Sulfate Capsules Under Fasting Conditions		
<b>Investigators:</b> James D. Carlson, Pharm.D., Principal Investigator Alan K. Copa, Pharm D., Sub-Investigators		
<b>Study Center(s):</b>  PRACS Institute, Ltd. (Clinical)      SFBC Analytical Laboratories, Inc. (Bioanalytical) East Grand Forks, MN 56721      401A Industrial Drive and Fargo, ND 58104      North Wales, PA 19454		
<b>Study dates:</b> Period I: May 29-31, 2004 Period II: June 5-7, 2004	<b>Phase of development:</b> Phase 1	
<b>Objectives:</b> This study compared the dose proportionality of 324mg Quinine Sulfate Capsules following a single oral dose (1 x 324mg capsule versus 2 x 324mg capsules) in healthy adult volunteers when administered under fasting conditions		
<b>Number of patients: enrolled:</b> 24 <b>completed:</b> 23		
<b>Study product (A):</b> Mutual Pharmaceutical's Quinine Sulfate Capsules (fasting conditions) <b>Dose:</b> 1 x 324mg Capsules <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 102 0105		
<b>Study product (B):</b> Mutual Pharmaceutical's Quinine Sulfate Capsules (fasting conditions) <b>Dose:</b> 2 x 324mg Capsules <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 102 0105		

<b>Name of Sponsor/Company:</b> Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	<b>Page 2 of 2</b>	<b>Mutual Pharmaceutical Company, Inc</b> <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>
<b>Name of Finished Product:</b> Quinine Sulfate Capsules, 324mg	<b>Report Date:</b> August 2004	
<b>Name of Active Ingredient:</b> Quinine sulfate	<b>Final Report Number:</b> R04-0376	

**Criteria for evaluation:** Dose Proportionality

**SUMMARY – CONCLUSIONS**

The results of this study indicate that Treatment A and Treatment B are not dose proportionate for the 23 subjects analyzed.

The following tables summarize the results of the analyses performed on the pharmacokinetic parameters comparing dose adjusted Treatment A to Treatment B:

<b>Quinine</b>	<b>Ln-Transformed C<sub>max</sub></b>	<b>Ln Transformed AUC<sub>0-t</sub></b>	<b>Ln Transformed AUC<sub>inf</sub></b>
Dose Adjusted Treatment A Geometric Mean	4126.31	61186.53	66715.41
Treatment B Geometric Mean	3174.89	54440.26	59166.93
% Ratio	129.97	112.39	112.76
90% Confidence Interval	(122.15, 138.29)	(106.56, 118.54)	(105.69, 120.3)

<b>Quinine</b>	<b>C<sub>max</sub></b>	<b>AUC<sub>0-t</sub></b>	<b>AUC<sub>inf</sub></b>
Dose Adjusted Treatment A Least Squares Mean	4247.02	64277.02	70886.14
Treatment B Least Squares Mean	3243.11	56394.65	61817.27
% Ratio	130.96	113.98	114.67
90% Confidence Interval	(123.28, 138.63)	108.03, 119.93)	(107.37, 121.97)

<b>Quinine</b>	<b>T<sub>max</sub></b>	<b>k<sub>elim</sub></b>	<b>t<sub>1/2</sub></b>
Dose Adjusted Treatment A Least Squares Mean	2.78	0.0592	12.76
Treatment B Least Squares Mean	2.80	0.0572	12.80
% Ratio	99.25	103.48	99.67
90% Confidence Interval	(84.8, 113.7)	(94.67, 112.28)	(85.69, 113.66)