

## Evaluation of Antimicrobial Finishes Final Report

Test Article: Two batches:  
NASK1  
NASK2  
Purchase Order: NA2410  
Study Number: 841196-S01A.1 Amended  
Study Received Date: 21 Aug 2015  
Study Completion Date: 18 Jan 2016  
Testing Facility: Nelson Laboratories, LLC  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0156 Rev 01  
Protocol Detail Sheet (PDS) Number: 201502980 Rev 01

**Summary:** This report details the methods used for assessing antimicrobial finishes. The challenge procedure consisted of inoculating uniform pieces of the test material with the test organism(s), then determining the percent reduction of the test organism(s) after specified exposure periods. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

According to PDS 201502980 Rev 01, the challenge level was intended to be  $\geq 10^6$  CFU per test article; however, *Streptococcus pneumoniae* was challenged with  $2.7 \times 10^5$  CFU per test article on average. The challenge concentration provides a point of comparison for the growth recovered from the test articles, and evidence that the growth conditions utilized in test system is capable of supporting the specified organism. The results obtained (log reduction values) were not impacted by having a lower potential maximum log reduction. All of the test method acceptance criteria were met; the results are valid.

**Results:** Values are considered approximate (~) when plate counts were outside of the statistically accurate range of 25-250 colony forming units (CFU)/plate for bacteria. Less than symbols (<) are applied to recovery values and greater than (>) symbols are applied to reduction values where no CFU were observed on the plates. This denotes the limit of detection for the test.

### Antimicrobial Finish Results:

*Klebsiella pneumoniae*, ATCC #4352:

Average Control Titer at Time Zero (CFU/Test Article):  $1.2 \times 10^7$

Test Article	Time Interval	Percent Reduction (%)	Log <sub>10</sub> Reduction
Control	0 Hour	N/A	N/A
NASK1	1 minute	-59	-0.20
	5 minutes	29	0.15
NASK2	1 minute	39	0.22
	5 minutes	~99.9971	~4.54

Study Director

Wellance T. Naeata, B.S.

Amended Report Date



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*Acinetobacter baumannii*, ATCC #19606:

Average Control Titer at Time Zero (CFU/Test Article):  $9.9 \times 10^7$

Test Article	Time Interval	Percent Reduction (%)	Log <sub>10</sub> Reduction
Control	0 Hour	N/A	N/A
NASK1	1 minute	~43	~0.25
	5 minutes	~56	~0.36
NASK2	1 minute	~93.9	~1.21
	5 minutes	>99.900	>3.00

*Streptococcus pneumoniae*, ATCC #29514:

Average Control Titer at Time Zero (CFU/Test Article):  $2.7 \times 10^5$

Test Article	Time Interval	Percent Reduction (%)	Log <sub>10</sub> Reduction
Control	0 Hour	N/A	N/A
NASK1	1 minute	15	0.08
	5 minutes	43	0.25
NASK2	1 minute	42	0.24
	5 minutes	~99.909	~3.04

Neutralization:

Test Article	Organism	Percent Neutralization (%)
NASK1	<i>K. pneumoniae</i>	103
NASK2		93
NASK1	<i>A. baumannii</i>	71
NASK2		114
NASK1	<i>S. pneumoniae</i>	96
NASK2		129

**Amendment Justification:** At the request of the sponsor, the results for Vancomycin-Resistant *Enterococcus faecalis* and *Mycobacterium terrae* were moved to a separate report.