

**SYNOPSIS**

<b>Name of Sponsor/Company:</b> Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	<b>Page 1 of 4</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> June 2004	
<b>Name of Active Ingredient:</b> Quinine sulfate	<b>Final Report Number:</b> RA3-085	
<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) East Grand Forks, MN 56721      401A Industrial Drive and Fargo, ND 58104      North Wales, PA 19454		
<b>Study dates:</b> Period I: February 21-23, 2004 Period II February 28-March 1, 2004 Period III March 06-08, 2004	<b>Phase of development:</b> Phase 1	
<b>Objectives:</b> This study evaluated the single dose relative bioavailability of the to-be-marketed product Quinine Sulfate capsules, 324mg manufactured by Mutual against a foreign Quinine Sulphate tablets, 300mg, and the food interactions of the Mutual product in healthy adult volunteers.		
<b>Number of patients: enrolled:</b> 27 <b>completed:</b> 25		
<b>Study product (A):</b> Mutual Pharmaceutical's Quinine Sulfate Capsules (fasting conditions) <b>Dose:</b> 324mg <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 102 0105  <b>Study product (B):</b> Quinine Sulphate Tablets <b>Dose:</b> 300mg <b>Mode of administration:</b> Oral <b>Batch number:</b> F.450661; The Government Pharmaceutical Organization  <b>Treatment (C) product:</b> Mutual Pharmaceutical's Quinine Sulfate Capsules (fed conditions) <b>Dose:</b> 324mg <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 102 0105		

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**Criteria for evaluation:** Bioavailability

**SUMMARY – CONCLUSIONS**

The results of this study indicate bioequivalence between dose adjusted Quinine Sulfate Capsules USP 324mg (Treatment A) and Quinine Sulphate 300mg Tablets (Treatment B) under fasting conditions.

The results also indicate there is not a significant food effect when Quinine sulfate Capsules, 324mg is administered under fed conditions.

The following tables summarize the results of the analyses performed on the pharmacokinetic parameters comparing Treatment A (dose adjusted to 300mg) with Treatment B:

**Treatment A (Dose Adjusted to 300mg) vs. 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>
Treatment A Geometric Mean	2008.74	29250.17	32036.83
Treatment B Geometric Mean	2195.26	30214.93	32512.15
% Ratio	91.50	96.81	98.54
90% Confidence Interval	(85.25, 98.22)	(91.91, 101.97)	(92.71, 104.73)

<b>Quinine</b>	<b>C<sub>max</sub></b>	<b>AUC<sub>0-t</sub></b>	<b>AUC<sub>inf</sub></b>
Treatment A Least Squares Mean	2084.29	30284.86	33487.29
Treatment B Least Squares Mean	2258.27	31584.60	34342.02
% Ratio	92.30	95.88	97.51
90% Confidence Interval	(84.21, 100.38)	(89.57, 102.2)	(89.42, 105.6)

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**Criteria for evaluation:** Bioavailability

**SUMMARY – CONCLUSIONS (CONTINUED)**

**Treatment A (Dose Adjusted to 300mg) vs. Treatment B: (continued)**

<b>Quinine</b>	<b>T<sub>max</sub></b>	<b>k<sub>elim</sub></b>	<b>t<sub>1/2</sub></b>
Treatment A Least Squares Mean	2.60	0.0556	13.51
Treatment B Least Squares Mean	2.51	0.0605	12.49
% Ratio	103.58	91.96	108.20
90% Confidence Interval	(90.98, 116.18)	(83.31, 100.61)	(95.84, 120.55)

The following tables summarize the results of the analyses performed on the pharmacokinetic parameters comparing Treatment C (fed conditions) with Treatment A (fasting conditions):

**Treatment C (Fed Conditions) vs. Treatment A (Fasting Conditions):**

<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>
Treatment C Geometric Mean	2438.84	32942.74	35114.58
Treatment A Geometric Mean	2169.43	31590.14	34599.61
% Ratio	112.42	104.28	101.49
90% Confidence Interval	(104.74, 120.66)	(99.01, 109.84)	(95.49, 107.86)

<b>Quinine</b>	<b>C<sub>max</sub></b>	<b>AUC<sub>0-t</sub></b>	<b>AUC<sub>inf</sub></b>
Treatment C Least Squares Mean	2535.89	34643.77	37419.45
Treatment A Least Squares Mean	2250.71	32705.79	36164.03
% Ratio	112.67	105.93	103.47
90% Confidence Interval	(104.45, 120.89)	(99.84, 112.01)	(95.74, 111.21)

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<b>Criteria for evaluation:</b> Bioavailability			
<b>SUMMARY – CONCLUSIONS (CONTINUED)</b>			
<b>Treatment C (Fed Conditions) vs. Treatment A (Fasting Conditions: (continued))</b>			
<b>Quinine</b>	<b>T<sub>max</sub></b>	<b>k<sub>elim</sub></b>	<b>t<sub>1/2</sub></b>
Treatment C Least Squares Mean	3.98	0.0655	11.28
Treatment A Least Squares Mean	2.60	0.0556	13.51
% Ratio	153.07	117.73	83.45
90% Confidence Interval	(140.91, 165.24)	(108.32, 127.13)	(72.03, 94.88)