

**SYNOPSIS**

<b>Name of Sponsor/Company:</b> Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	<b>Page 1 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> Cilostazol Tablets, 50mg	<b>Report Date:</b> August 2004	
<b>Name of Active Ingredient:</b> Cilostazol	<b>Final Report Number:</b> 11801	
<b>Title of Study:</b> A Comparative Bioavailability Study of Cilostazol Tablets, 50mg Under Fasting Conditions		
<b>Investigators:</b> Dilip K. Guha-Ray, MD, Principal Investigator		
<b>Study Center(s):</b> Bioanalytical Systems, Inc. (Clinical) 302 West Fayette street Baltimore, MD 21201  SFBC Analytical Laboratory (Analytical) 401 A Industrial Drive North Wales, PA 19454		
<b>Study dates:</b> Period I: June 22–24, 2004 Period II: June 29-July 1, 2004	<b>Phase of development:</b> Phase 1	
<b>Objectives:</b> The objective of this study was to compare the plasma levels of cilostazol produced after administration of the test formulation with those produced after administration of a marketed reference product, under fasting conditions.		
<b>Number of patients: enrolled:</b> 32 <b>completed:</b> 29		
<b>Test product (A):</b> Mutual Pharmaceutical's Cilostazol Tablets <b>Dose:</b> 50mg <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 474 0128  <b>Reference product (B):</b> Otsuka Pharmaceutical's Pletal® Tablets <b>Dose:</b> 50mg <b>Mode of administration:</b> Oral <b>Batch number:</b> 3G99PBT1P		

<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> Cilostazol Tablets, 50mg	<b>Report Date:</b> August 2004	
<b>Name of Active Ingredient:</b> Cilostazol	<b>Final Report Number:</b> 11801	

**Criteria for evaluation:** Bioequivalence

**SUMMARY – CONCLUSIONS**

**Bioequivalence:** The cilostazol 50mg tablet manufactured by Mutual Pharmaceutical Co, Inc. was determined to be bioequivalent to the marketed Pletal® 50mg tablet when both were administered under fasting conditions. The 90% confidence intervals surrounding the ratio of the test product mean versus the reference product mean were within the 0.80 to 1.25 bioequivalence limits for both AUC and CMAX.

	<b>Ratio of Means (test/reference)</b>	<b>90% Confidence Interval</b>
AUC 0-T	0.99	[0.95; 1.03]
AUC 0-Infinity	0.99	[0.91; 1.08]
CMAX	0.99	[0.89; 1.11]