

Microbial Challenge of Two Mouthwash Formulations

Sample Description: Mouthwash

Test Date: 8/7/99

Part A Lot Number: MW-001-08699-1A

Project Number: 105-011

Part B Lot Number: MW-023-08699-1B

Test Method Reference: Modified CL-002.00 (See Comments)

Challenge Time: 1 min

Mixing Time: 15 seconds

Test Organism: S. aureus ATCC 29213

Initial Suspension: 4.7×10^{11}

Test Sample	Challenge Inoculum (Log#cfu/ml Product)	Recovered (Log#cfu/ml Product)	Log Reduction
Mouthwash	4.2×10^{10} (10.6)	0	>10.6
Control (Saline)	4.2×10^{10}	1.9×10^{10}	

Sample Description: Mouthwash

Test Date: 8/7/99

Part A Lot Number: MW-024-080699-1A

Project Number: 105-011

Part B Lot Number: MW-025-080699-1B

Test Method Reference: Modified CL-002.00 (See Comments)

Challenge Time: 1 min

Mixing Time: 15 seconds

Test Organism: S. aureus ATCC 29213

Initial Suspension: 4.7×10^{11}

Test Sample	Challenge Inoculum (Log#cfu/ml Product)	Recovered (Log#cfu/ml Product)	Log Reduction
Mouthwash	4.2×10^{10} (10.6)	3.8×10^1 (1.58)	9.02
Control (Saline)	4.2×10^{10}	1.9×10^{10}	

Comments.

Protocol was modified at follows:

Mouthwash samples were tested using a modification of protocol CL-002.00 provided by Frontier Pharmaceutical, Inc. As per protocol, 5 grams of part A and 5 grams of part B were mixed for fifteen seconds.

The inoculum was prepared in the standard manner, attempting to obtain as high a concentration of organisms as was possible. Instead of the usual 0.1 ml, however, 1.0 ml of inoculum was used. The effect of this was to allow for a ten fold increase in the quantity of organisms used in the challenge. Following mixing, the mouthwash was challenged with the organisms for 1 minute. D/E broth, 90 ml, was then used to neutralize the mouthwash and dissolve the mixture. The mixture was transferred into a mixing bottle and shaken. The rest of the procedure was as per protocol CL-002.00. Samples were diluted as appropriate, and counted on pour plates using Tryptic Soy Agar.

A control study was run, in which a 10 ml sample of saline was challenged, instead of the mouthwash.

Reviewed by:


Lorrence H. Green, Ph.D.

Date


8/14/99