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Microbial Challenge of The Penetrator and DioxiRinse

Sample Description: The Penetrator

Test Date: 12/4/00

Part A Lot Number: 1299

Project Number: 105-021

Part B Lot Number: 1300

Test Method Reference: Modified CL-002.00 (See Comments)
Challenge Time: 30 seconds
Mixing Time: 15 seconds
Test Organism: K. pneumoniae ATCC 10031
Initial Suspension: 7.16×10^{10}

Test Sample	Challenge Inoculum (Log#cfu/ml Product)	Recovered (Log#cfu/ml Product)	Log Reduction
Penetrator	6.5×10^{9} (9.8)	0 (0.0)	>9.8
Control (Saline)	6.5×10^{9}	4.3×10^{9}	

Sample Description: DioxiRinse

Test Date: 12/4/00

Part A Lot Number: 1301

Project Number: 105-021

Part B Lot Number: 1302

Test Method Reference: Modified CL-002.00 (See Comments)
Challenge Time: 60 seconds
Mixing Time: 15 seconds
Test Organism: K. pneumoniae ATCC 10031
Initial Suspension: 7.16×10^{10}

Test Sample	Challenge Inoculum (Log#cfu/ml Product)	Recovered (Log#cfu/ml Product)	Log Reduction
DioxiRinse	6.5×10^{9} (9.8)	0 (0.0)	>9.8
Control (Saline)	6.5×10^{9}	4.3×10^{9}	

Comments.

Protocol was modified at follows:

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 Penetrator sample was challenged for 30 seconds instead of one minute, while the DioxiRinse was challenged for one minute. D/E broth, 90 ml, was then used to neutralize the sample 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 Trypticase Soy Agar.

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

Reviewed by: Lorene H Ida **Date** 12/6/12