

**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> March 2006	
<b>Name of Active Ingredient:</b> Quinine sulfate	<b>Final Report Number:</b> R05-1613	
<b>Title of Study:</b> A Relative Bioavailability Study of Quinine Sulfate Capsules Under Fasting and Fed 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) 625 DeMers Avenue                      401A Industrial Drive East Grand Forks, MN 56721          North Wales, PA 19454		
<b>Study dates:</b> Period I: December 10 – 15, 2005 Period II: December 17 – 19, 2005	<b>Phase of development:</b> Phase 1	
<b>Objectives:</b> This limited food effect study was designed to compare the relative bioavailability (rate and extent of absorption) of Quinine Sulfate Capsules, 324mg following a single oral dose (2 x 324mg capsules) in healthy volunteers under fasting and fed conditions.		
<b>Number of patients: enrolled:</b> 22 <b>completed:</b> 22		
<b>Study product:</b> Mutual Pharmaceutical's Quinine Sulfate Capsules <b>Dose:</b> 2 x 324mg Capsules <b>Mode of administration:</b> Oral <b>Batch number:</b> 55765 <b>Expiration Date:</b> August 2007		

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**Criteria for evaluation:** Bioavailability

### SUMMARY – CONCLUSIONS

The results of this study indicate the absence of a food effect on  $C_{max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-\infty}$  for quinine when Quinine Sulfate Capsules USP 324mg are administered with food compared to when they are administered without food. The results of this study indicate the time to  $C_{max}$  may be prolonged following administration under fed conditions.

The following tables summarize the results of the analyses performed on the pharmacokinetic parameters:

#### Summary of Ln-Transformed Pharmacokinetic Parameters

Quinine	Ln-Transformed $C_{max}$	Ln Transformed $AUC_{0-t}$	Ln Transformed $AUC_{0-\infty}$
Fed Conditions Geometric Mean	3332.41	48942.43	51699.75
Fasting Conditions Geometric Mean	3197.25	47258.21	50005.77
% Ratio	104.23	103.56	103.39
90% Confidence Interval	(99.13, 109.59)	(100.77, 106.44)	(99.75, 107.16)

#### Summary of Pharmacokinetic Parameters

Quinine	$C_{max}$	$AUC_{0-t}$	$AUC_{0-\infty}$
Fed Conditions Least Squares Mean	3424.30	51228.07	54409.12
Fasting Conditions Least Squares Mean	3293.84	49484.64	52643.14
% Ratio	103.96	103.52	103.35
90% Confidence Interval	(99.13, 108.8)	(100.65, 106.4)	(99.3, 107.41)

Quinine	$T_{max}$	$k_e$	$t_{1/2}$
Fed Conditions Least Squares Mean	4.19	0.0665	10.71
Fasting Conditions Least Squares Mean	2.68	0.0642	11.38
% Ratio	155.97	103.56	94.09
90% Confidence Interval	(136.98, 174.96)	(96.98, 110.14)	(85, 103.17)