

**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, 100mg	<b>Report Date:</b> May 2004	
<b>Name of Active Ingredient:</b> Cilostazol	<b>Final Report Number:</b> 11788	
<b>Title of Study:</b> A Comparative Bioavailability Study of Cilostazol Tablets, 100mg 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: March 12–14, 2004 Period II: March 19-21, 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> 28		
<b>Test product (A):</b> Mutual Pharmaceutical's Cilostazol Tablets <b>Dose:</b> 100mg <b>Mode of administration:</b> Oral <b>Batch number:</b> BB 475 0121  <b>Reference product (B):</b> Otsuka Pharmaceutical's Pletal® Tablets <b>Dose:</b> 100mg <b>Mode of administration:</b> Oral <b>Batch number:</b> 2F95PAR1P		

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<b>Criteria for evaluation:</b> Bioequivalence														
<b>SUMMARY – CONCLUSIONS</b>														
<p><b>Bioequivalence:</b> The cilostazol 100mg tablet manufactured by Mutual Pharmaceutical Co, Inc. was determined to be bioequivalent to the marketed Pletal® 100mg 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.</p>														
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th data-bbox="310 896 646 968"></th> <th data-bbox="646 896 1057 968" style="text-align: center;"> <b>Ratio of Means (test/reference)</b> </th> <th data-bbox="1057 896 1468 968" style="text-align: center;"> <b>90% Confidence Interval</b> </th> </tr> </thead> <tbody> <tr> <td data-bbox="310 968 646 1005">AUC 0-T</td> <td data-bbox="646 968 1057 1005" style="text-align: center;">0.98</td> <td data-bbox="1057 968 1468 1005" style="text-align: center;">[0.92; 1.04]</td> </tr> <tr> <td data-bbox="310 1005 646 1043">AUC 0-Infinity</td> <td data-bbox="646 1005 1057 1043" style="text-align: center;">0.95</td> <td data-bbox="1057 1005 1468 1043" style="text-align: center;">[0.87; 1.03]</td> </tr> <tr> <td data-bbox="310 1043 646 1081">CMAX</td> <td data-bbox="646 1043 1057 1081" style="text-align: center;">1.00</td> <td data-bbox="1057 1043 1468 1081" style="text-align: center;">[0.92; 1.10]</td> </tr> </tbody> </table>				<b>Ratio of Means (test/reference)</b>	<b>90% Confidence Interval</b>	AUC 0-T	0.98	[0.92; 1.04]	AUC 0-Infinity	0.95	[0.87; 1.03]	CMAX	1.00	[0.92; 1.10]
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