

SYNOPSIS

Name of Sponsor/Company: Mutual Pharmaceutical Co., Inc. 1100 Orthodox Street Philadelphia, PA 19124	Page 1 of 2	Mutual Pharmaceutical Company, Inc <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>
Name of Finished Product: Lovastatin Tablets, 40mg	Report Date: December 2004	
Name of Active Ingredient: lovastatin	Final Report Number: LVI-P4-125	
Title of Study: A Single Dose Crossover Comparative Bioavailability Study of Lovastatin 40mg Tablets in Healthy Male Volunteers / Fasting State		
Investigators: Eric Sicard, M.D., Clinical Investigator Christian Aumais, M.D., Sub-Investigator		
Study Center(s): Algorithme Pharma, Inc. (Clinical) 9000 Boulevard de L'Acadie Montreal, Quebec, Canada H4N 2Y8 Bioassay (Bioanalytical) 10550 Rockley Road Suite 150 Houston, Texas 77099		
Study dates: Period I: September 25, 2004 Period II: October 2, 2004	Phase of development: Phase 1	
Objectives: Evaluate and compare the relative bioavailability and therefore the bioequivalence of two formulations of lovastatin after a single oral dose administration under fasting conditions.		
Number of patients: enrolled: 54 completed: 51		
Test product (A): Mutual Pharmaceutical's Lovastatin Tablets Dose: 40mg Mode of administration: Oral Batch number: BB 534 0129 Reference product (B): Mevacor® Tablets Dose: 40mg Mode of administration: Oral Batch number: P4016		

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Criteria for evaluation: Bioequivalence

SUMMARY – CONCLUSIONS

Bioequivalence: Mutual Pharmaceutical’s Lovastatin 40mg tablets were bioequivalent to Merck & Co., Inc.’s Mevacor® tablets on the basis of C_{max} , AUC_T and AUC_{∞} parameters of lovastatin.

PARAMETER	GEOMETRIC LS MEANS		RATIO	90% CONFIDENCE LIMITS	
	TEST	REFERENCE		LOWER	UPPER
C_{max}	1.59	1.69	93.87	84.58	104.18
AUC_T	26.72	25.60	104.41	96.22	113.29
AUC_{∞}	30.28	28.54	106.09	96.74	116.34